Washington State Health Care Authority

June 13, 2025 Meeting Materials
Health Technology Clinical Committee

Frenotomy and frenectomy with breastfeeding support

Contents

Health Technology Clinical Committee Application for Membership

Washington State Health Care Authority

1 Contact information

First name: Charlotte

Middle initial: W

Last name: Lewis

Address:

Phone number:

Best method, time to reach you:

Email:

Today's date: 3/12/25

2 Personal information (optional)

Gender:

☐ Male ☑ Female ☐ X/non-binary[1]

Pronouns (select all that apply)

☑ She/her ☐ He/him ☐ They/them ☐ Other (subj./obj.):

Race or Ethnicity

☐ American Indian or Alaska Native

☐ Asian or Pacific Islander American

☐ Black/ African American

☐ Latino, Hispanic, Spanish

☑ White/ Caucasian

☐ Other:

3 Professional training

Education (list degrees): BS, MS, MD, MPH

Health care practitioner licenses: WA MD00036058

Professional affiliations: Fellow of the American Academy of Pediatrics

Board certifications, formal training, or other designations: American Board of Pediatrics

Current position (title and employer): Professor, UW

Current practice type and years in practice: academic clinic medicine--27 years

Total years as an active practitioner: 31

Location of practice (city): Seattle

1 *Non-binary (X) is an umbrella term used to describe those who do not identify as exclusively male or female. This includes but is not limited to people who identify as genderqueer, gender fluid, agender, or bigender.*

4 Experience

Provide a brief explanation (up to 150 words each) addressing the following:

1) Why you would like to serve on the clinical committee;

I have performed thousands of sublingual frenotomies on infants. I have a good understanding of the evidence surrounding frenotomy to promote breastfeeding. I understand the limitations to frenotomies and believe that " oral ties" are being overdiagnosed and overtreated. There is limited to no evidence to support routinely perfoming a frenotomy on buccal and lip ties for breastfeeding or other concerns and yet these procedures are increasingly performed, often for cash payment, by health professionals--primarily dentists--with limited expertise in infant feeding and breastfeeding, and limited capacity for follow up of feeding problems to ensure that they have been addressed.

2) The value of informing health policy decisions with scientific evidence, including any examples incorporating new evidence into your practice;

Evaluating evidence and incorporating it into practice forms the foundation for everything I do as a physician. As a professor in the UW School of Medicine, it is expected that I will stay updated on evidence related to my field and rely on this to inform patient care and the education I provide to trainees. Recently, I have been very involved in using evidence to counter misinformation about community water fluoridation.

3) How your training and experience will inform your role on the committee

I perform frenotomies but I also lead a feeding team at Seattle Children's where I have seen that a lot of unnecessary procedures are being performed on babies with feeding dificulties because their parents are desperate for solutions. Some providers performing frenotomies lack experience and expertise to evaluate and treat feeding problems in infancy, yet they have no problem performing procedures intended to improve feeding. I believe we need a more evidence-based and multidisciplinary approach to evaluating and treating feeding problems, inluding tongue tie.

4) Treating populations that may be underrepresented in clinical trials: women, children, elderly, or people with diverse ethnic and racial backgrounds, including recipients of Medicaid or other social safety net programs?

My life's work has been devoted to reducing disparities among those experiencing poverty and/or racial or ethnic minorities. My research has focused on improving access to dental care for publicly-insured children.

5 Ability to serve

Are you able to participate in all-day meetings, an estimated six times per year? ☐ Yes ☐ No

Are you willing to commit to the responsibilities of a committee member, including:

- Attending meetings prepared for the topics of the day;
- Actively participating in discussions;
- Making decisions based on the evidence presented and the public interest1? ☐ Yes ☐ No

Could you, or any relative, benefit financially from the decisions made by the HTCC? ☐ Yes ☐ No

6 References

Provide three professional references:

1.

First name: Beth
Last name: Ebel
Relationship: colleague
Title: professor
Contact email:
Phone number:

2.

First name: Barb
Last name: Baker
Relationship: colleague
Title: teaching associate
Contact email:
Phone number:

3.

First name: Rose
Last name: Toves
Relationship: colleague
Title: RN3
Contact email:
Phone number:

For your application to be reviewed, please include:

✓ Completed application ✓ curriculum vitae ✓ **conflict of interest disclosure**

Download this form and send the completed version to **shtap@hca.wa.gov**

OR mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

1 *Detailed in Washington Administrative Code (WAC) and committee bylaws*

Health Technology Clinical Committee Conflict of Interest Disclosure

Washington State Health Care Authority

Instructions
This conflict of interest (COI) form must be completed by an applicant for appointment to the state of Washington Health Technology Clinical Committee (HTCC) or clinical expert serving in a temporary capacity on the HTCC, as well as appointment to any of its subcommittees or work groups.
Those wishing to provide public comment at HTCC meetings are also requested to complete this COI form, but are not required to do so.

Instructions specific to HTCC applicants
As stewards of public funds, the practicing clinicians who serve (or apply to serve) on the Committee strive to uphold the highest standards of transparency and impartiality. Identifying financial, professional, and other interests contributes to the effective management of perceived, potential, and/or real conflicts of interest/bias that could affect Committee determinations (WAC 182-55). Management of potential conflicts of interest on specific topics are addressed in committee bylaws.

1 Applicant information

First name: Charlotte

Middle initial: W

Last name: Lewis

Phone number:

Email:

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.
List amounts totaling $1,000 or more from a single source.
Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.
Indicate the source and date of the financial interest. For each chosen category, include date and if your activities are ongoing.
Indicate the recipient. Family: spouse, domestic partner, child, stepchild, parent, sibling (his/her spouse or domestic partner) currently living in your home.

Financial interest categories

Use these categories to indicate the nature of the financial interest:

A. Payment from parties with a financial or political interest in the outcome of work as part of your appointment or activity.
B. Employment including work as an independent contractor, consultant, whether written or unwritten.
C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected.
D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.
E. Participating on a company's proprietary governing boards.
F. Participating in a speakers bureau.
G. Receiving honoraria.

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
A-G	none	none	Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

3 Other interests

Please respond to the following questions. Disclose all interests that may apply to health technology assessment (HTA) topics covered in upcoming meetings.

Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

I spoke on team-based care for tongue tie at a UW meeting for community feeding therapists in WA

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

No

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

I suppose if sublingual frenotomies were no longer covered, that could affect the number of patients who come to my clinic, however, that clinic is a very small part of my work.

4 Signature

I have read the Conflict of Interest Disclosure form. I understand the purpose of the form and agree to the application of the information to determine conflicts of interest. The information provided is true and complete as of the date the form was signed. If circumstances change, I am responsible for notifying HTA program staff in order to amend this disclosure. I will complete this form annually by July 1st of each year of committee membership (*applies to HTCC committee only*).

To sign this request, do not use the "Fill & Sign" function; instead, simply click in the signature field to add your signature.

Signature

Date

3/12/25

Download this form and send the completed version to **shtap@hca.wa.gov**.

Or mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

CURRICULUM VITAE

Charlotte W. Lewis, MD, MPH

1. CONTACT INFORMATION	
Charlotte W. Lewis, MD, MPH	
University of Washington Department of Pediatrics, Division of General Pediatrics	
Children's Health Institute	
2. PERSONAL DATA	
Place of Birth: [redacted]	
3. EDUCATION	
1985	BS, Nutrition Science, University of California, Davis (with honors)
1988	MS, Clinical Nutrition, Cornell University, Ithaca, NY
1994	MD, University of California, San Francisco, CA
2000	MPH, University of Washington, Seattle, WA
4. POSTGRADUATE TRAINING	
1987	Dietetic Intern, Cornell University, Ithaca, NY
1988	Pediatric Nutrition Fellow, Riley Hospital for Children, Indianapolis, IN
1994-1997	Pediatric Resident, Harbor-UCLA Medical Center, Torrance, CA
1998-2000	Robert Wood Johnson Clinical Scholar, University of Washington, Seattle, WA
2022-2023	CLIME Teaching Scholars Program
5. FACULTY POSITIONS HELD	
1989-1990	Lecturer in Nutrition, School of Medicine, Indiana University, Indianapolis, IN
1997-1998	Pediatric Chief Resident, Harbor-UCLA Medical Center, Torrance, CA
1998-2000	Acting Instructor, Pediatrics, University of Washington, Seattle, WA
2000-2001	Acting Assistant Professor, Pediatrics, University of Washington, Seattle, WA
2001-2007	Assistant Professor, Pediatrics, University of Washington and Adjunct Assistant Professor, Pediatric Dentistry, University of Washington, Seattle, WA
2007-2021	Associate Professor, Pediatrics, University of Washington and Adjunct Associate Professor, Pediatric Dentistry, University of Washington, Seattle, WA
2021-present	Professor, Pediatrics, University of Washington and Adjunct Professor, Pediatric Dentistry, University of Washington, Seattle, WA
6. HOSPITAL POSITIONS HELD	
1997-1998	Attending Physician, Pediatric Emergency Department, Harbor-UCLA, Torrance, CA
1998-2000	Attending Physician, Children and Teen's Clinic, Harborview Medical Center, Seattle, WA
2000	Attending and Fast Track Physician, Emergency Department, Seattle Children's Hospital, Seattle, WA
2000-2015	Attending Physician, Craniofacial Center, Seattle Children's Hospital, Seattle, WA
2000-2018	Attending Physician, General Medicine Inpatient Service, Seattle Children's Hospital, Seattle, WA
2011-2012	Attending Physician, Pediatric Residency Continuity Clinic, UW Roosevelt Pediatric Clinic, Seattle, WA

2011-present	Attending Physician, Newborn Nursery and Progressive Care Nursery, University of Washington Medical Center, Seattle, WA. ● In addition to my responsibilities as inpatient attending in the well-baby and progressive care nurseries, I see patients in a weekly ankyloglossia clinic at UWMC in which I evaluate patients for ankyloglossia and other feeding problems and I perform sublingual frenotomies.
2015-present	Multidisciplinary Infant Nutrition and Feeding Team (MINFT), Seattle Children's Hospital (SCH), Seattle, WA. ● In the face of institutional need for a multidisciplinary team to address and coordinate the nutrition and feeding care of children with complex medical conditions, I developed and lead the MINFT inpatient consult service and outpatient clinic at Seattle Children's Hospital. ● Prior to MINFT's implementation, these children's feeding and nutritional care was scattered and piece-meal, leaving many families frustrated and children without a coordinated plan to adequately address their feeding and nutritional problems. ● MINFT consists of SCH feeding therapists and nutritionists. As a family- and patient-centered team, we work closely with subspecialists at SCH, with community PCPs, and early intervention services providers to optimize an infant's feeding and nutrition and to support their families. ● We care for infants with a variety of medical conditions who have feeding and nutritional problems, most notably dysphagia, faltering growth, feeding refusal, and enteral feeding tube dependence. ● We conduct a comprehensive assessment of a child's feeding abilities and nutritional needs and provide short and long-term feeding and nutritional planning, education, and care coordination for the patient, family, primary care provider, and other healthcare team members.

7. HONORS

1985	Graduation with honors, UC Davis
2003	Robert Wood Johnson Clinical Scholars Program mentorship award

8. BOARD CERTIFICATION

1998-present	Certified, American Board of Pediatrics, General Pediatrics (MOC cycle 12/2023-12/2028)

9. CURRENT STATE LICENSE

1998-present	State of Washington License: MD00036058

10. PROFESSIONAL ORGANIZATIONS

1994-present	American Academy of Pediatrics

11. TEACHING RESPONSIBILITIES

(a) Medical students and students in other health professions

TABLE: UW SOM courses taught

Course	Title	Credits	Years	Students	Responsibility
Conjoined 516	What Every Physician Needs to Know about Oral Health.	1	2005 and 2006	Medical students	Course Co-director

(b) Pediatric Residents

TABLE: Pediatric resident teaching responsibilities

2002-2020	Noon Conference, biannual lecture, Dental Overview for Pediatricians
2005-2021	Noon Conference, biannual lecture, Dental Trauma and Emergencies
2006-2009	Noon Conference, yearly lecture: Pierre Robin Sequence
2015	Noon Conference: Responsible Use of the Electronic Medical Record
2015-present	Newborn Nursery Resident Lecture Series: Normal and Abnormal Physical Findings in the Newborn.
2016-present	Newborn Nursery Resident Lecture Series: Newborn Sepsis. A Comparative, Case-based Approach.
2017-present	Newborn Nursery Resident Lecture Series: Hemolytic Disease of the Newborn
2018-present	Newborn Nursery Resident Lecture Series: Common Craniofacial Problems in General Pediatrics
2023-present	Newborn Nursery Resident Lecture Series: Fetal Lung Fluid Clearance and Transient Tachypnea of the Newborn.

(c) Subspecialty Fellows

TABLE: Subspecialty fellows teaching responsibilities

2004-2012	An Overview of Craniofacial Care. University of Washington Graduate Program in Orthodontics.

(d) Mentoring

TABLE: Fellow and junior faculty mentoring (past 5 years)

2024- present	Mackenzie Wyatt, MD I am a member of Dr Wyatt's scholarly oversight committee. She is a pediatric pulmonary fellow with an interest in cystic fibrosis, sickle cell disease, and health disparities.
2021-2023	Marnina Gottesman, MD I was chair of Dr Gottesman's scholarly oversight committee and advise her on research design and methodology on her project to improve emergency department care for children with autism. She recently completed her fellowship.
2017-presemt	Elizabeth Abernathey, MD I began my mentoring relationship with Dr. Abernathey when she was a resident and have continued in that role, primarily focusing on career development, through her adolescent fellowship and now, on faculty at Seattle Children's.
2010-present	Helen Lee, MD, MPH. I began mentoring Dr Lee when she was a UW post-doctoral fellow. I have mentored her through a number of grant submissions, research projects and manuscripts related to dental care disparities and access to operative dental care. I continue to mentor her now that she is an associate professor of anesthesia at the University of Illinois. We have co-authored 5 papers together. I have also provided career development guidance and advice.
2018-2019	Whitney Waite, MD, MPH I was a member of Dr. Waite's scholarly oversight committee. In that role, I met with her regularly to review and guide her research ideas and progress. Dr Waite left her position in

	2019 to travel with her family.

