

## Frenotomy and Frenectomy with Breastfeeding Support

# Peer review and public comment on draft evidence report

May 14, 2025

Health Technology Assessment Program (HTA)

**Washington State Health Care Authority** 

PO Box 42712 Olympia, WA 98504-2712 (360) 725-5126 www.hca.wa.gov/hta

<u>ww.nca.wa.gov/nta</u> shtap@hca.wa.gov

#### Prepared by:

RTI International—University of North Carolina Evidence-based Practice Center Research Triangle Park, NC 27709 www.rti.org





This document was created in response to peer review and public comments on a Draft Health Technology Assessment (HTA) report prepared by the RTI-UNC Evidence-based Practice Center through a contract to RTI International from the State of Washington Health Care Authority (HCA). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of the State of Washington HCA and no statement in this document should be construed as an official position of the State of Washington HCA.

The information in the document is intended to help the State of Washington's independent Health Technology Clinical Committee make well-informed coverage determinations. This document and its associated Evidence Report are not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this document and the associated Evidence Report in the same way as any medical reference and in conjunction with all other pertinent information (i.e., in the context of available resources and circumstances presented by individual patients).

This document is in the public domain and may be used and reprinted without permission except those copyrighted materials that are clearly noted in the document. Further reproduction of those copyrighted materials is prohibited without the specific permission of copyright holders.

#### Acknowledgments

The following individuals contributed to the report associated with this document:

Lead Investigator: Jennifer Cook Middleton, PhD

Co-Investigator: Meera Viswanathan, PhD

Project Coordinator/Research Specialist: Jessica Vaughan, MPH

Research Analyst: Nila Sathe, MA, MLIS

Clinical Consultant: Wade Harrison, MD, MPH Information Specialist: Mark Howell, MLS Scientific Reviewer: Leila C. Kahwati, MD MPH

Editing and Document Preparation: Mary Gendron, BA; Alexander Cone, BA

### **Contents**

Peer Review Comments and Responses	4
Public Comments and Responses	
List of Tables	
Table 1. External Peer Reviewers of the Draft Evidence Report	4
Table 2. Peer Reviewer Comments on Draft Evidence Report and Response	5
Table 3. Individuals Submitting Public Comments on the Draft Evidence Report	9
Table 4. Public Comments on Draft Evidence Report and Responses (Commentor 1)	9

#### **Peer Review Comments and Responses**

Two independent, external peer reviewers were invited to provide comments on the Draft Evidence Report and were provided with an honorarium for their review. The peer reviewer's name, affiliations, and conflicts of interest are reported in *Table 1*.

Table 1. External Peer Reviewer of the Draft Evidence Report

Name	Title/Affiliation	Summary of Conflicts of Interest Reported
Nikhila P. Raol, MD, MPH	Associate Professor of Otolaryngology- Head and Neck Surgery and Pediatrics, Baylor College of Medicine Pediatric Otolaryngologist and Surgical Director of Swallowing Program, Texas	Financial conflicts: None reported.  Non-financial conflicts: Peer reviewer performs frenotomies on patients when indicated. She has previously written a case report, three reviews, and a prospective study under review on the topic of ankyloglossia.
(Reviewer 1)	Children's Hospital	
David O. Francis, MD, MS	Associate Professor, Division of Otolaryngology - Head & Neck Surgery, Department of Surgery, University of	<u>Financial conflicts:</u> None reported. <u>Non-financial conflicts:</u> Peer reviewer has a primary clinical specialty of otolaryngology – Head & Neck Surgery. He has
(Reviewer 2)	Wisconsin School of Medicine and Public Health	previously authored an AHRQ systematic review of ankyloglossia and treatment.

The peer reviewers did not identify any missing studies and did not identify any studies that should have been excluded from the report. We addressed many of the comments submitted by the reviewers in the Final Evidence Report, though some comments or suggestions were outside the scope of the HTA. We considered the revisions made based on peer review comments as minor revisions. Specific peer review comments and responses are provided in *Table 2*.

