Effective Health Care

Treatment of Bell's Palsy

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 inform the update their 2013 clinical practice guideline on the treatment of Bell's palsy. Specifically, the nominator is interested in the benefits and harms of oral corticosteroid treatment in children, surgical treatment among patients with complete paralysis and absent volitional nerve activity, and acupuncture treatment, as there was limited evidence addressing these questions in the previous guideline. Due to limited program resources, the program is unable to 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: Treatment of Bell's Palsy

Topic #: 0694

Nomination Date: 07/05/2016

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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 comprehensive evidence review of treatments for Bell's Palsy would not be duplicative. While eight evidence reviews were identified across the three key questions, no comprehensive review exists. We identified two reviews, including a 2016 Cochrane review, related to KQ 1. We also identified a 2013 Cochrane review examining the effects of surgery in the management of Bell's palsy (KQ2), and four completed and one in-process evidence review examining the effects of acupuncture for Bell's palsy (KQ3).
- Impact: A new systematic review on the proposed topic has limited impact potential. While there are research gaps, there is very little new evidence that fills those gaps.
- Feasibility: A limited evidence review on treatments for Bell's Palsy is feasible at this time.
    - *Size/scope of review:* Our search of PubMed resulted in a total of 82 unique titles. Upon title and abstract review, we identified a total of 8 studies

potentially relevant to the key questions in the nomination. One study examined oral corticosteroids (KQ1), five examined facial nerve decompression (KQ2), and two examined acupuncture (KQ3).
    - *ClinicalTrials.gov:* We identified 1 relevant clinical trial on ClinicalTrials.gov.
- Value: While there is not a large evidence base available, there may still be value in an evidence review. An updated evidence review, even with limited evidence and impact on previous conclusions, would be needed to inform an update of the AAO-HNSF guidelines. This organization has previously produced guidelines, and is transparent about its methodology.

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Introduction

Bell's palsy is the most common diagnosis of facial nerve paralysis.[1] It is characterized by rapid onset facial paresis or paralysis of unknown etiology and may cause oral incompetence and an inability to close the eyelid. Most patients completely recover within 6 months, but long term effects can occur in up to 30% of patients. The nominator plans to use an Agency for Healthcare and Research Quality (AHRQ) review to inform their 2018 update to their clinical practice guideline.

Topic nomination #0694 was received on July 5, 2016. It was nominated by the American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF).The questions for this nomination are:

Key Question 1. What are the benefits and harms of oral corticosteroid treatment among children with Bell's palsy?

Key Question 2: Among adults and children with Bell's palsy with complete paralysis and absent volitional nerve activity, what are the benefits and harms of surgical facial nerve decompression (including the transmastoid approach and the middle fossa approach)?

Key Question 3: What are the benefits and harms of acupuncture for treating adults and children with Bell's palsy?

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

Table 1. Key Questions with PICOs

Key Question	1. What are the benefits and harms of oral corticosteroid treatment among children with Bell's palsy?	2. Among adults and children with Bell's palsy with complete paralysis and absent volitional nerve activity, what are the benefits and harms of surgical facial nerve decompression (including the transmastoid approach and the middle fossa approach)?	3. What are the benefits and harms of acupuncture for treating adults and children with Bell's palsy?
Population	Children with Bell's palsy	Adults and children with Bell's palsy with complete paralysis and absent volitional nerve activity	Adults and children with Bell's palsy
Interventions	Oral corticosteroids	Surgical facial nerve decompression	Acupuncture
Comparators	Placebo	Usual care	Usual care
Outcomes	Benefits (eg, rates of recovery) Harms (eg, headache, nervousness, edema, elevated blood pressure, elevated glucose)	Benefits (eg, rates of recovery) Harms (eg, conductive or sensorineural hearing loss, injury to facial nerve, risk injury to the facial nerve; risk of cerebrospinal fluid leak; infection; risks of temporal lobe retraction such as temporary or permanent aphasia, seizures, and stroke; and nonspecific risks with general anesthesia)	Benefits (eg, rates of recovery) Harms (adverse events, eg, facial weakness, persistent lacrimation, infection, needlesickness, needle breakage, hematoma)

Methods

To assess topic nomination *#0694, Treatment of Bell's Palsy* 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. Appendix B includes the list of the sources searched and potentially relevant titles identified by our research librarian.

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 it was hypothetically possible for this review to influence the current state of practice through various dissemination pathways (practice recommendation, clinical guidelines, etc.).

Feasibility of New Evidence Review

We conducted a literature search in PubMed from July 2011 and July 2016. Because a small number of articles were identified, we reviewed all 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. See Appendix C 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 or not the topic would inform clinical policy in community and/or clinical settings, and if there was a partner organization that would use this evidence review to influence practice.