12. EDITORIAL RESPONSIBILITIES

2014-present	Fluoride Science, Associate Editor
2024-present	Advances in Pediatrics (Elsevier), Associate Editor

13. SPECIAL NATIONAL RESPONSIBILITIES

2000	Session moderator, Surgeon General's Conference on Children's Oral Health, Washington, DC
2002-2007	American Academy of Pediatrics, Oral Health Forum
2005-2006	Reviewer, NIH-NIDCR Study Section: Special Emphasis Panel on Health Care
2005-2009	Abstract reviewer, Pediatric Academic Societies
2006-2008	Session moderator, Pediatric Academic Societies
2007-2008	Reviewer, NIH-NIDCR Study Section: Data Analysis and Statistical Methodology (R03)
2008	Reviewer, NIH-NIDCR Study Section: Oral Health Disparities Centers
2012	Reviewer, NIH-NIDCR Study Section: Oral Health Considerations for Medically Complex Populations
2013	Expert reviewer. Evidence review for: "Prevention of Dental Caries in Preschool Children" for the U.S. Preventive Services Task Force
2014-present	Project Advisory Committee, American Academy of Pediatrics, Campaign for Dental Health
2018-2020	Expert consultant. United States Environmental Protection Agency (EPA). Food and Water Watch vs. EPA, DJ #90-5-1-4-21106. In this contract with the US EPA, I provide review and analysis of evidence related to the benefits of community water fluoridation, in the form of expert consultation, drafting expert report and rebuttal report, and deposition.
2020	Reviewer, NIH-NIDCR Study Section: Predoctoral and Postdoctoral Fellowship Applications
2022	Expert reviewer. Evidence review for: "Prevention of Dental Caries in School-age Children" for the U.S. Preventive Services Task Force

14. SPECIAL LOCAL RESPONSIBILITIES

2001	Intern Selection Committee, Department of Pediatrics, University of Washington
2003-2007	Coordinator, biweekly research seminar series at Child Health Institute
2004	Conference Director, Craniofacial Overview for Orthodontists (state-wide CME course)
2004	Abstract reviewer, Western Society for Pediatric Research
2004-2005	Expert panel member, Children's Preventive Oral Health Learning Collaborative, Washington State
2004-2010	ECOH (Early Childhood Oral Health) Steering Committee member, University of Washington, Department of Pediatric Dentistry
2008-2010	University of Washington Faculty Senate
2008-2012	Co-chair, Seattle Children's Hospital Work-Life Balance Committee. ● In this position, together with Cora Breuner, MD, we organized an annual work-life balance conference on a topic relevant to physician wellness featuring a nationally prominent keynote speaker. ● This committee also surveyed SCH physicians about work-life balance topics and made recommendations to hospital leadership about important issues related to physician work-life balance including childcare needs and affordability, elder care, and promotion flexibility for faculty with young children.
2013-2021 (*pro tem* 2021-2022)	Washington State Medical Commissioner, appointed by Governor Jay Inslee representing Congressional District 7. Washington State Department of Health.

	• As a Washington Medical Commission, each year I personally reviewed and made recommendations for approximately 300-400 complaints made to the Medical Commission by members of the public and other entities about Washington allopathic physicians and physician assistants. • Additionally, I performed in-depth reviews of medical records and investigative reports and prepared a written summary and recommendations for disciplinary action for approximately 40 complaints/year in which substantial allegations have been made against MDs or PAs. These case summaries are presented and discussed at 2-day meetings in Tumwater, WA and throughout the state occurring every 6 weeks. • I participated in disciplinary hearings and settlement conferences for medical providers accused of misconduct and deviations from standard of care. • I participated in hearings related to state rule making (e.g., ambulatory surgery, opioid prescribing) • I underwent Sexual Misconduct and Response Training (SMART) and reviewed cases of alleged sexual misconduct involving physicians or physician assistants. • I served on 2 Medical Commission subcommittees: 1) Telemedicine and 2) The Electronic Medical Record. I was the lead author for WA guidelines on electronic medical record (EMR) use by physicians and physician assistants, providing the first comprehensive overview of appropriate EMR use for the Washington Medical Commission.
2018-2019	Co-chair General Pediatrics Training Grant Committee. Together with Dr. Fred Rivara, I led a committee to develop and write an NIH training grant application on health inequities that received a score of 16 and led to funding to implement a children's healthy equity training program for historically underrepresented post-graduate physicians and scientists.
2022-present	Medical director, Island County Early Intervention Feeding Team. In this volunteer position, I meet monthly with the newly formed feeding team to review cases and to help to grow their feeding program.
2024-present	Perinatal Mental Health in ESIT (Early Support for Infants and Toddlers) Taskforce. I have joined this taskforce sponsored by Northwest Center Hospital-to-Home System Change Team, funded by WA DCYF Perinatal Mental Health Initiative, to work on developing systems to better support the emotional well-being of families within ESIT.

15. GRANTS AND CONTRACTS

Active Funding

None

Pending Funding

None

Completed Funding

1K23DE014062 07/30/2001-07/31/2006
The National Institute of Dental and Craniofacial Research Annual direct funding: $123,525
The Primary Provider and Preventive Oral Health
In a series of related studies, to identify pediatricians current and potential role in improving the oral health of their patients.
Role: Mentored Career Development Award

1R21DE014960-01 09/30/2002-08/31/2004
The National Institute of Dental and Craniofacial Research Annual direct funding: $125,000
Dental and Orthodontic Access in Craniofacial Care
To develop tools to characterize barriers to accessing dental and orthodontic care for patients with craniofacial disorders and to identify potential strategies by which access to care may be improved.
Role: Co-PI

1R21DE017364-A1 09/01/2006-08/31/2008
The National Institute of Dental and Craniofacial Research
Caries Prevalence in Orofacial Clefting: A Pilot Study for Oral Health Case Management.
To describe the epidemiology and risk factors for caries in children born with cleft lip and palate and potential for case management to improve the oral health of these children.
Annual direct funding: $100,000
Role: PI

1R21DE018012-A2 09/01/2007-08/30/2010
The National Institute of Dental and Craniofacial Research Annual direct funding: $150,000
Oral Health Status and Habits of Young Children with Developmental Delay
Using a health behavior conceptual model, to characterize the influence of parental beliefs and behaviors on the oral health of young children in early intervention programs.
Role: PI

1R03DE017199-A1 09/30/2007-08/30/2010
The National Institute of Dental and Craniofacial Research Annual direct funding: $100,000
Dental Care in Children with and without Special Health Care Needs
Using population-based data and methods, to compare dental care utilization and expenditures among US children with and without special health care needs.
Role: PI

University of Washington Bridge Fund 06/01/2010-06/30/2011
Identifying Children with Special Dental Care Needs Annual direct cost: $40,000
Using both qualitative and large dataset methods, to better characterize the characteristics and epidemiology of children with special health care needs who encounter difficulty accessing dental care.
Role: PI

American Academy of Pediatrics 03/01/2011-06/30/2011
Barriers and Facilitators of Oral Health Promotion Annual direct funding: $25,000
by AAP Chapter Oral Health Advocates
Using qualitative research, to identify factors that promoted or interfered with Chapter Oral Health Advocates' (COHAs) outreach and education of peers about oral health and fluoride varnish and to develop strategies for future success of the COHA program.
Role: PI

1R03 DE023608-01 08/01/2013-07/31/2015
The Forsyth Institute/National Institute of Dental and Craniofacial Research (NIDCR): Annual direct cost: $56,235
Hospital Volume for Orofacial Cleft Repair and Risk of Complications.
To describe the epidemiology of US primary cleft lip and cleft palate repairs, their timeliness, distribution by hospital type, and relationship between hospital volume and perioperative complications.
Role: Site PI

16. BIBLIOGRAPHY (†mentoring role)

(a) Peer-reviewed Manuscripts

1. Braveman P, Bennett T, Lewis CW, Egerter S, Showstack J. Access to prenatal care following major Medicaid eligibility expansions. *JAMA*. 1993 Mar 10;269(10):1285-1289. PMID: 8437308.

2. Lewis CW, Frongillo EA, Roe DA. Drug-nutrient interactions in three long-term-care facilities. *J Am Diet Assoc*. 1995 Mar;95(3): 309-315. PMID: 7860942.

3. Lewis CW, Grossman D, Domoto P, Deyo R. The role of the pediatrician in oral health: A national survey. *Pediatrics*. 2000 Dec;106(6): E84. PMID: 11099627.

4. Lewis CW, Nowak A. Stretching the safety net too far. Waiting times for operative dental care. *Pediatr Dent* 2002 Jan-Feb;24(1):6-10. PMID:11874063.

5. Lewis CW, Riedy C, Grossman D, Domoto P, Roberts M. Oral health of young Alaska Native children and their caregivers in Southwestern Alaska. *Alaska Med*. 2002 Oct-Dec;44(4):83-87. PMID: 12650085.

6. Bakalian S, Lewis, CW. Question from the clinician: fluoridated water. *Pediatr Rev*. 2003 Feb;24(2):70. PMID: 12563042.

7. Lewis CW, Carron J, Perkins J, Sie K, Feudtner C. Tracheotomy in pediatric patients: a national perspective. *Arch Otolaryngol Head Neck Surg*. 2003 May;129:523-529. PMID: 12759264.

8. Lewis CW, Lynch H, Johnston B. Dental complaints in emergency departments: A national perspective. *Ann Emerg Med*. 2003 Jul;42(1):93-99. PMID: 12827128.

9. Brown JC, Klein EJ, Lewis CW, Johnston B, Cummings P. Emergency department analgesia for fracture pain. *Ann Emerg Med*. 2003 Aug;42(2):197-205. PMID: 12883507.

10. Lewis CW, Milgrom P. Fluoride. *Pediatr Rev*. 2003 Oct;24(10):327-36. PMID: 14523159.

11. Lewis CW, Cantrell DC, Domoto PK. Oral health in the pediatric practice setting: A survey of Washington State pediatricians. *J Public Health Dent*. 2004 Spring;64(2):111-114. PMID: 15180081.

12. Lewis CW, Lynch HA, Richardson LP. Fluoride varnish use in primary care: what do providers think? *Pediatrics*. 2005 Jan;115(1);e69-76. PMID: 15629967.

13. †Stern RE, Lewis CW, Yueh B, Norton S, Sie K. Recent epidemiology of pediatric cochlear implantation: Disparity among children of different ethnicity and socioeconomic status. *Laryngoscope*. 2005 Jan; 115(1):125-131. PMID: 15630380.

14. †Smith R and CW Lewis. Availability of dental appointments for young and Medicaid insured children in King County Washington. Implications for access. *Pediatr Dent*, 2005 May-Jun;27(3):207-11. PMID: 16173224.

15. Perkins J, Lewis CW, Gruss J, Eblen L, Sie K. Furlow palatoplasty for management of velopharyngeal insufficiency: a prospective study of 148 consecutive patients. *Plast Reconstr Surg*. 2005 Jul;116(1):72-80. PMID: 15988249.

16. †Harsha WJ, Perkins JA, Lewis CW, Manning SC. Pediatric admissions and procedures for lymphatic malformations in the United States: 1997 and 2000. *Lymphat Res Biol*. 2005 Summer;3(2):58-65. PMID: 1600054.

17. †Harsha WJ, Perkins JA, Lewis CW, Manning SC. Head and neck endocrine surgery in children: 1997 and 2000. *Arch Otolaryngol Head Neck Surg*. 2005 Jul;131(7):564-70. PMID: 16027277.

18. Lewis CW, Ose M, Aspinall C, Omnell L. Community orthodontists and craniofacial care: Results of a Washington state survey. *Cleft Palate-Craniofac J*. 2005 Sep;42(5):521-525. PMID: 16149834.

19. Lewis CW, Robertson A, Phelps, S. Unmet dental care needs among children with special health care needs. Implications for the Medical Home. *Pediatrics*. 2005 Sep;116(3):e426-31. PMID: 16140688.

20. †Lam D, Starr J, Perkins J, Lewis CW, Eblen, L, Dunlap J, Sie, K. A Comparison of nasendoscopy and multiview videofluoroscopy in assessing velopharyngeal insufficiency. *Otolaryngol Head Neck Surg*. 2006 Mar;134(3):394-402. PMID: 16500434.

21. Mouradian WE, Reeves A, Kim S, Lewis CW, Keerbs A, Slayton R, Gupta D, Oskouian R, Schaad D, Kalet T, Marshall S. A new oral health elective for medical students at the University of Washington. *Teach Learn Med*. Fall 2006; 18(4):336-42. PMID: 17144840.

22. Nyweide K, Feldman K, Gunther DF, Done S, Lewis CW, Van Eenwyk C. Hypocalciuric hypercalcemia presenting as neonatal rib fractures: a newly described mutation of the calcium-sensing receptor gene. *Pediatr Emerg Care*. 2006 Nov; 22(11):722-4. PMID: 17110864.

23. Lewis CW, Mouradian WE, Slayton RL, Williams AC. Dental insurance and its impact on preventive dental care visits for U.S. children. *J Am Dent Assoc*. 2007 Mar;138(3):369-380. PMID: 17332043.

24. Lewis CW, Johnston BD, Linsenmeyar K, Williams AC, Mouradian WE. Preventive dental care for children in the United States: A national perspective. *Pediatrics*. 2007 Mar;119(3): e544-553. PMID: 17332174.

25. Richardson LP, Lewis CW, Casey-Goldstein M, McCauley E, Katon W. Pediatric primary care providers and adolescent depression: a qualitative study of barriers to treatment and the effect of the black box warning. *J Adolesc Health*. 2007 May;40(5):433-9. PMID: 17448401.

26. †Dashow JE, Lewis CW, Hopper RA, Gruss JS, Egbert MA. Bupivacaine administration and postoperative pain following anterior iliac crest bone graft for alveolar cleft repair. *Cleft Palate Craniofac J*. 2009 Mar;46(2):173-8. PMID: 19254053.

27. Hopper RA, Lewis CW, Umbdenstock R, Garrison MM, Starr JR. Discharge practices, readmission, and serious medical complications following primary cleft lip repair in 23 U.S. children's hospitals. *Plast Reconstr Surg*. 2009 May;123(5):1553-9. PMID: 19407628.

28. Lewis CW, Teeple E, Robertson A, Williams A. Preventive dental care for young Medicaid-insured children in Washington State. *Pediatrics*. 2009 Jul;124(1):e120-7. PMID: 19564258.

29. Lewis CW, Boulter S, Keels M, Krol D, Mouradian W, O'Connor K, Quinonez R. Oral health and pediatricians: results of a national survey. *Acad Pediatr*. 2009 Nov-Dec;9(6):457-61. PMID:19945080.

30. *Lewis CW. Dental care and children with special health care needs in the United States. A population-based perspective. *Acad Pediatr*. 2009 Nov-Dec;9(6):420-6. PMID: 19945077. PMCID: PMC2787477.

31. †Iida H, Lewis CW, Warren L, Chuang Z, Grembowski D. Dental care needs, use, and expenditures among US children with and without special health care needs. *J Am Dent Assoc*. 2010 Jan;141(1):79-88. PMID: 20045826.

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47. Lewis CW. Teeth: Small but Mighty and Mighty Important. A comprehensive review of children's dental health for primary care clinicians. *Curr Pediatr Rev*. 2020;16(3):215-231. PMID: 32108010.

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(b) Book Chapters

1. Lewis CW, Anand SK. Fluids and electrolytes disturbances. In: Berkowitz C (ed). Pediatrics: A Primary Care Approach. Philadelphia, B.C. Sanders; Second edition, 2000.

2. CW Lewis. Childhood obesity. *In*: Berkowitz C (ed). Pediatrics: A Primary Care Approach. Philadelphia, B.C. Sanders; Second edition, 2000.