**Table 2. Peer Reviewer Comments on Draft Evidence Report and Response** 

Item	Comment	Response
Introduction		
Are there any additional issues you think we should cover in the introduction?	Reviewer 1: N/A  Reviewer 2: It read well and was comprehensive. Breast feeding efficacy is used throughout the report and it would be helpful to define what that means with first use. It is my understanding that it is measured using a PROM from the mother's perspective, but the construct it is actually measuring is not defined well.	Reviewer 1: We thank the reviewer for his comments.  Reviewer 2: Thank you for your comments regarding the measurement of breastfeeding self-efficacy both here and within the text of the report. This outcome was defined by the Breastfeeding Self-Efficacy Scale (BSES), which was reported in several studies. We have added clarifying text to the report to define what we mean by breastfeeding self-efficacy, specifically, a mother's confidence in her ability to breastfeed.
Do you see anything inaccurate, superfluous, or unclear?	Reviewer 1: 1.2 The reported burden is based on papers out of Johns Hopkins using the KID. The problem with this number is that it only refers to inpatient diagnoses and procedures. Will be important to also state that this number is likely an underestimation because most of these kids are diagnosed and managed as outpatients, as well as the fact they are often seen by non-insurance billing professionals like dentists.  1.3. second paragraph, last sentence—would include insurance coverage based on provider type  1.4. change electrocauterizers to electrocautery or Bovie electrocautery  Reviewer 2: No. Everything seems well-reasoned and is accurate. There are a few minor typos and suggestions for choice of words that are in the document in tracked changes.	Reviewer 1: Thank you for your comment.  We have examined the source in more detail and agree that the information may be incomplete as it only includes patient diagnoses and procedures in insured patients as captured by Optum systems and does not include the total number of patients analyzed per year, making rates impossible to calculate. We have added additional information to the report to clarify the limitations of this evidence base.  We agree with the reviewer's suggestion for sections 1.3 and 1.4 and have added additional text or edited text accordingly.  Reviewer 2: We thank the reviewer for his comments. See below for responses to comments from reviewer 2 contained in comments in the draft report.
Any additional comments?	Reviewer 1: Overall seems complete outside of the comment above for 1.2—I think this is super pertinent and should be stressed.  Reviewer 2: None.	Reviewer 1: See response above.  Reviewer 2: We thank the reviewer for his comments.
Methods		
Do you see any problems with our methods?	Reviewer 1 Small point—efficacy vs. effectiveness → these are not exactly the same so would be good to clarify which one (perhaps EQ should be effectiveness question)	Reviewer 1: We thank the reviewer for his comment and have revised the text to effectiveness.  Reviewer 2: We thank the reviewer for his
	PubMed was the major database queried. How come another large database was not searched like Embase? Perhaps not needed for this type of report, but typically used in systematic reviews	comments.

	Reviewer 2: The methods represent the state-of-the-art in	
	systematic reviews. I have no concerns.	
	Systematic remains in a controller	
Any additional	Reviewer 1: N/A	We thank the reviewers for their comments.
comments		
about the	Reviewer 2: None.	
Methods		
section?		
Results		
Are there any	Reviewer 1: In comparing to a systematic review and	Reviewer 1: Thank you for bringing these
studies you	meta-analysis that our team did, there were a number of	articles to our attention. PMID 35235369 was
believe we may	studies not included. It is possible that you excluded	included for the SQ but was excluded from
have missed?	these for other reasons, but I am attaching our study to	the EQ due to a lack of a comparison group.
	ensure that these came through your search. PMID	PMID 24937906 was similarly included for
	35235369 does look at lip and tongue tie release. Not	the SQ but excluded from the CQ due to a
	sure if it was excluded for any particular reason.	lack of a comparison group.
	Also not a great study but DMID 24027006 doos look at	Reviewer 2: We thank the reviewer for his
	Also not a great study but PMID 24937906 does look at cost. You might have found it and excluded it though	comments.
	because of low quality.	comments.
	because of low quality.	
	Reviewer 2: This is guite comprehensive and I am not	
	aware of any additional studies that could have been	
	included based on the inclusion criteria.	
Are there	Reviewer 1: No. Included studies seem appropriate.	We thank the reviewers for their comments.
studies that you		
believe we	Reviewer 2: None.	
should have		
excluded?		
Do you believe	Reviewer 1: No.	We thank the reviewers for their comments.
we have		
inaccurately	Reviewer 2: Yes. The results clearly described the studies	
described any	and their outcomes.	
studies?		
Any additional	Reviewer 1: Table 3 anesthesia these numbers right?	Reviewer 1: Thank you; the typo was
comments	They don't match the other numbers and should likely be	revised.
about the	explained.	
Results?	D	Reviewer 2: We thank the reviewer for his
D:	Reviewer 2: None	comments.
Discussion Do you think wo	Deviewer 1: I think reflux should be	Poviowar 1: We included reflex as an elicible
Do you think we	Reviewer 1: I think reflux should be	Reviewer 1: We included reflux as an eligible
missed any	mentioned/emphasized, as well as this concept of anterior	outcome, but only one study provided related
important	vs. posterior tongue tie, as these are in the literature and	evidence and provided evidence on the
points?	in the community but do not have adequate data. It may	outcome of gastroesophageal symptoms.
	be beneficial to expand the discussion on lip tie and	Due to the limited amount of evidence, we did not discuss this outcome in detail in the
	mention buccal/cheek ties (because these are all claimed	
	to co-occur).	discussion.
	Reviewer 2: I thought the discussion was thorough and	We have added some information on
	appropriate and described the current state of the	posterior tongue tie to the introduction.
	literature related to frenotomy and frenectomy.	Cheek/buccal ties were outside of the scope
	Interaction related to instructionly and instructionly.	The one of the scope