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. While Bell's Palsy primarily affects the pediatric population, there is significant incidence of the condition in individuals up to age 45 years. A

‘‘gold standard’’ treatment has yet to be defined, and as such, medical and surgical intervention is variable. No explicit cost estimates for the diagnosis and management of Bell’s palsy are available, but with 35,000 to 100,000 cases annually in the United States, based on aforementioned estimates of incidence, the cost of addressing Bell’s palsy is undoubtedly significant.

Desirability of New Review/Duplication

A comprehensive evidence review of treatments for Bell’s Palsy would not be duplicative. While eight evidence reviews were identified across the three key questions, no comprehensive review exists. For KQ 1, we identified two evidence reviews, including a Cochrane review,[2] examining oral corticosteroids in children as treatment for Bell’s Palsy.[2,3] For KQ 2, we identified one Cochrane review, which examined surgical facial nerve decompression as a treatment for Bell’s Palsy.[4] For KQ 3, we identified five evidence reviews, one of which is in-process,[5] examining acupuncture as a viable treatment option for Bell’s Palsy.[5-9] For more details, see Appendix B.

Impact of a New Evidence Review

A new systematic review on the proposed topic has limited impact potential. There is little new evidence that fills the gaps identified in the AAO-HNSF guideline on this topic.

Feasibility of a New Evidence Review

A limited comprehensive evidence review for treatments for Bell’s Palsy is feasible at this time. We identified eight studies published studies over the last five years across the three key questions. This included one retrospective cohort study[10] on oral corticosteroids for children (KQ 1); two non-randomized trials,[11,12] one pre-post study,[13] one prospective study with historical control[14], and one retrospective cohort study[15] examining surgical facial nerve decompression (KQ 2); and one RCT[16] and one RCT protocol[17] investigating acupuncture as a treatment for Bell’s Palsy. Additionally, our search of ClinicalTrials.gov yielded one relevant trial researching acupuncture for Bell’s Palsy.[18]

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

Key Question	Duplication (Completed or In-Process Evidence Reviews)	Feasibility (Published and Ongoing Research)
KQ 1: Oral corticosteroids for children	Total number of completed or in-process systematic reviews - 2 • Cochrane – 1[2] • Other – 1[3]	Size/scope of review Relevant Studies Identified: 1 • Retrospective cohort - 1[10] ClinicalTrials.gov None identified.
KQ 2: Surgical facial nerve decompression	Total number of completed or in-process systematic reviews –1 • Cochrane - 1[4]	Size/scope of review Relevant Studies Identified: 5 • n-RCT – 2[11,12] • Pre-Post – 1[13] • Prospective with historical control - 1[14] • Retrospective cohort - 1[15] ClinicalTrials.gov None identified.
KQ 3: Acupuncture	Total number of completed or in-progress systematic reviews – 5 • Other – 4[6-8,9] • Other (in-process)- 1[5]	Size/scope of review Relevant Studies Identified: 2 • RCT – 1[16] • RCT protocol - 1[17] ClinicalTrials.gov Relevant Trials: 1 • Controlled trial – 1[18]

Abbreviations: KQ=Key Question; nRCT=Non-Randomized Controlled Trial; RCT=Randomized Controlled Trial

Value

While we identified a limited evidence base, there may still be value in an evidence review. An updated evidence review, even with limited evidence and impact on conclusions, would be needed to update the AAO-HNSF guidelines. This organization has previously produced guidelines, and is transparent about its methodology.

Summary of Findings

- Appropriateness and importance: The nomination is both appropriate and important.
- Duplication: A comprehensive evidence review of treatments for Bell's Palsy would not be duplicative. While eight evidence reviews were identified across the three key questions, no comprehensive review exists. We identified two reviews, including a 2016 Cochrane review, for KQ 1. We also identified a 2013 Cochrane review examining the effects of surgery in the management of Bell's palsy (KQ2), and four completed and one in-process evidence review examining the effects of acupuncture for Bell's palsy (KQ3).
- Impact: A new systematic review on the proposed topic has limited impact potential. While there are research gaps, there is very little new evidence that fills those gaps.
- Feasibility:
    - *Size/scope of review:* Our search of PubMed resulted in a total of 82 unique titles. Upon title and abstract review, we identified a total of 8 studies potentially relevant to the key questions in the nomination. One study examined oral corticosteroids (KQ1), five examined facial nerve decompression (KQ2), and two examined acupuncture (KQ3).
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18. Prednisone and Acupuncture for the Treatment of Facial Neuritis: a Multiple Center, CER in China. 2014;NCT01201642.