3. CW Lewis. Dental disorders. In: Osborn, Dewitt, First and Zenel (eds). Pediatrics. Philadelphia, Elsevier Mosby, 2005.

4. CW Lewis. Oral lesions in children. In: Berkowitz C (ed). Pediatrics: A Primary Care Approach. Philadelphia, B.C. Sanders; Third edition, 2008.

5. Lewis CW and SK Anand. Fluids and electrolytes disturbances. In: Berkowitz C (ed). Pediatrics: A Primary Care Approach. Philadelphia, B.C. Sanders; Third edition, 2008.

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8. CW Lewis. Oral lesions in children. In: Berkowitz C (ed). Pediatrics: A Primary Care Approach. Philadelphia, B.C. Sanders; Fourth edition, 2011.

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12. CW Lewis. Dental health in childhood. In: Gullotta TP**,** Bloom M (eds). The Encyclopedia of Primary Prevention and Health Promotion. New York, Springer; Second edition, October 2014.

13. CW Lewis. Oral lesions in children. In: Berkowitz C (ed). Pediatrics: A Primary Care Approach. Philadelphia, B.C. Sanders; Sixth edition, 2020.

14. CW Lewis. Dental disorders. In: Berkowitz C (ed). Pediatrics: A Primary Care Approach. Philadelphia, B.C. Sanders; Sixth edition, 2020.

15. CW Lewis. Oral lesions in children. In: Berkowitz C (ed). Pediatrics: A Primary Care Approach. Philadelphia, B.C. Sanders; Seventh edition, expected 2025.

16. CW Lewis. Dental disorders. In: Berkowitz C (ed). Pediatrics: A Primary Care Approach. Philadelphia, B.C. Sanders; Seventh edition, expected 2025.

(c) Published books, video, audio, software, podcasts

1. CW Lewis. The role of the pediatric dentist in the care of children with cleft lip and/or cleft palate. Audio Recording. Practical Reviews in Pediatric Dentistry. February 2018.

2. CW Lewis. Fluoride in the water. Johns Hopkins Bloomberg School of Public Health. Public Health on Call Podcast. November 22, 2024.

(d) Other publications

1. Gleiner S and C Lewis. Question from the clinician: Fluoride supplementation and dental caries. *Pediatr Rev*. 2002 May;23:186-187. PMID: 11986495.

2. Lewis CW. Pediatric oral health: The important role of the family doctor. *Washington Family Physician*. Spring 2002: 13-17.

3. Lewis CW. Children with special health care needs may encounter difficulty finding dental care. *J Evid Based Dent Pract*. 2005 Jun;5(2):76-7. PMID: 17138337.

4. Lewis CW. Fluoride. Pediatrics for Parents. Fall 2014.

5. Lewis CW, Johnson M for the Washington State Medical Quality Assurance Commission. Physicians' and Physician Assistants' Use of the Electronic Medical Record. State of Washington, Medical Quality Assurance Commission Guideline. Olympia, WA. Approved August 21, 2015.

(e) Recently submitted manuscripts

Lewis C, Fisher-Owens S. Confidence in community water fluoridation.

(f) Abstracts (last 5 years)

1. Sisk B, Lewis C, Barone L, Quinonez R, Krol D, Braun P. Trends in pediatricians' practices and perceived barriers related to oral health assessments: 2008-2018. Poster presentation, Pediatric Academic Societies, 2019.

2. Hasan R, Hess J, Pagano M, Staley E, Tsang H, Lewis, C. Routine direct antiglobulin testing on cord blood samples to evaluate neonatal hemolysis risk is of limited utility. Poster Presentation, Association for the Advancement of Blood & Biotherapies, 2021

17. INVITED LECTURES

(a) National/International

4/2001	Invited speaker: Oral Health/Total Health, Oakland, CA. Session Title: California Responds to the Surgeon General's Conference on Oral Health. Presentation Title: Will Professional Education Respond to Workforce Challenges?

5/2003	Workshop Leader: Pediatric Academic Societies annual national meeting, Baltimore, MD. Session Type: Workshop, Session Title: Getting Funded the K Way (NIH Mentored Career Development awards).
11/2005	Keynote speaker: Maternal and Child Health Bureau Division 8, Oral Health Institute. Denver, CO. Presentation Title: The Pediatrician and Oral Health.
11/2008	Invited speaker: National Summit on Children's Oral Health, Chicago, IL. Session Title: A New Era of Collaboration. Presentation Title: Children with Special Health Care Needs. What Have We Learned about their Dental Health from a Population Perspective since The Surgeon General's Conference?
4/2010	Invited speaker: MCHB Tri-Center Meeting, Seattle, WA. Session Title: Leadership for Change: Responding to the Surgeon General's Report. Presentation Title: The Role of the Pediatrician in Oral Health: How Far Have We Come?
6/2010	Invited speaker: American Academy of Pediatrics Partnership to Reduce Oral Health Disparities in Early Childhood. Washington, DC. Presentation Title: Fluoride and the Pediatrician: Unanswered Questions and Uncertain Role.
10/2012	Invited speaker: American Academy of Pediatrics National Conference & Exhibition, New Orleans, LA. Session Type: Oral Health Section. Presentation Title: Chapter Oral Health Advocates.
5/2014	Keynote speaker: Pew Charitable Trusts, Washington, DC. Session Title: Investing in Prevention: Strategies for Advancing Oral Health. Presentation Title: Healthy Teeth. Healthy Future. The Power of Fluoride.
5/2014	Workshop leader: Pediatric Academic Societies national annual meeting, Vancouver, BC. Session Type: Workshop Title: Ready-Made: Conducting Pediatric Research using Publicly Available Datasets.
3/2018	Invited Speaker: American Academy of Pediatrics Campaign for Dental Health, Itasca, IL. Session Title: Building Effective Statewide Teams for Oral Health. Presentation Title: Fluoride and Non-fluoride Evidence-based Oral Health Preventive Strategies
7/2020	Invited Speaker. American Dental Association 75th Anniversary. Community Water Fluoridation, Chicago, IL. Presentation Title: Fluoridation Advocacy: How to Share Evidence-Based Findings with Lay Audiences.
12/2023	Invited Speaker. Australia Breastfeeding Conferences (remote presentation). Presentation Title: Newborn Visual Diagnosis: Overview of Normal and Abnormal Findings of the Head and Neck.
2/2025	Invited Speaker. Vermont Oral Health Network, winter meeting (remote presentation). Presentation Title: Community Water Fluoridation and the American Academy of Pediatrics.
(b) Regional	
8/1999	Grand Rounds, Seattle Children's Hospital, Presentation Title: Fluoride: An Update for Pediatricians.
4/2000	Invited speaker: Seminar Title: Duncan Seminar, Seattle Children's Hospital. Presentation Title: The Oral Health of Children with Special Health Care Needs.
4/2001	Invited speaker: Puget Sound Pediatric Society, Seattle, WA. Presentation Title: Oral Health. More than just a Pretty Smile.
4/2002	Invited speaker: Yakima Family Medicine Program. Yakima, WA. Presentation Title: Dental Development.
6/2002	Invited speaker: Yakima Family Medicine Program. Yakima, WA. Presentation Title: Dental Trauma.
10/2002	Invited speaker: Healthy Moms Healthy Babies Coalition of Washington State. Seattle, WA. Presentation Title: Breastfeeding and Oral Health: Controversies, Connections and Questions.
10/2002	Grand Rounds, Seattle Children's Hospital. Presentation Title: Fluoride and Xylitol: An Update for Pediatricians.

3/2005	Invited speaker: Washington State ABCD (Access to Baby and Childhood Dentistry) Coordinators' Meeting. Seattle, WA. Presentation Title: Fluoride Varnish: Lessons Learned from Early Adopters.
7/2006	Invited speaker: Family Medicine Grand Rounds, Group Health Cooperative. Seattle, WA. Presentation Title: Pediatric Oral Health: An Overview
5/2007	Invited speaker: Putting Medical Homes into Practice: Washington State Medical Home Leadership Network. Renton, WA. Presentation Title: The Medical and Dental Home Working Together
10/2011	Invited speaker: Idaho State Oral Health Initiative. Boise, ID. Presentation Title: Lessons Learned and Other Thoughts on Oral Health Integration into the Medical Home.
2/2012	Invited speaker: Seattle Pediatric Dentistry Study Club. Seattle, WA. Presentation Title: Improving the Dental Care Experience for Children with Autism Spectrum Disorder.
4/2013	Invited speaker: Oral Health Sciences Seminar, University of Washington School of Dentistry. Presentation Title: Addressing Oral Health Disparities among Children with Special Health Care Needs.
2/2014	Grand Rounds, Seattle Children's Hospital. Presentation Title: Fluoride: An Evidence-based Counter Offensive.
4/2017	Invited Speaker: Medical Quality Assurance Commission CME Lecture, Olympia, WA. Presentation Title: Dental Disparities: What is the Role of the Physician?
10/2017	Invited Speaker: Western Washington Lactation Journal Club, Seattle, WA. Presentation Title: Newborn Face Time: Common and Uncommon Physical Examination Findings above the Neck.
5/2018	Invited Keynote Speaker, UW CHDD Washington State Community Feeding Teams Annual Meeting, Seattle, WA. Presentation Title: It Takes a Team: Evaluating and Managing Ankyloglossia.
10/2018	Invited Speaker: The Washington Medical Commission Annual Educational Conference, Seattle, WA. Presentation Title: Communication in Healthcare Settings. How Complaints to the Washington Medical Commission are Rooted in Poor Engagement.
4/2021	Dental Injuries: A Self-guided Overview for Pediatricians. Washington Chapter of the AAP.
11/2022	Invited Speaker. AAP Alaska Grand Rounds, Anchorage, AK (remote presentation). Presentation title: Fluoride.
5/2023	Invited Speaker. UW CHDD Washington State Community Feeding Teams Annual Meeting, Seattle, WA. Presentation title: When a Baby Won't Eat: Managing Tube-feeding and Weaning from a Multidisciplinary Perspective.
(c) Other	
None	

Frenotomy

Heather Schultz, MD, MHA
Associate Medical Director
Health Care Authority

Washington State Health Care Authority

What is ankyloglossia?

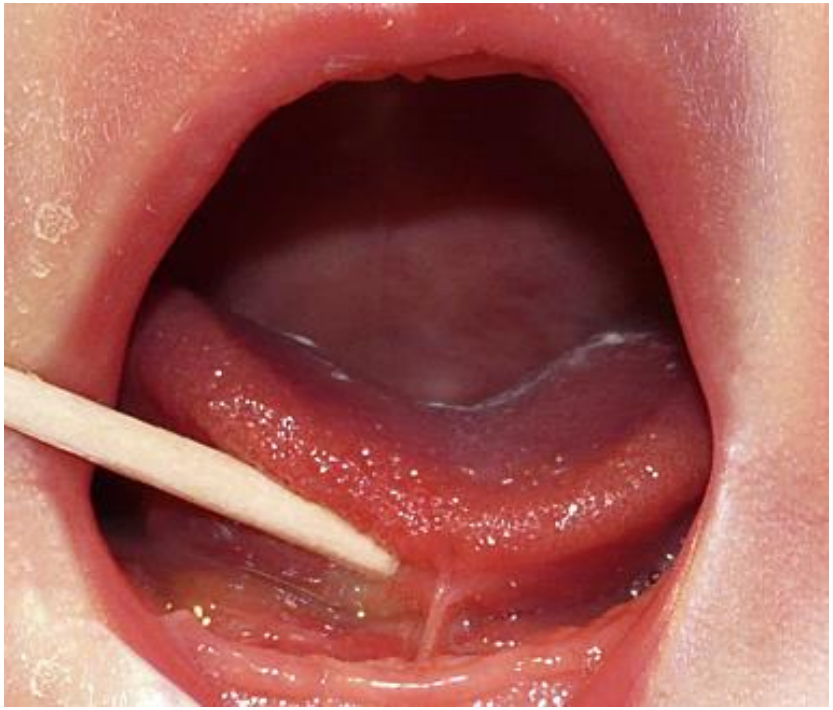


Photo courtesy of Glenn C Isaccson MD, FAAP, FACS 2025 UpToDate

Washington State Health Care Authority

What is frenotomy?

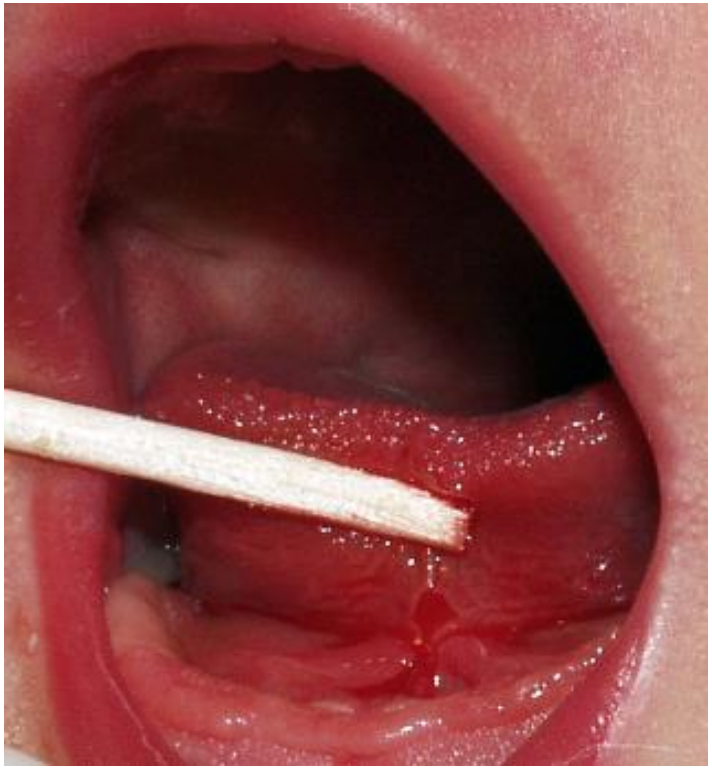
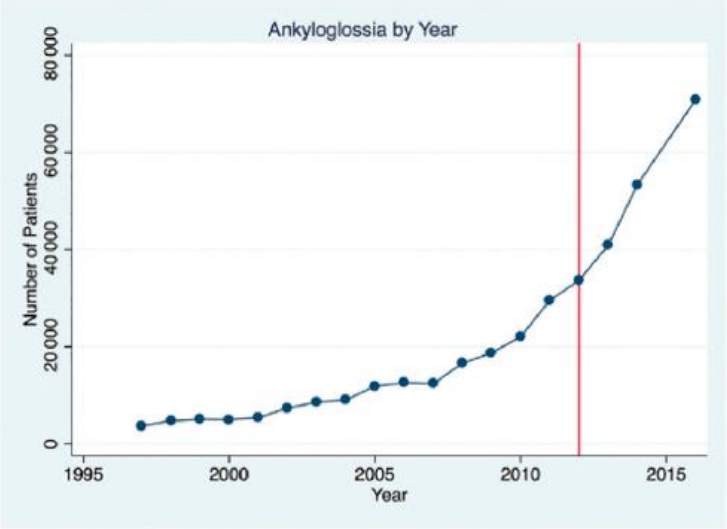
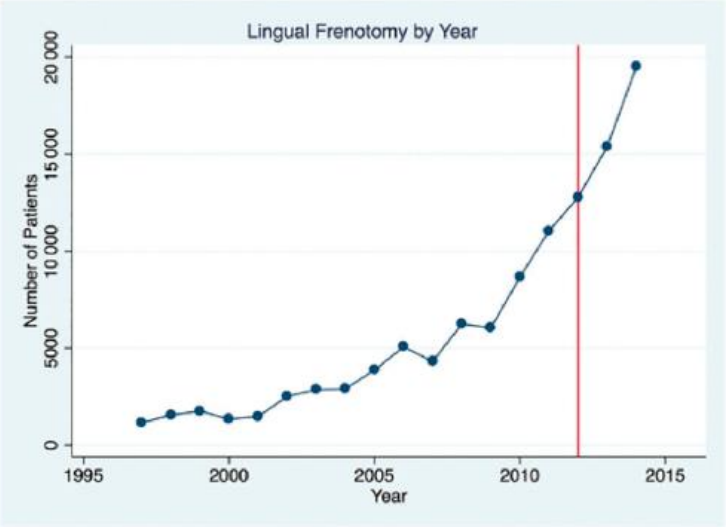


Photo courtesy of Glenn C Isaccson MD, FAAP, FACS 2025 UpToDate

Why focus on frenotomy?