Do you disagree with any of the	Reviewer 1: No—it is concise and to the point. Appropriate for this type of report.	of this HTA due to the limited evidence that currently exists and the rarity of the condition. Our search results were consistent with the previous research in that effectiveness studies were only identified within populations undergoing frenotomy for tongue-tie. For safety, some studies examined the safety of frenotomy for tongue-tie, lip-tie, and other oral tie types including cheek/buccal ties, but the evidence was limited and nondescriptive (did not provide information on cheek ties specifically). Reviewer 2: We thank the reviewer for his comment.
discussion		
items?	Reviewer 2: I agree with the conclusions and comments made in the discussion.	
Any additional comments about the Discussion?	Reviewer 1: No.  Reviewer 2: None.	We thank the reviewers for their comments.
Other Sections		
Any comments on the structured abstract, conclusion, figures, tables, and appendices?	Reviewer 1: Tables are a little hard to read because of a lot of information. Might actually help to have more tables that are clearer with less info.  Reviewer 2: I made a minor comment made regarding some wording (in tracked changes) in the structured abstract for consideration.	Reviewer 1 and 2: We thank the reviewers for their comments.  Reviewer 2: We have updated the wording.
General Comme		
Is the report clearly written, adequately detailed, and of an appropriate	Reviewer 1: Yes. Length is very digestible. Clearly written with details without extending the text too much.  Reviewer 2: It is clearly written and is appropriate length to comprehensively report on this topic.	We thank the reviewers for their comments.
length?		

Please make any additional comments you feel would help us improve the report. Reviewer 1: It may be useful to discuss baseline breastfeeding rates in this country and discuss the impact on increasing rates of frenotomy on changes in breastfeeding for the recommended 6 months. In short, the rate has grown 2% over several years—to a meager 27-28% EBF at 6 months.

Reviewer 2: This report is quite thorough and represents the existing published, knowledge base on frenotomy and frenectomy and also highlights opportunities for future study and limitations of literature. Overall, it is the most comprehensive study on this topic that I am aware of. It is also important to point out that it is quite objective and the authors were careful in not including any subjectivity in their interpretation of the available studies.

Reviewer 2 comments in document:

- Structured abstract, results, line 202: "How would one measure infant breastfeeding selfefficacy? What does that mean?"
- 2. ES 1.4, line 258: Highlighted "electrocauterizer," commented "Electrocautery devices would be better here."
- 3. 1.4, line 661: Highlighted "electrocauterizer," commented "Electrocautery devices better term."
- 4. 2.3.3, line 731: Highlighted "person," commented "Mother?"
- 5. Table 4: "Who administers these? Is that important for this assessment. I assume that was considered with risk of bias? It appears some are patient-reported and others, like LATCH, require an external expert to rate (for example latch, type of nipple etc)."
- 6. Table 4, row 1, column 2: highlighted "efficiency" and commented "efficacy or efficiency"

Reviewer 1: There are too many variables related to breastfeeding rates to make any definite statements on the influence of frenotomy on overall rates of breastfeeding at 6 months.

Reviewer 2: We thank the reviewer for his comment.

Reviewer 2 comments in document:

- 1. See response above.
- We have changed the wording.See response to reviewer 1 above.
- 3. See above.
- 4. We agree and adjusted the language accordingly.
- The administration of these tests varied from study to study, and some of them did not report the method of administration. We did take this into consideration when evaluating risk of bias.
- 6. Thank you for catching this error. We have changed the word to "efficacy."

#### **Public Comments and Responses**

The Draft Workplan and Key Questions were posted for public comment.

The Draft Evidence Report was posted for public comment from March 4, 2025, to April 4, 2025. Two public comments were submitted. The names and affiliations of those submitting comments are summarized in *Table 3*.

Table 3. Individuals or Organizations Submitting Public Comments on the Draft Evidence Report

Name	Title/Affiliation
Dr. Keith McDonald (Public	A Kids Place Dentistry for Children
Commenter 1)	

Public comments and responses to comments are detailed in *Tables 4 and 5*. Complete copies of the comments submitted by individuals follow the table.

**Table 4. Public Comments on Draft Evidence Report and Specific Responses (Commentor 1)** 

Public Comment	Response
There is a well-documented protocol for assessing and treating infant lip and tongue ties. Most of the Pediatric dentists are executing a somewhat similar protocol with an objective assessment criteria and an objective post procedure assessment/follow up. Some of the experts in the field are Dr. Bobby Ghaheri; Dr. Richard Baxter (Author of the Book "Tongue Tied"); The Breathe Institute; Light Scalpel company; Dr. Lany Kotlow; Dr. Marty Kaplan. In the state of Washington, Dr. James Thomas at Health Latch.	Thank you for your comment.
I have also treated over 200 + cases (Lightscalpel CO2 laser) with very controlled and mostly predictable results, with mothers having improvement with nursing and infants having improvement with symptoms associated with a poor latch, following the release of either the lip, tongue, or both. These mothers are not only reassessed by the provider following the release, but also by the lactation consultant, midwife, or occupational feeding therapist.	Thank you for sharing your personal experiences with the procedure.