Appendices

Appendix A: Selection Criteria Summary

Appendix B: Search for Systematic Reviews (Duplication)

Appendix C: 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 Bell's Palsy 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 Bell's Palsy, and there was limited evidence available on these three questions in the original guidelines. There is 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 reviews[3] examining benefits and safety of corticosteroid treatment for children with Bell's palsy. We identified one Cochrane evidence review[4] examining the effects of surgery in the management of Bell's palsy. We identified four completed[6-9] and one in-process[5] evidence review examining the benefits and harms of acupuncture treatment for Bell's palsy. Though there are evidence reviews covering parts of the scope of the nomination, there is no single evidence review examining the full scope of benefits and harms of corticosteroid, surgery and acupuncture treatments in children and adults with Bell's palsy.

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)?	The standard of care is unclear.
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	There is practice variation that can be address with an evidence review, which will inform the update of 2013 clinical practice guidelines.
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 one published study for KQ1 in 2013[10]. We identified published research for KQ2 (one in 2012[14], one in 2013[13], and 3 in 2015[11,12,15]). We found one published study in 2015[17], one published protocol in 2015[16], and one ongoing clinical trial[18] for KQ3.
6. Value	
6a. The proposed topic exists within a clinical, consumer, or policy-making context that is amenable to evidence-based change	The topic exists within a clinical and policy-making context that is amendable to evidence-based change.
6b. Identified partner who will use the systematic review to influence practice (such as a guideline or recommendation)	There is an identified partner. While there is not a large evidence base available, there may still be value in an evidence review. In order for the AAO-HNSF to update their guidelines, they need an evidence-based systematic review on which to base their conclusions, even if there is no new information.

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

Appendix B. Search for Systematic Reviews (Duplication)

Listed below are the sources searched and results of our search for existing guidance. A research librarian conducted the search and selected potentially relevant evidence based on the key question in the nomination and the associated PICOTS. An investigator reviewed each of the links to evidence below for inclusion. The links below do not represent the evidence selected for inclusion (see main topic brief).

Bell's Palsy	
Source	**Evidence**
Search for Duplication: August 10, 2016	
AHRQ and Other Federal Products	
AHRQ: Evidence reports and technology assessments, USPSTF recommendations, and related DEcIDE projects, and Horizon Scan	None.
VA Products: PBM, and HSR&D (ESP) publications, and VA/DoD EBCPG Program	None.
Cochrane Systematic Reviews and Protocols http://www.cochranelibrary.com/	*Corticosteroids for Bell's palsy (idiopathic facial paralysis) 2016* http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001942.pub5/full *Surgical interventions for the early management of Bell's palsy 2012* http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD007468.pub3/full *Acupuncture for Bell's palsy 2010 (excluded because it was published before 2011)* http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD002914.pub5/full
PubMed Health http://www.ncbi.nlm.nih.gov/pubmedhealth/	*Corticosteroid and antiviral therapy for Bell's palsy: a network meta-analysis 2011* http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0031551/ *Do children with Bell's palsy benefit from steroid treatment? A systematic review. 2012* http://www.ncbi.nlm.nih.gov/pubmed/22503409 *Acupuncture for Bell's palsy: a systematic review and meta-analysis. 2012* http://www.ncbi.nlm.nih.gov/pubmed/21994030 *Effectiveness of acupuncture in treatment of facial spasm: a meta-analysis. 2012* http://www.ncbi.nlm.nih.gov/pubmed/22875561
HTA (CRD database): Health Technology Assessments http://www.crd.york.ac.uk/crdweb/	None.

PROSPERO Database (international prospective register of systematic reviews and protocols) http://www.crd.york.ac.uk/prospero/	*The effectiveness and safety of acupuncture and corticosteroids in Bell's palsy: a systematic review protocol* http://www.crd.york.ac.uk/prospero/display_record.asp?ID=CRD42015019636
CADTH (Canadian Agency for Drugs and Technologies in Health) https://www.cadth.ca/	None.
DoPHER (Database of promoting health effectiveness reviews) http://eppi.ioe.ac.uk/webdatabases4/Intro.aspx?ID=9	None.
ECRI institute https://www.ecri.org/Pages/default.aspx	None.
Other	*Efficacy of Acupuncture for Bell's Palsy: A Systematic Review and Meta-Analysis of Randomized Controlled Trials* http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0121880 *Is acupuncture beneficial in the treatment of Bell's palsy?: Best Evidence topic (BET)* http://www.ncbi.nlm.nih.gov/pubmed/22564830