Identification and Management of Ankyloglossia and Its Effect on Breastfeeding in Infants: Clinical Report. Pediatrics. 2024;154(2): e2024067605

Washington State Health Care Authority

Agency Medical Director Concerns

Efficacy	High concern
Safety	Medium concern
Cost	Medium concern

Current state agency policies

UMP/UDP
(PEBB/SEBB)

Medical benefit covers when diagnosis is made by a qualified healthcare professional when interfering with feeding

Dental benefit covers without criteria

Apple Health
(Medicaid)

Dental and medical benefit covers without criteria

Labor and Industries

Not relevant to job related illness or injury

Washington State Health Care Authority

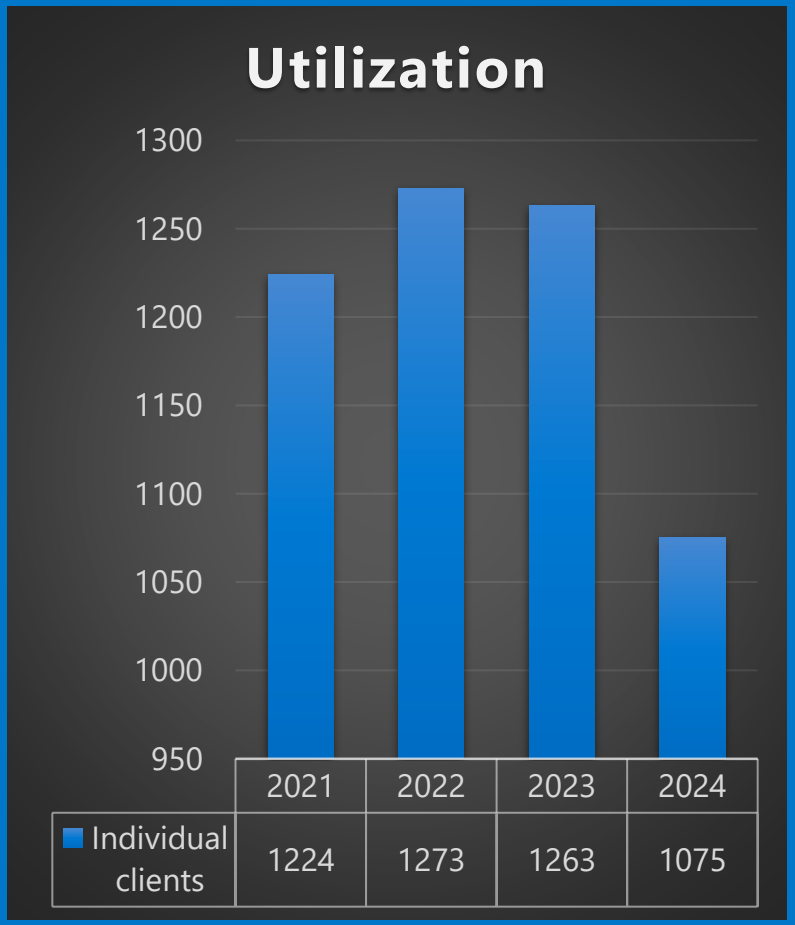
Current state agency frenotomy utilization and cost data

Medical lingual frenotomy

Medical labial frenotomy

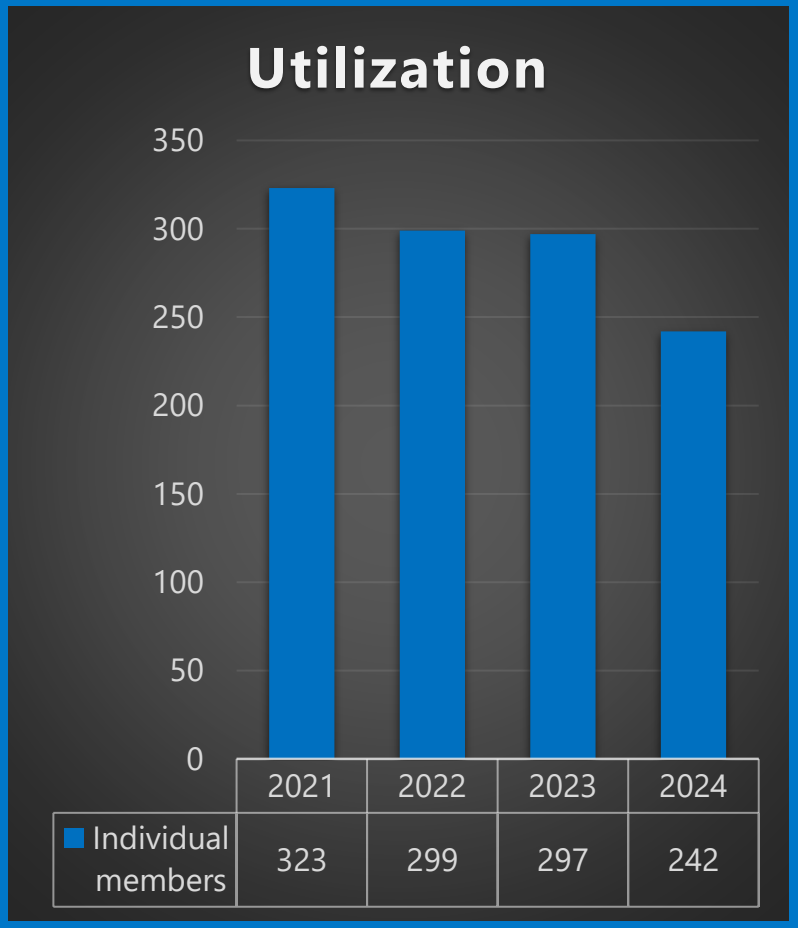
Dental lingual and labial frenotomy

Apple Health medical lingual frenotomy



Washington State Health Care Authority

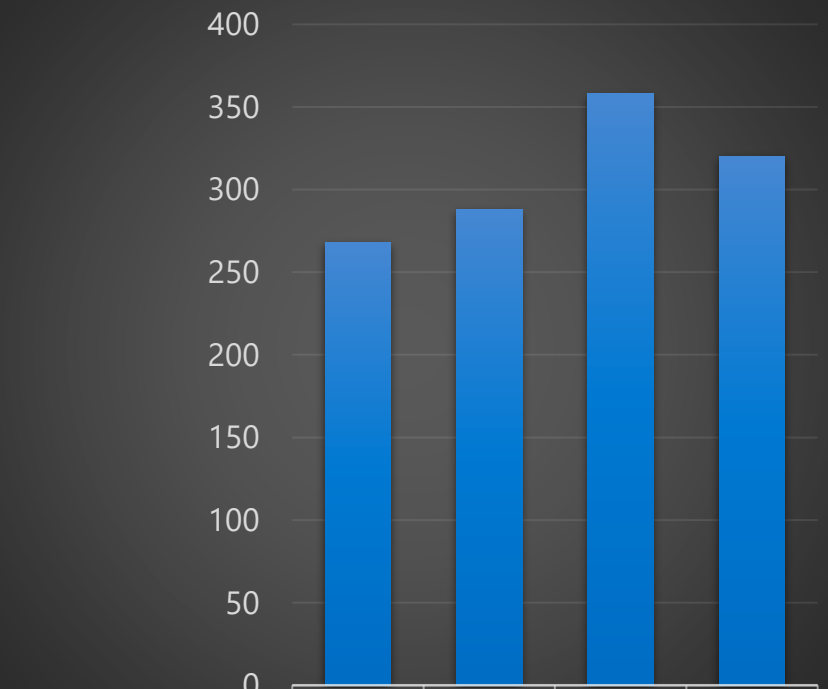
UMP medical lingual frenotomy



Washington State Health Care Authority

Apple Health medical labial frenotomy

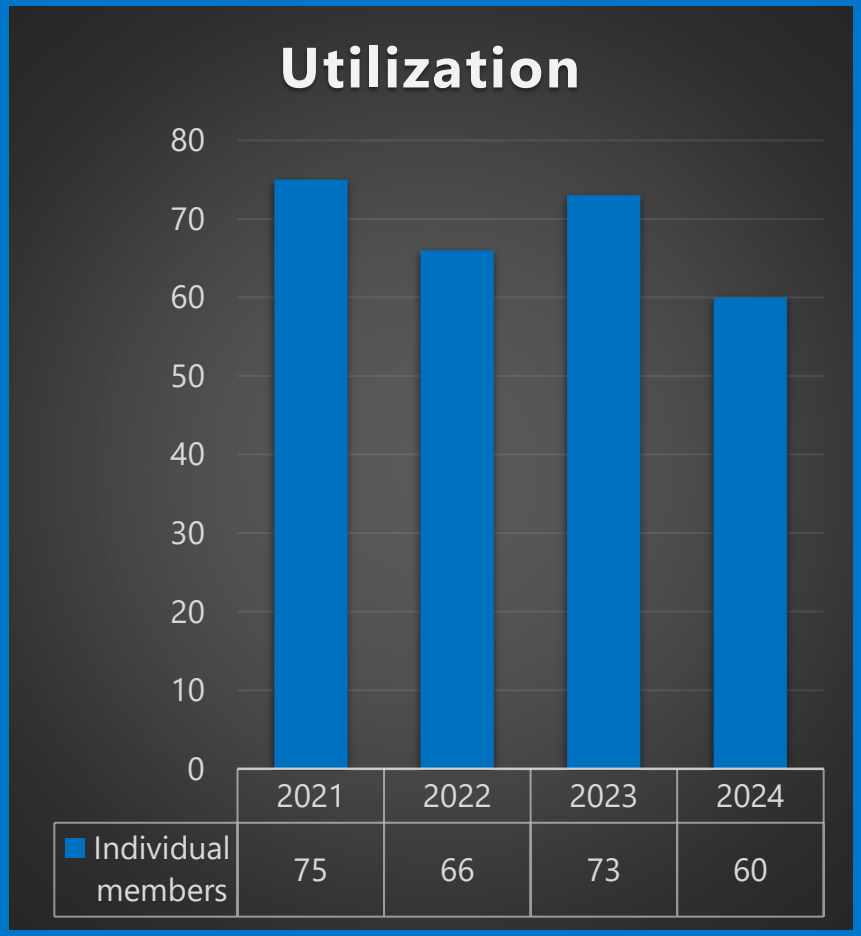
Utilization



Cost

Washington State Health Care Authority

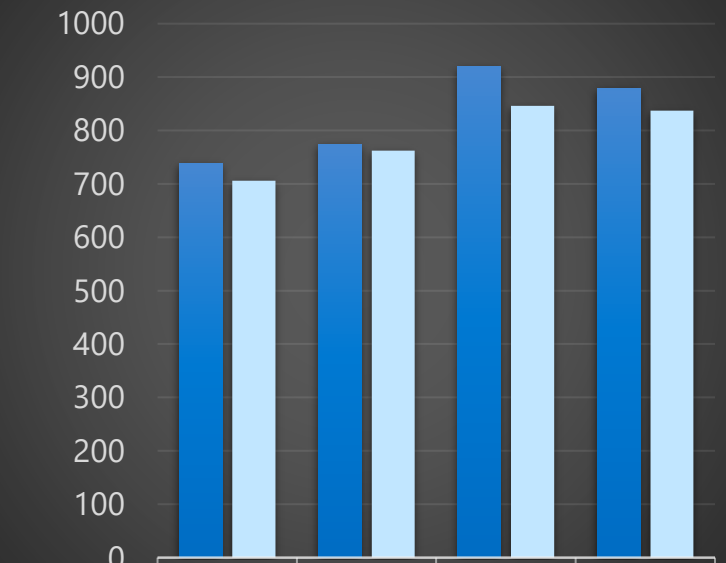
UMP medical labial frenotomy



Washington State Health Care Authority

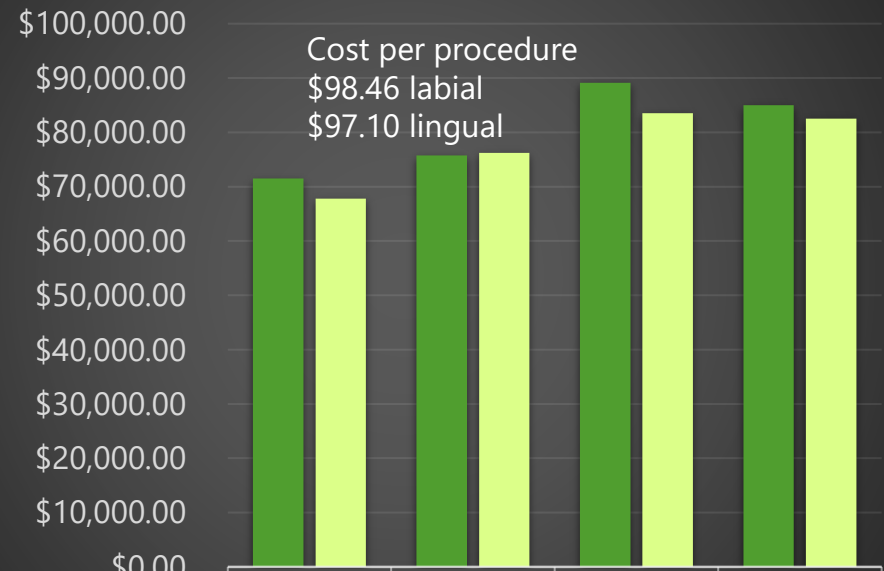
Apple Health dental frenotomy

Utilization



	2021	2022	2023	2024
Lingual	739	774	920	879
Labial	706	762	846	837

Cost

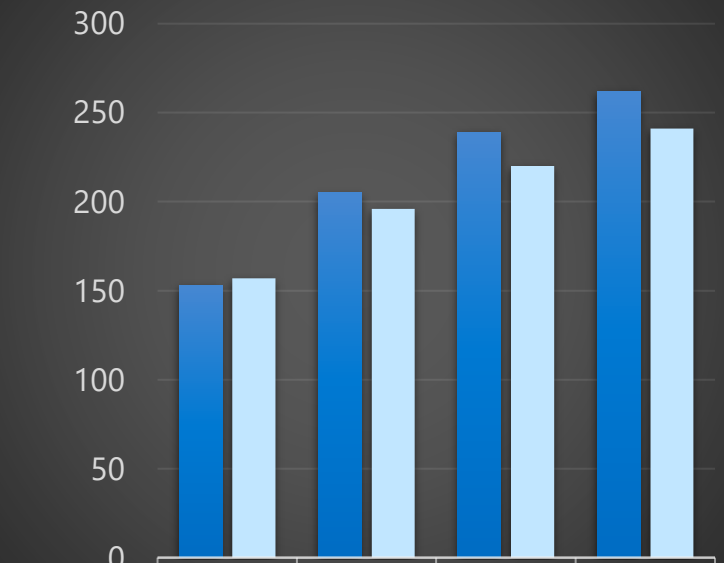


	2021	2022	2023	2024
Total cost lingual	$71,489.00	$75,757.00	$89,143.00	$84,999.00
Total cost labial	$67,779.00	$76,242.00	$83,517.00	$82,499.00

Washington State Health Care Authority

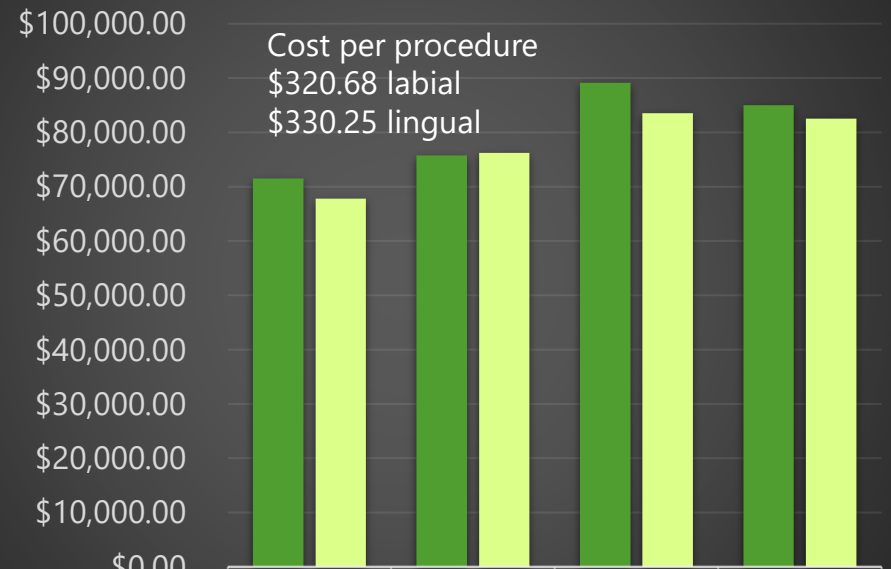
UDP dental frenotomy

Utilization



	2021	2022	2023	2024
Lingual	153	205	239	262
Labial	157	196	220	241

Cost



	2021	2022	2023	2024
Total cost lingual	$71,489.00	$75,757.00	$89,143.00	$84,999.00
Total cost labial	$67,779.00	$76,242.00	$83,517.00	$82,499.00

Washington State Health Care Authority

What does utilization data tell us?

Medical lingual frenotomy use is stable in Apple Health and UMP

Medical labial frenotomy use is occurring despite lack of evidence in Apple Health and UMP

Dental labial and lingual frenotomy use are increasing in Apple Health and UDP

AMDG Recommendation Considerations

Significant limitations to the evidence base

National and local increase in diagnosis and procedure utilization

Concern for potential risk of harms when frenotomy used inappropriately in healthy population

Supported by clinical guidelines for use in limited situations

AMDG Recommendations

Coverage with criteria of lingual frenotomy for breastfeeding difficulties:

Symptomatic ankyloglossia not improved with lactation support	Other causes of breastfeeding problems have been evaluated and treated	Performed or referred by a primary care provider with expertise caring for newborns

Non-coverage of labial frenotomy for breastfeeding difficulties

Questions?

shtap@hca.wa.gov

Washington State Health Care Authority

Washington State Health Care Authority

Frenotomy and frenectomy with breastfeeding support

Order of scheduled presentations:

- **No presentation requests were received before May 30, 2025**

Frenotomy and frenectomy with breastfeeding support

Health Technology Assessment

Contributors:
Jennifer Cook Middleton, PhD; *Lead Investigator*
Meera Viswanathan, PhD; *Co-Investigator*
Jessica Vaughan, MPH; *Project Coordinator*
Nila Sathe, MA, MLIS; *Analyst*
Wade Harrison, MD, MPH; *Clinical Consultant*
Leila C. Kahwati, MD MPH; *Scientific Reviewer*
Mark Howell, MLS; *Information Specialist*
Mary Gendron, BA; Alexander Cone, BA; *Editorial Support*
External Peer Reviewers (David O. Francis, MD, MS; Nikhila P. Raol, MD, MPH)

Presented by:
Jennifer Cook Middleton, PhD

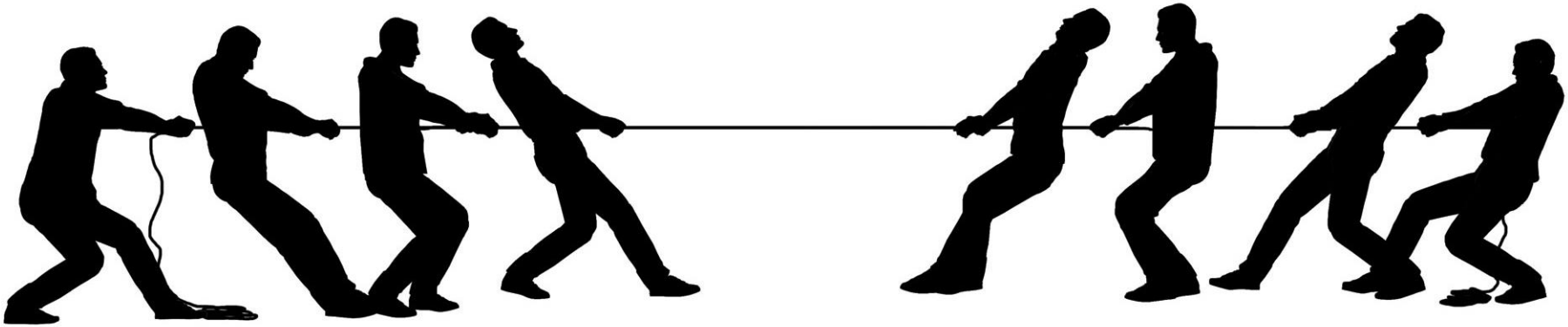
June 13, 2025

jcmiddle@email.unc.edu

Overview of Presentation

- Background
- Methods
- Results
- Discussion

Conflicts of Interest



Background

Frenotomy and frenectomy with breastfeeding support - Overview

- Frenotomy, frenectomy, frenuloplasty, and related procedures are used to address the congenital conditions of ankyloglossia and tight labial frenum
  - Ankyloglossia or “tongue-tie” includes a tightened frenum and restricts movement of tongue
  - Tighten labial frenum or “lip-tie” connects the upper lip to the gums
- Conditions can lead to difficulties in newborn latching during nursing and other breastfeeding difficulties

Technology Description

- Lingual frenotomy - releasing of tongue-tie
- Lingual frenectomy - removal of the lingual frenulum
- Frenuloplasty (z-plasty) - plastic surgery of the tongue
- Labial frenectomy - releasing of labial frenum or lip-tie
- Procedures are conducted with a laser, scalpel, or surgical scissors

Policy Context for Washington

- The topic was selected by the state because of:
  - High concerns for efficacy
  - Medium concerns for safety
  - Medium concerns for cost

Clinical Context

- Estimates of tongue-tie vary from <1% to about 11%
- Unclear diagnostic methods
- Anterior tongue-tie - most common, where the frenum attaches near the tip of the tongue and is visible
- Posterior tongue-tie - less common, frenulum is attached further back on the tongue and harder to see
  - No consensus on the definition

Debate Related to the Procedure

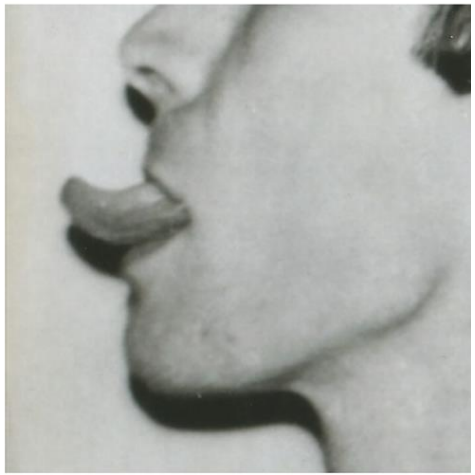
Popular Latest Newsletters

The Atlan

Tongue Posture Is a Bi
With Little Evidence

Treatments to address improper tongue po
health remedy, but they may be doing mo

By Christina Szalinski and Undark



Mark and Colleen Hayward / Getty

SEPTEMBER 12, 2021

Original Research—Pediatric Otolaryngology

AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY FOUNDATION

Otolaryngology–Head and Neck Surgery
2024, Vol. 170(5) 1442–1448

DOI: 10.1002/ohn.643
http://otojournal.org
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Is Public Interest Associated with Real-World Management of Ankyloglossia?

Danial F. Naseem, BBA*, Amar H. Sheth, MD*, Alan G. Cheng, MD, and Z. Jason Qian, MD

Abstract

Objectives. Assess the relationship between public interest in ankyloglossia as determined by internet search volume and real-world medical claims data.

Study Design. Retrospective Cohort Study.

Setting. This retrospective cohort study was conducted using claims data from the Merative™ Marketscan® Research Databases. The internet search data was collected from Google Trends.

Methods. Annual Google Trends data were compiled using search terms associated with "ankyloglossia" and "frenotomy" for the years 2011 to 2021. We obtained incidence of ankyloglossia diagnoses and frenotomy procedures in children under 12 months from Marketscan relative to all infants enrolled. We compared associations between search and incidence data among US states and over time.

Results. Google search correlated with ankyloglossia incidence ($r = 0.4104$, $P = .0031$) and with frenotomy incidence ($r = 0.4062$, $P = .0034$) per state. Ankyloglossia diagnoses increased with Google search index (coefficient = 0.336, 95% confidence interval [CI] 0.284, 0.388) and year (coefficient = 0.028, 95% CI 0.025, 0.031). Similarly, frenotomy procedures increased with Google search index (coefficient = 0.371, 95% CI 0.313, 0.429) and year (coefficient = 0.027, 95% CI 0.024, 0.030).

Conclusions. Associations between online ankyloglossia search trends and both diagnosis and treatment rates, persist across US regions and timeframes. Internet search trends are pivotal in shaping pediatric health care decisions, driving clinical

cause tongue protrusion difficulty and speech articulation, which has been shown to improve with frenotomy.[1-6] However, these sequelae are not specific to ankyloglossia and may be present with other etiologies of breastfeeding difficulties and speech articulation difficulty.[1,7]

The diagnosis and treatment of tongue ties have been the subject of controversy for decades, which has led to differing opinions amongst health care professionals on the diagnostic criteria and utility of surgical correction of the tongue tie.[8-12] Nevertheless, the rate of ankyloglossia diagnosis has increased over the past 2 decades.[9,11] This trend is theorized to be due to increased breastfeeding rates, availability of lactation consultants, and overall awareness of ankyloglossia by health care providers and the general public.[13,14] These individual factors should be studied in order to better understand the driving forces behind this health care trend. The association between general public awareness of ankyloglossia on frenotomy procedures has not previously been explored.

Here, we use a novel combination of internet search volume data (Google Trends) and real-world insurance claims data (Merative™ Marketscan®) to study the association between presumably parental health-information seeking and frenotomy procedures among United States regions and over time. We hypothesize that internet search interest is correlated with the incidence of ankyloglossia diagnoses and frenotomy procedures. These results will be important for informing clinicians on how to navigate and direct the future landscapes of elective pediatric procedures.

Methods

The New York Times

ns Warn Against Overuse of Surgeries

e American Academy of Pediatrics said that lems were rarely caused by infant tongue-ties.

9 min Learn more

Share full article

edure in an oral surgery clinic in Manhattan, N.Y., last year.
Times

Methods

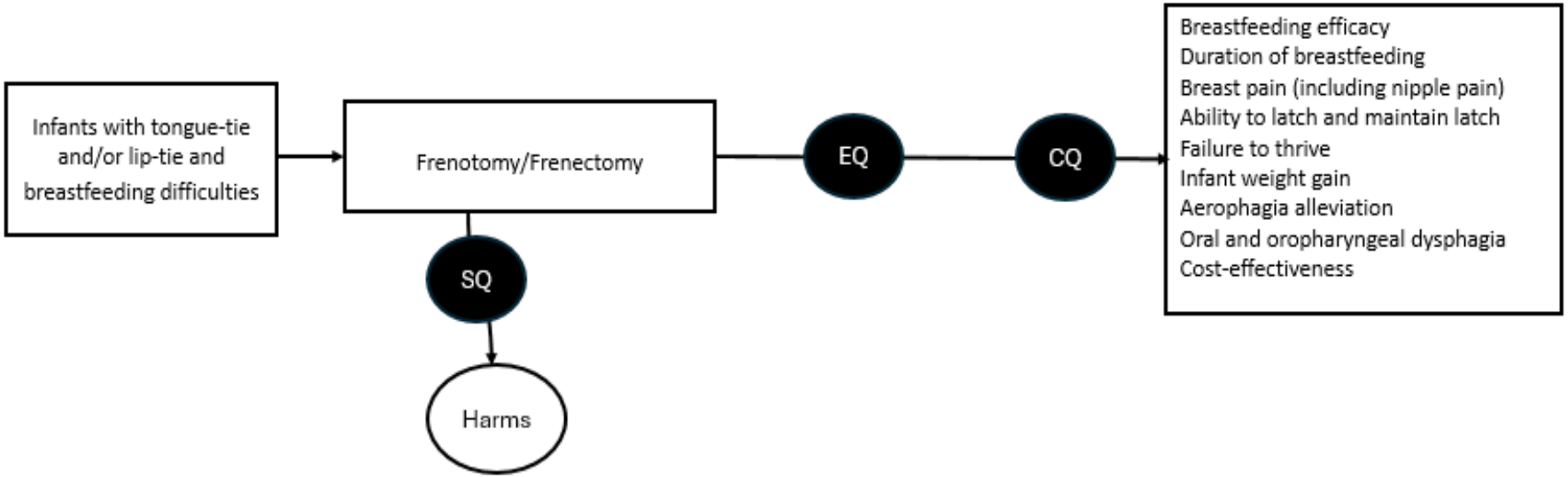
Key Questions

- **Effectiveness Question (EQ).** What is the effectiveness and comparative effectiveness of frenotomy or frenectomy for tongue-tie and/or lip-tie on breastfeeding outcomes?

- **Safety Question (SQ).** What are the harms of frenotomy or frenectomy for tongue-tie and/or lip-tie as a support for breastfeeding?

- **Cost Question (CQ).** What is the cost-effectiveness of frenotomy or frenectomy for tongue-tie and/or lip-tie for breastfeeding support?

Analytic Framework



Abbreviations: EQ = Effectiveness Question; SQ = Safety Question; CQ = Cost Question

Search

- MEDLINE (via PubMed), Cochrane Library
- Database inception to 8/30/2024

Study Selection/PICOTS

	Include	Exclude
Population	Breastfeeding infants up to 1 year of age with tongue-tie and/or lip-tie	Physical/anatomic comorbidities Hypotonia Pierre Robin syndrome or sequence Down syndrome Craniofacial or airway abnormalities (i.e., cleft palate) Born at less than <37 weeks gestation
Intervention	Frenotomy, frenectomy, frenulotomy, frenulopasty, or z-plasty to improve breastfeeding using all methods	Procedures done for indications other than breastfeeding support
Comparator	EQ: Active treatment; placebo; no treatment SQ: No comparators were necessary CQ: Any comparator	EQ: No comparator group SQ: NA CQ: No comparator group
Design	EQ: Controlled trials, cohort studies with comparisons, crossover studies, and case-control studies SQ: All EQ designs plus studies without a comparator group CQ: Cost-effectiveness analysis or cost-utility	EQ: Case reports, case series, qualitative studies SQ: Qualitative studies, and all study designs not already specified CQ: Studies that use non-U.S.-based cost inputs

Abbreviations: CQ=Cost Question; EQ=Effectiveness Question; NA=Not applicable; SQ=Safety Question

Study Selection/PICOTS

	Include	Exclude
Outcomes	EQ: Breastfeeding, including latch, nipple pain, nipple excoriations, nipple infections (mastitis), weight gain, aerophagia, swallowing function, failure to thrive, milk transfer, low milk supply, breastfeeding cessation/duration of breastfeeding, and other feeding issues SQ: Any harms, including excessive bleeding, airway obstruction, pain, transient poor feeding secondary to discomfort, dysphagia, complications related to dysphagia such as aspiration pneumonia, surgical site infection, nerve damage, salivary gland damage, ranulae, scarring, soft tissue damage, oral aversion, readherence of tongue- or lip-tie, need for further surgery/revision, ED visits, hospitalizations, extension of current hospitalization CQ: Cost-effectiveness or cost-utility	Outcomes not listed as eligible Cost-effectiveness based on cost inputs from countries other than the U.S.

Abbreviations: CQ=Cost Question; ED=Emergency department; EQ=Effectiveness Question; SQ=Safety Question

Study Selection/PICOTS

	Include	Exclude
Timing	EQ: Outcomes measured after intervention/comparator through 12 months of age SQ: No time limitation CQ: No time limitations	EQ: Outcomes measured after 12 months of age
Setting	• All inpatient or outpatient pediatric care • Countries categorized as “very high” on the 2023/2024 United Nations Human Development Index	Countries not categorized as “very high” on the 2023/2024 United Nations Human Development Index

Abbreviations: CQ=Cost Question; EQ=Effectiveness Question; SQ=Safety Question;

Risk of Bias Assessment

- Risk of bias was assessed at the individual study level
  - Cochrane Risk of Bias version 2 instrument for RCTs
  - ROBINS-I tool for Nonrandomized comparative studies
- Each study assessed as having one of the following risks:
  - High risk of bias
  - Some concerns for bias
  - Low risk of bias

ROB domains

- Randomization (for RCTs)
- Allocation concealment (for RCTs)
- Performance bias (e.g., blinding)
- Deviations from intervention
- Missing data and attrition
- Outcome measure validity and assessor blinding
- Selective outcome report
- Confounding (for observational studies)

Abbreviations: e.g.=For example; ROB=risk of bias; RCT=randomized controlled trial; ROBINS-I=Risk of Bias In Non-randomised Studies - of Interventions

Methodological Quality of Single-Arm Studies

- Modified version of the tool developed by Murad et al.
  - Reviews the representativeness of the sample
  - Adequacy of ascertainment of the exposure and outcome
  - Whether design features support causal inference
  - Whether reporting permits replication or generalizable inference

Certainty of the Evidence – GRADE approach

- **Domains assessed:**
  - Risk of bias
  - Consistency
  - Directness
  - Precision
  - Publication bias

- **Certainty of evidence**
  - ⨁◯◯◯ VERY LOW
  - ⨁⨁◯◯ LOW
  - ⨁⨁⨁◯ MODERATE
  - ⨁⨁⨁⨁ HIGH

- Bodies of evidence start at ***HIGH***

- Certainty level may be downgraded based on domain assessments:
  - No concerns
  - Serious concerns (↓ one level)
  - Very serious concerns (↓ two levels)
  - Extremely serious concerns (↓ three levels)

- Observational evidence may be upgraded based on:
  - Large effect (↑ one level)
  - Dose response (↑ one level)
  - Plausible confounding and bias accounted for (↑ one level)

Results

Search Results

- Titles/abstracts screened: **1,131**
- Full text articles screened: **145**
- Cumulative evidence included: **60 studies (59 articles)**

EQ: 13 (12)
7 RCTs
6 NRSIs

SQ: 58 (57)
7 RCTs
4 NRSIs
47 Single arm

CQ: 0

Abbreviations: CQ=Cost Question; EQ=Effectiveness Question; NRSI=Nonrandomized study of interventions; RCT=randomized controlled trial; SQ=Safety Question

Brief Overview of Effectiveness Evidence– Maternal

Specific outcome	Favors frenotomy	No difference	Favors control	Cannot determine a difference
Breastfeeding pain				6 RCTs, N=452
Breastfeeding effectiveness				1 RCT, N=105
Breastfeeding self-efficacy	3 RCTs, N=312			
Any breastfeeding at ≤2 months				1 RCT, N=105 1 NRSI, N=159
Any breastfeeding at >2 months		1 RCT, N=163		4 NRSIs, N=471

	High certainty of evidence
	Moderate certainty of evidence
	Low certainty of evidence
	Very low certainty of evidence

Abbreviations: N=number; NRSI=nonrandomized study of interventions; RCT=randomized controlled trial

Brief Overview of Effectiveness Evidence– Maternal (continued)

Specific outcome	Favors frenotomy	No difference	Favors control	Cannot determine a difference
Exclusive breastfeeding at ≤2 months		1 NRSI, N=159		2 RCTs, N=265
Exclusive breastfeeding at >2 months				1 RCT, N=163 3 NRSIs, N=380
Improvement in breastfeeding				2 RCTs, N=114
Breastfeeding problems				1 NRSI, N=33

High certainty of evidence
Moderate certainty of evidence
Low certainty of evidence
Very low certainty of evidence

Abbreviations: N=number; NRSI=nonrandomized study of interventions; RCT=randomized controlled trial

Brief Overview of Effectiveness Evidence– Infant

Outcome category	Specific outcome	Favors frenotomy	No difference	Favors control	Cannot determine a difference
Infant outcomes	Infant weight gain				1 RCT, N=163
	Infant breastfeeding assessment				2 RCTs, N=165
	Gastroesophageal symptoms				1 RCT, N=48

	High certainty of evidence
	Moderate certainty of evidence
	Low certainty of evidence
	Very low certainty of evidence

Abbreviations: N=number; NRSI=nonrandomized study of interventions; RCT=randomized controlled trial

Brief Overview of Safety Evidence

- Majority of reported adverse events were not severe or related to the procedure
- Rates of adverse events varied across studies

Characteristics of Included Effectiveness Studies (n=13)

- Tongue-tie only
- 7 RCTs and 6 NRSIs
- 3 Low ROB and 10 High ROB
- 23% U.S. based and 77% non-U.S.
- Various providers using methods including scissors (54%), unspecified method (38%), or laser (8%)
- Comparators[1] included breastfeeding support (54%), sham (23%), time variations (31%), or no frenotomy (46%)

[1] Comparator groups were not mutually exclusive.

Abbreviations: EQ=Effectiveness Question; n=number; NSRI=nonrandomized study of interventions; RCT=randomized controlled trial; ROB=risk of bias

Effectiveness Outcomes Rated Very Low COE

- Breastfeeding pain
- Breastfeeding effectiveness
- Breastfeeding at 2 months or less
- Exclusive breastfeeding at more than 2 months
- Change in breastfeeding
- Infant weight gain
- Infant Breastfeeding Assessment Tool (IBFAT)
- Gastroesophageal Symptom Questionnaire for Infants (GSQ-I)

Abbreviations: COE=certainty of evidence

Breastfeeding Self-Efficacy (BSES)

№ of Studies (№ of Participants)	Summary of Findings	CERTAINTY
3 RCTs (296)	Significantly larger changes for frenotomy vs. control (delayed or no frenotomy) in 2 of 3 studies Study 1 (delayed frenotomy): median change [IQR]: 9 (1.8 to 12.3) vs. 1 (−4 to 7.5); *p*=0.002 at 5 days, planned crossover Study 2 (delayed frenotomy with breastfeeding support): mean change 13.4 vs. −1.0; 95% CI, 9.2 to 19.7; *P*<0.001 at 10 days, planned crossover Study 3 (No frenotomy with breastfeeding support): median difference at 3 months, −0.3; 95% CI, −5.2 to 5.8, after significant unplanned crossover	⊕⊕◯◯ LOW for benefit

Abbreviations: CI=confidence Interval; IQR=interquartile range; №=number; RCT=randomized controlled trial; vs.=versus

Breastfeeding Self-Efficacy (BSES) Included Study Characteristics

- 3 RCTs
  - Tongue-tie only
  - Sample sizes ranged from 47 to 166
  - 2 with unclear methods; 1 with laser
  - Procedure conducted by various providers (midwife, doctor, nurse, missing), lead authors, or NR
  - 2 studies in a hospital; 1 study at private practice
  - 1 U.S. study; 2 UK studies

Breastfeeding Self-Efficacy (BSES) Sample Items

Item
Determine that my baby is getting enough milk
Successfully cope with breastfeeding like I have with other challenging tasks
Breastfeed my baby without using formula as a supplement
Ensure that my baby is properly latched on for the whole feeding
Manage the breastfeeding situation to my satisfaction
Manage to breastfeed even if my baby is crying
Keep wanting to breastfeed
Comfortably breastfeed with my family members present
Be satisfied with my breastfeeding experience
Deal with the fact that breastfeeding can be time-consuming
Finish feeding my baby on one breast before switching to the other breast
Continue to breastfeed my baby for every feeding
Manage to keep up with my baby's breastfeeding demands
Tell when my baby is finished breastfeeding

Source: Dennis CL. The breastfeeding self-efficacy scale: psychometric assessment of the short form. *J Obstet Gynecol Neonatal Nurs. 2003;32(6):734-744.*

Any breastfeeding at > 2 months

№ of Studies (№ of Participants)	Summary of Findings	CERTAINTY
1 RCT (163)	No statistically significant differences for frenotomy vs. no frenotomy, after unplanned crossovers	⊕⊕◯◯ LOW for no difference
4 cohorts with comparison (1 publication reported 2 studies) (471)	Similar prevalence between study arms (frenotomy vs. no frenotomy)	⊕◯◯◯ VERY LOW

Abbreviations: №=number; RCT=randomized controlled trial

Exclusive breastfeeding at 2 months or less follow-up

№ of Studies (№ of Participants)	Summary of Findings	CERTAINTY
2 RCTs (265)	No statistically significant differences for frenotomy vs. no frenotomy	⊕◯◯◯ VERY LOW
1 cohort with comparison (159)	No difference at 1 month follow-up for frenotomy vs. control	⊕⊕◯◯ LOW No difference

Abbreviations: №=number; RCT=randomized controlled trial; vs.=versus

Characteristics of Safety Studies (n=58)

- Tongue-tie only, tongue-tie and/or other tie types, and unspecified ties
- 7 RCTs, 4 NRSIs, and 47 single arm
- 3 Low ROB, 8 High ROB, 47 ROB unassessed
- Various providers using scissors (67%), laser (14%), and unspecified method (19%)
- Comparators[1] included breastfeeding support (9%), sham (5%), time variations (7%), no frenotomy (7%), or no comparator (81%)
- 29% U.S. based and 71% non-U.S.

[1] Comparator groups were not mutually exclusive.

Abbreviations: n=number; NRSI = nonrandomized study of interventions; RCT=randomized controlled trial; ROB=risk of bias

Safety Outcomes

- Categorized by method: scissors, lasers, or unspecified
- Most adverse events were minor (e.g., bleeding, crying, pain)
- Serious complications (e.g., oral damage, weight loss, feeding issues, readmission) occurred less often
- Adverse event rates varied across studies

Abbreviations: e.g.=for example

Safety: Frenotomy for tongue-tie and/or lip-tie by scissors

Indication	Comparative Studies	Single-Arm Studies
Tongue-tie only	7	28
Tongue-tie and/or lip-tie	NA	5
Unspecified tie type	NA	1

Abbreviations: NA=Not applicable

Safety: Frenotomy with scissors for tongue-tie only

- 7 comparative studies
  - Samples ranged from 36 to 302
  - Specific adverse events: minor bleeding, recurrence, revisions, and needed paracatomol
  - Adverse events ranged from 2.6% (recurrence, need for repeat surgery) to 5% (minor bleeding)
  - 3 studies reported no complications or adverse events

Safety: Frenotomy with scissors for tongue-tie only

- 28 single arm studies
  - Samples ranged from 10 to 474
  - Specific adverse events: bleeding, brown posset, feeding deteriorated, fever, need a syringe for feeding, irritability/crying, need for repeat procedure, readmission, refusal to drink, reoccurrence, scarring, soreness/discomfort, swelling, ulcers, worse pain and latch difficulties
  - Adverse events ranged from 0.5% (e.g., feeding deteriorated, syringe needed for feeding, brown posset due to swallowed blood) to 100% (bleeding, ulcers)
  - 14 studies reported no complications or adverse events

Abbreviations: e.g.=for example

Safety: Frenotomy with scissors for tongue-tie and/or lip-tie

- 5 single arm studies
  - Samples ranged from 33 to 491
  - Specific adverse events: revisions, need for cauterization with silver nitrate, and pain
  - Adverse events ranged from 1% (needed cauterization for persistent oozing) to 24.4% (pain)
  - 2 studies reported no complications or adverse events

Safety: Frenotomy with scissors for unspecified ties

- 1 single arm study (n=30) reported no complications or harms occurred

Abbreviations: n=number

Safety: Frenotomy for tongue-tie and/or lip-tie by laser

Indication	Comparative Studies	Single-Arm Studies
Tongue-tie only	1	2
Tongue-tie and/or other specified tie type	NA	5

Abbreviations: NA=Not applicable

Safety: Frenotomy with laser for tongue-tie only

- 1 comparative study (n=47) reported no adverse events or unanticipated problems
- 2 single arm studies
  - Samples ranged from 56 to 146
  - Specific adverse events: Bleeding, carbonization of the irradiated site, crying, frequently awake, heart rate, need for repeat procedure, pain, refusal of pacifier
  - Adverse events ranged from 4.6% (need for repeat procedure) to 96.4% (crying)

Abbreviations: n=number

Safety: Frenotomy with laser for tongue-tie and/or other tie types (specified)

- 5 single arm studies
  - Sample sizes ranged from 22 to 146
  - Specific adverse events: crying, pain, reoccurrence, temporary hypergranulation of wound tissue
  - Adverse event estimates ranged from 0.7% (temporary hypergranulation of wound tissue) to 82% (pain)
  - 2 studies reported that no complications were reported

Safety: Frenotomy for tongue-tie and/or lip-tie by unspecified method

Indication	Comparative Studies	Single-Arm Studies
Tongue-tie only	3	3
Tongue-tie and/or other tie type	NA	2
Unclear/ unspecified tie type	NA	1

Abbreviations: NA=Not applicable

Safety: Frenotomy (method unspecified) for tongue-tie only

- 3 comparative studies
  - Sample sizes ranged from 25 to 169
  - Specific adverse events: bleeding, crying, salivary duct damage, accidental cut to tongue and salivary, need for repeat procedure
  - Adverse events estimates ranged from 0.6% (salivary duct damage, cut to tongue and salivary, bleeding) to 100% (bleeding, crying)
- 3 single arm studies
  - Sample sizes ranged from 58 to 158
  - 2 studies reported that no complications were reported
  - 1 study reported that 4% needed a repeat procedure

Safety: Frenotomy (method unspecified) for tongue-tie and/or other ties (specified and unspecified)

- 1 single arm study (n=84) reported that 99% of the sample reported no complications
- 1 case series study (n=16) describing the adverse events experienced by participants reported issues related to feeding, breathing, bleeding, pain, and weight loss

Abbreviations: n=number

Safety: Frenotomy (method unspecified) for unspecified ties

- 1 single arm study (n=414)
  - 27% of participants had unplanned visits
  - 23% had a repeat procedure

Abbreviations: n=number

Cost Effectiveness Studies

- No eligible cost-effectiveness studies were identified

Discussion

Summary of the Evidence – Maternal Outcomes

Specific outcome	Favors frenotomy	No difference	Favors control	Cannot determine a difference
Breastfeeding pain				6 RCTs, N=452
Breastfeeding effectiveness				1 RCT, N=105
Breastfeeding self-efficacy	3 RCTs, N=312			
Any breastfeeding at ≤2 months				1 RCT, N=105 1 NRSI, N=159
Any breastfeeding at >2 months		1 RCT, N=163		4 NRSIs, N=471

	High certainty of evidence
	Moderate certainty of evidence
	Low certainty of evidence
	Very low certainty of evidence

Abbreviations: N=number; NRSI=Nonrandomized study of interventions; RCT=randomized controlled trial

Summary of the Evidence – Maternal Outcomes (continued)

Specific outcome	Favors frenotomy	No difference	Favors control	Cannot determine a difference
Exclusive breastfeeding at ≤2 months		1 NRSI, N=159		2 RCTs, N=265
Exclusive breastfeeding at >2 months				1 RCT, N=163 3 NRSIs, N=380
Improvement in breastfeeding				2 RCTs, N=114
Breastfeeding problems				1 NRSI, N=33

High certainty of evidence
Moderate certainty of evidence
Low certainty of evidence
Very low certainty of evidence

Abbreviations: N=number; NRSI=Nonrandomized study of interventions; RCT=randomized controlled trial

Summary of the Evidence – Infant Outcomes

Outcome category	Specific outcome	Favors frenotomy	No difference	Favors control	Cannot determine a difference
Infant outcomes	Infant weight gain				1 RCT, N=163
	Infant breastfeeding assessment				2 RCTs, N=165
	Gastroesophageal symptoms				1 RCT, N=48

	High certainty of evidence
	Moderate certainty of evidence
	Low certainty of evidence
	Very low certainty of evidence

Abbreviations: N=number; NRSI=Nonrandomized study of interventions; RCT=randomized controlled trial

Limitations of the Evidence Base

- Overall
  - Small sample sizes, the inability to maintain randomization and concealment, and poor outcome measurement
- Effectiveness Studies
  - Short follow up times due to the small window of time for mother and infant dyads to achieve breastfeeding efficacy
  - Difficult to determine the level of exposure to other interventions that could impact outcomes in longer-term studies
- Safety Studies
  - Majority were single-arm studies
  - Comparative studies only provided overall adverse data
  - Lack of consistency in how adverse events and complications were classified

Ongoing Study

Registration Number	Sponsor	Description	N	Status	Estimated Completion Date
NCT02141243	University of South Florida	• Infants at Tampa General Hospital with Class III or IV ankyloglossia. • Group 1: Sham frenotomy followed by lingual frenotomy. • Group 2: Lingual frenotomy followed by sham procedure. • Infants with continued feeding difficulties will undergo a labial frenotomy. • The goal is to determine when lingual frenotomies, labial frenotomies, or both are required to improve outcomes (i.e., Wong-Baker FACES Pain Rating Scale, LATCH score).	120	Completed	May 2018

Abbreviations: N=number; LATCH=Latch, Audible Swallowing, Type of Nipple, Comfort, Hold;

Future Research Needs

- Compare methods (scissors vs. lasers) and timing (early vs. later)
- Assess breastfeeding improvement overtime without frenotomy
- Consider context (e.g., access to breastfeeding support)
- Include longer-term outcomes and using large healthcare datasets
- Collect data on outcomes including nipple trauma/infections, swallowing, milk transfer, feeding issues
- Use standardized measures and multiple data sources to assess safety

Abbreviations: e.g.=for example; vs.=versus

Clinical Practice Guideline Synthesis

Title/Organization	Year	Excerpts of Findings
American Academy of Otolaryngology—Head and Neck Surgery	2020	**For frenotomy:** A survey of expert pediatric otolaryngologists agreed that **frenotomy in infants with ankyloglossia can lead to an improvement in breastfeeding, not all infants with ankyloglossia need a frenotomy, and there are more common conditions that may impede breastfeeding.** **The academy recommends further study to refine evidence.**
American Academy of Pediatric Dentistry	2022	**For surgical interventions on the frenulum:** Recognizes that **difficulties with breastfeeding may have another cause and not all infants with ankyloglossia require surgical intervention**. Recommends a team-based approach to treatment planning. **The academy supports further research in the causative association between ankyloglossia and difficulties in breastfeeding.**

Clinical Practice Guideline Synthesis (continued)

Title/Organization	Year	Excerpts of Findings
American Academy of Pediatrics	2024	**For frenotomy:** It is **unclear if release of a tight lingual frenulum in neonates improves breastfeeding**. Because symptoms of ankyloglossia overlap those of other breastfeeding difficulties, a team partnership is necessary. **Frenotomy may decrease maternal nipple pain.** **Further research is necessary.**
The Academy of Breastfeeding Medicine	2021	**For surgical tongue-tie release:** If there is the presence of a restrictive sublingual frenulum, frenotomy **can be an effective way to increase maternal comfort and milk transfer and may prevent premature breastfeeding cessation**. **The academy recommends more research** on “a **clear definition of ‘tongue-tie’ in distinction from the normal sublingual frenulum,” optimal surgical methods, and long-term outcomes.**

Clinical Practice Guideline Synthesis (continued)

Title/Organization	Year	Excerpts of Findings
International Board of Lactation Consultant Examiners	2017	Members of the International Board of Lactation Consultant Examiners **should not diagnose tongue-tie but may refer parents to a clinician who can diagnose.**
Canadian Paediatric Society	2015; Reaffirmed 2024	**For frenotomy:** **Does not recommend for all infants with ankyloglossia**. **Infants who experience significant breastfeeding difficulties may benefit from frenotomy.** Frenotomy should be performed by a clinician "experienced with the procedure and using appropriate analgesia."
Canadian Agency for Drugs and Technologies in Health	2016	**For frenectomy:** Frenectomy is a **safe procedure with demonstrated short-term breastfeeding effectiveness** as perceived by the mother. There is **less evidence on objective and long-term breastfeeding measurements.**

Payer Coverage

Condition	Aetna	Premera Blue Cross	Regence BlueShield	UnitedHealth Dental	Washington Apple Health
Labial frenoplasty/frenuloplasty	✓	—	✓	—	✓
Lingual frenoplasty/frenuloplasty	✓	✓	✓	✓	✓
Labial frenectomy/frenulectomy	✓	—	✓	—	✓
Lingual frenectomy/frenulectomy	✓	✓	✓	✓	✓

Limitations of this Health Technology Assessment

- Scope
  - English-language only
  - Very highly developed countries only
  - Two databases from inception through August 2024
  - Did not use unpublished data or data presented only in abstracts
  - Excluded effectiveness outcomes from uncontrolled studies
- Analysis
  - Did not GRADE the body of evidence from uncontrolled safety study outcomes

Abbreviations: GRADE=Grading of Recommendations Assessment, Development and Evaluation

Conclusions

- Limited evidence for evaluating the effectiveness and safety of frenotomy for breastfeeding support in infants up to 1 year of age with tongue-tie and/or lip-tie and no evidence reporting on cost-effectiveness

Additional Slides

No Difference Details

Any breastfeeding at > 2 months

№ of Studies (№ of Participants)	Summary of Findings	CERTAINTY
1 RCTs (163)	No statistically significant differences for frenotomy vs. no frenotomy ITT (outcomes with significant unplanned crossover) 3 months: 67/80 (88%) vs. 75/89 (86%); aRR, 1.02; 95% CI, 0.90 to 1.16; *p*=0.73 6 months: 55/66 (83%) vs. 60/71 (85%), aRR, 0.98; 95% CI, 0.84 to 1.14 Per protocol (at 3 months) n=65/75 (90%) vs. 16/24 (27%); aRR, 1.27; 95% CI, 0.99 to 1.64; *p*=0.06	⊕⊕◯◯ LOW for no difference
4 cohorts with comparison (1 publication reported 2 studies) (471)	Similar prevalence between study arms (frenotomy vs. no frenotomy) Study 1[33]: At 3 months, 112/120 [93%] vs. 31/30 [79%]; calculated PR, 1.17; 95% CI, 0.99 to 1.39) At 6 months, 110/120 [92%] vs. 31/39 [79%]; calculated PR, 1.15; 95% CI, 0.97 to 1.36 Study 2[36]: At mean 6 to 7 months, 68/82 (83%) vs. 6/9 (67%); calculated RR, 1.24; 95% CI, 0.78 to 1.99 Study 3(Dixon et al 2018, study 1): At median 87 days, 127/164 (77%) vs. 18/22 (82%); calculated PR, 0.94; 95% CI, 0.76 to 1.17 Study 4(Dixon et al 2018, study 2): At median 118 days, 24/34 (71%) vs. 1/1 (100%), calculated Peto OR, 0.247; 95% CI, 0.003 to 18.89	⊕◯◯◯ VERY LOW

Very Low COE Outcomes

Breastfeeding Pain

№ of Studies (№. Participants)	Summary of Findings	CERTAINTY
6 RCTs[26-31] (426)	Inconsistent changes in pain scores. Variations in outcome measures and comparators, and timing precluded additional syntheses	⨁◯◯◯ VERY LOW

Breastfeeding Effectiveness

№ of Studies (№. Participants)	Summary of Findings	CERTAINTY
1 RCT[29] (105)	No significant difference between frenotomy vs delayed frenotomy (LATCH score of 1 [interquartile ranges from 0–2] in both arms; *P*=0.52 at 5 days)	⨁◯◯◯ VERY LOW

Breastfeeding at 2 months or less

№ of Studies (№ of participants)	Summary of Findings	CERTAINTY
1 RCT[29] (105)	No significant differences at 5 days for frenotomy vs. delayed frenotomy (48/53 [91%] vs. 44/52 [85%], OR, 0.57; 95% CI, 0.17 to 1.88)	⨁◯◯◯ VERY LOW
1 cohort with comparison[33] (159)	No difference at 1 month follow-up for frenotomy vs. no frenotomy (114/120 [95%] vs.33/39 [85%]; calculated PR, 1.12; 95% CI, 0.98 to 1.29)	⨁◯◯◯ VERY LOW

Exclusive breastfeeding at more than 2 months

№ of Studies (№ of Participants)	Summary of Findings	CERTAINTY
1 RCT[31] (145)	No difference at 3 months for frenotomy vs. no frenotomy (38/80 [54%] vs. 39/89 [53%]; aRR,1.03; 95% CI, 0.65 to 1.62); outcome had significant unplanned crossover[31]	⊕◯◯◯ VERY LOW
3 cohorts with comparison[32,33] (1 publication reports 2 studies[32]) (380)	No difference for frenotomy vs. control Study 1 (Dixon et al. 2018 study 1[32]): 89/164 [54%] vs.10/22 [46%]; calculated RR, 1.19; 95% CI, 0.74 to 1.93 at median 87 days followup Study 2 (Dixon et al. 2018, study 2[32]): 19/34 [56%] vs. 0/1 [0%]; calculated Peto OR, 8.91; 95% CI, 0.17 to 455.73) at median 118 days Study 3[33]: at 3 months 81/120 [68%] vs. 28/39 [72%]; PR, 0.94, 95% CI, 0.75 to 1.19) and at 6 months (79/120 [66%] vs. 29/39 [7%]; PR, 0.92; 95% CI, 0.72 to 1.16)	⊕◯◯◯ VERY LOW

Change in breastfeeding

№ of Studies (№ of Participants)	Summary of Findings	CERTAINTY
Change in breastfeeding		
2 RCTs[8,26] (114)	Significant improvement in frenotomy arm vs. control in both RCTs Study 1: 78% (21/26) vs. 47% (14/30); *p*<0.02; calculated RR; 1.73; 95% CI: 1.13 to 2.65[26] Study 2:96% (27/28) vs. 3% (1/29); *p*<0.001; calculated RR: 28.0; 95% CI, 4.07 to 192.12[8]	⨁◯◯◯ VERY LOW
1 cohort study[34] (33)	Fewer problems in frenotomy arm vs. control participants (13% [n=3/23] vs. 60% [n=6/10]; calculated RR: 0.22; 95% CI, 0.07 to 0.70)[34]	⨁◯◯◯ VERY LOW

Infant Weight Gain

№ of Studies (№ of Participants)	Summary of Findings	CERTAINTY
Infant Weight Gain		
1 RCT[31] (163)	No significant difference at 3 months, z-score for weight for age, −1.0 (SD 1.6) vs. −1.1 (SD 1.3); adjusted mean difference in z-score: 0.10 (95% CI, −0.83 to 1.03; *p*=0.83)	⨁◯◯◯ VERY LOW

Infant Breastfeeding Assessment Tool (IBAT)

№ of Studies (№ of Participants)	Summary of Findings	CERTAINTY
2 RCTs[27,29] (162)	Study 1[27]: Significant improvement in score immediately after procedure (calculated mean difference: 3.53; 95% CI, 1.22 to 5.84) Study 2[29]: No change in median score 5 days after procedure: 0 (95% CI, −1.8 to 1) vs. 0 (95% CI, 0 to 1); *p*=0.36	⨁◯◯◯ VERY LOW

Gastroesophageal Symptom Questionnaire for Infants (GSQ-I)

№ of Studies (№ of Participants)	Summary of Findings	CERTAINTY
1 RCT[30] (48)	No significant differences (after Bonferroni corrections for multiple comparison) for calculated mean differences and CIs for 10 of 12 domain measures in the GSQ-I;[c,d] 4 domains did not exclude the null (refusal to feed [times], episodes of hiccups [times], choking/gagging [severity], irritability/fussiness [times]). Six; 6 domains excluded the null but had *p* values that did not meet the threshold for multiple comparisons (*p*=0.004) (arching back [times and severity], episodes of hiccups [severity], irritability/fussiness [severity], refusal to feed [severity], and vomiting [times]) Statistically significant differences for number of times infants experienced choking/gagging (−9.8, 95% CI, −-16.9 to −3.7;, uncorrected *p*=0.002) and severity of vomiting/regurgitation (−1.9;, 95% CI, −3.0 to −-0.8;, uncorrected *p*=0.001))	⨁◯◯◯ VERY LOW

Study Characteristics	Subcharacteristics	EQ Number of Studies (%)	SQ Number of Studies (%)
Population characteristics			
Mean age at procedure	≤1 week	2 (15)	7 (12)
	≤2 weeks	1 (8)	6 (10)
	≤1 months	3 (23)	13 (22)
	≤2 months	2 (15)	14 (24)
	≤6 months	2 (15)	3 (5)
	NR[a]	3 (23)	15 (26)
Gender	Majority male (>50%)	10 (77)	41 (71)
	Majority female (>50%)	0 (0)	1 (2)
	NR	3 (23)	16 (28)
Race or ethnicity	Majority White/European (>50%)	3 (23)	14 (24)
	Majority non-White (>50%)	0 (0)	0 (0)
	Not reported	10 (77)	44 (76)
Oral tie type	Tongue-tie only	13 (100)	39 (67)
	Tongue-tie and/or other tie types	0 (0)	13 (22)
	NR[b]	0 (0)	6 (10)

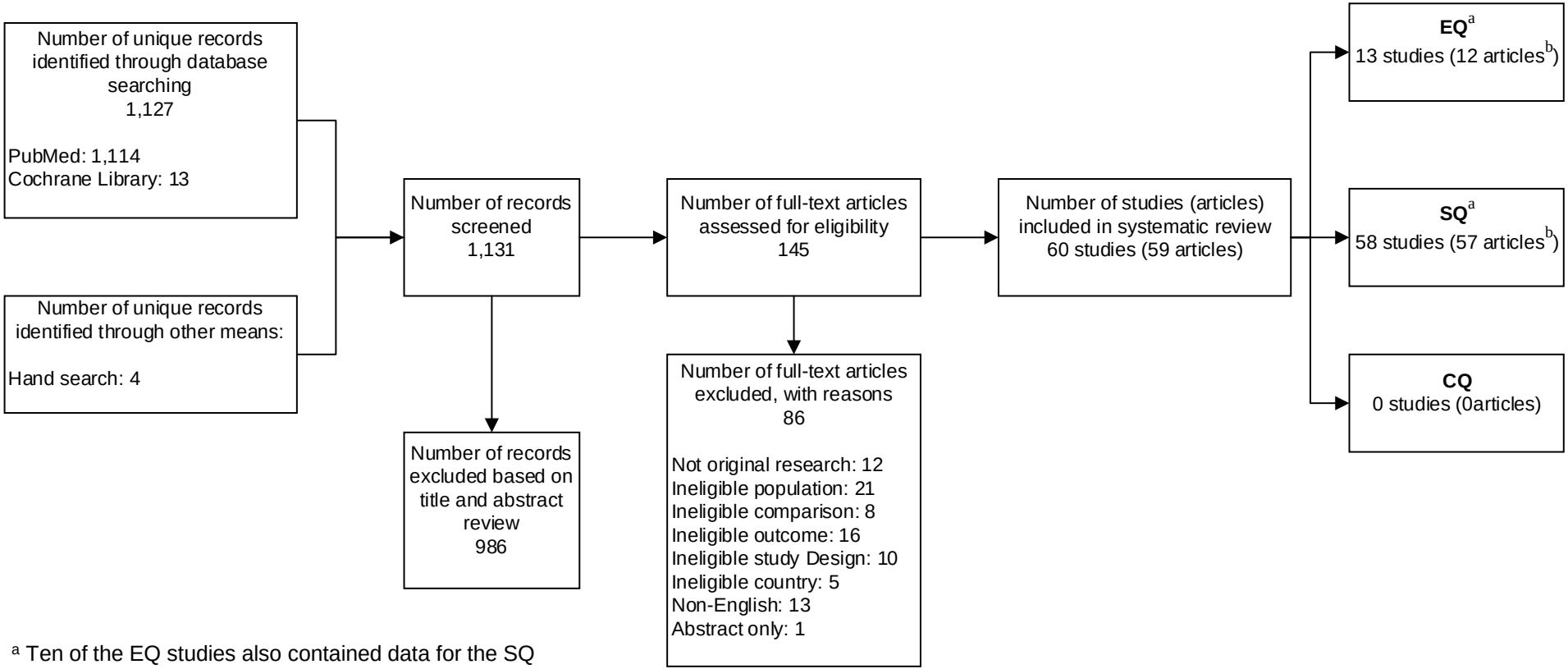
Intervention characteristics			
Frenotomy method	Scissors	7 (54)	39 (67)
	Laser	1 (8)	8 (14)
	Unspecified	5 (38)	11 (19)
Provider	Various providers[c]	2 (15)	9 (16)
	Pediatrician/general practitioner	0 (0)	3 (5)
	ENT/Otolaryngology	1 (8)	8 (14)
	Lactation consultants/midwives	0 (0)	1 (2)
	Dentist/oral surgeon	0 (0)	5 (9)
	Surgeon Specialty unspecified	2 (15)	6 (10)
	Physician specialty unspecified	0(0)	1(2)
	NR/unclear	8 (62)	25 (43)
Anesthesia/analgesia/anesthetic	Topical or other method	6 (46)	20 (34)
	None	1 (8)	15 (26)
	NR	6 (46)	23 (40)
Lactation consultant/contact	Varying intensity	9 (69)	42 (72)
	NR	4 (31)	16 (28)

Other study characteristics			
Design	RCT	7 (54)	7 (12)
	NRSI	6 (46)	4 (7)
	Single arm	NA	47 (81)
Comparator	Breastfeeding support	7(54)	5 (9)
	Sham	3(23)	3(5)
	Immediate or delayed frenotomy	4 (31)	4 (7)
	No frenotomy	6 (46)	4 (7)
	No comparison	NA	47 (81)
Geographical Setting	United States	3 (23)	17 (29)
	Outside the United States	10 (77)	41 (71)
ROB	Low	3 (23)	3 (5)
	Moderate	0 (0)	0 (0)
	High	10 (77)	8 (14)
	Other[d]	NA	47 (81)
Funding	Industry	0 (0)	0 (0)
	No industry	6 (46)	13 (22)
	Unfunded	1 (8)	16 (28)
	Not reported	6 (46)	29 (50)

GRADE interpretation

Grade	Definition
High	**We are very confident that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has few or no deficiencies. We believe that the findings are stable, that is, another study would not change the conclusions.
Moderate	**We are moderately confident that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has some deficiencies. We believe that the findings are likely to be stable, but some doubt remains.
Low	**We have limited confidence that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has major or numerous deficiencies (or both). We believe that additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.
Very Low	**We have very limited confidence that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has numerous major deficiencies. We believe that substantial additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.

Literature Flow Diagram



[a] Ten of the EQ studies also contained data for the SQ
[b] One article contained information on two studies

Outcome Measures-Reference Slide

Scale Name	Description	Scoring Range
Breastfeeding Self-Efficacy Tool–Short Form (BSES - SF)	14-item validated survey that measures breastfeeding efficiency and confidence	Individual items ranging from 1 or 0[a] (not very confident) to 5 (very confident). Range of score is 0 or 5–70, with higher scores indicating lower breastfeeding impairment/higher confidence.
EuroQoL-5 Dimensions, 5-level version (EQ-5D-5L)	5 dimensions assess health-related quality of life and anxiety and depression: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression	Levels for each domain are as follows: no problems, slight problems, moderate problems, severe problems, and unable to.
Infant Breastfeeding Assessment Tool (IBFAT)	4 domains assess breastfeeding behavior of infants: readiness to feed, rooting, fixing [latching on], and sucking pattern	Each domain is scored out of 3. A minimum score is 0 and a maximum score is 12, with a higher school indicating better breastfeeding.
Gastroesophageal Symptom Scale - Infant (GSQ-I)	Times occurred and severity of 6 symptoms associated with infant reflux; scale covers the last 7 days	Time: respondents report the number of times the issue occurred. Severity: respondents rate symptoms between 1 (not at all severe) and 7 (most severe).
Latch, Audible swallowing, Type of nipple, Comfort, Hold (LATCH)	5 domains assess breastfeeding quality: latch, audible swallowing, type of nipple, comfort, and hold	Each domain is evaluated from 0–2 points, with 10 being a score indicating highest quality breastfeeding.
Short-Form McGill Pain Questionnaire (SF-MPQ)	3-section scale adapted from the MPQ. Section one: a set of 15 words describing pain Section two: a visual analog scale Section three: a list of descriptors comprising the present pain intensity measure	Section one: Each word is graded on a 0–4 scale. Section two: Scores range between 0 (mild pain) and 10 (worst possible pain). Section three: Graded on a 0–5 point list. The measures are combined with a total possible score of 50 indicating the most severe pain.
Visual Analog Scale (VAS)	Scale of 0–10 laid out on a horizontal line	Pain is rated between 0 (no pain) and 10 (worst pain).

Additional Results Slides

Table 18. Summary of adverse events comparing frenotomy with scissors to no frenotomy (i.e., sham, no frenotomy, or breastfeeding support) for tongue-tie

№ of Studies	N at Follow-up	Summary of Findings
Explicitly reported that no complications occurred		
2 RCTs 1 Cohort Study	150	No complications or harms from the procedure
Minor bleeding		
1 RCT 2 Cohorts	376	5% of participants reported minor bleeding
Recurrence of tongue-tie		
1 Cohort	302	2.6% of ties reoccurred secondary to scarring
Revisions/repeat surgery		
3 Cohort	621	2.6% of participants needed a repeat surgery
Required paracetomol for analgesia		
2 Cohorts	319	1 participant required paracetamol for analgesia

Table 19. Summary of adverse events from single-arm studies of frenotomy with scissors for tongue-tie only

№ of Studies	N at Follow-up	Summary of Findings
Explicitly reported that no complications occurred		
14 Single arm	1,292	No complications or harms were reported from the procedure.
Adverse events		
1 Single arm	474	4.4% reported adverse events.
Bleeding		
5 Single arm	1,060	2.8% to 100% reported bleeding during or after the procedure.
Brown posset due to swallowed blood		
1 Single arm	215	0.5% reported “brown posset” due to swallowed blood.
Feeding deteriorated		
1 Single arm	175	0.5% reported that feeding deteriorated after the procedure.
Fever		
1 Single arm	126	0.8% reported infant having a fever for 1 day.
Need a Syringe for feeding		
1 Single arm	175	0.57% of previously breastfeeding infants required syringe feeding after the procedure.
Irritability/Crying		
5 Single arm	921	3% to 60% reported irritability or crying after the procedure.
Need for repeat procedure		
4 Single arm	792	0.66% to 6.5% reported needing a repeat procedure.

Table 19. Summary of harms from single-arm studies of frenotomy with scissors for tongue-tie only (continued)

Readmission		
1 Single arm	474	1.1% of participants had to be readmitted.
Refusal to drink from breast or bottle		
1 Single arm	126	0.8% of infants refused to drink from breast or bottle for 2 hours after the procedure.
Reoccurrence/reattachment		
2 Single arm	264	1.5% to 2% reported reattached of tongue-tie or reoccurrence.
Scarring		
1 Single arm	474	38% reported scarring.
Soreness/discomfort		
2 Single arm	251	0.5% to 5.6% reported soreness or discomfort.
Swelling		
2 Single arm	649	4.1% to 5% reported swelling.
Ulcers		
4 Single arm	984	2% to 100% reported ulcers.
Worse pain and latch difficulties		
1 Single arm	175	0.57% reported worse pain and latch difficulties at follow-up.

Table 20. Summary of adverse events for single-arm studies of frenotomy with scissors for tongue-tie and/or lip-tie

№ of Studies	N at Follow-up	Summary of Findings
Explicitly reported that no complications occurred		
2 Single arm	715	Reported no complications or harms.
Frenotomies were revised		
1 Single arm	33	6% of frenotomies were revised.
Need for cauterization with silver nitrate		
1 Single arm	157	1% needed cauterization with silver nitrate for persistent oozing.
Pain		
1 Single arm	41	24.4% reported notable postoperative pain.

Table 21. Summary of adverse events from single-arm studies of frenotomy with laser for tongue-tie only

№ of Studies	N at Follow-up	Summary of Findings
Bleeding		
1 Single arm	56	30.4% reported bleeding during the procedure and 1 case had punctiform bleeding due to accidental trauma 7 days after the procedure.
Carbonization of the irradiated site		
1 Single arm	56	19.6% needed the irradiated site carbonized during procedure.
Crying		
1 Single arm	56	96.4% had a high pitched, easily consolable cry after procedure.
Frequently awake		
1 Single arm	56	26.8% were reported to be frequently awake.
Heart rate		
1 Single arm	56	83.9% heart rate increase <20% after procedure. Heart rate return to baseline after procedure, n (%): 9 (16.1)
Need for repeat procedure		
1 Single arm	146	4.6% had a second lingual frenotomy within 1 month.
Pain (C.R.I.E.S. Scale)		
1 Single arm	56	Pain intensity raised significantly during procedure, mean difference = 5 points; $p<0.001$ C.R.I.E.S. score after procedure, mean (SD): 4.4 (1.1) C.R.I.E.S. score 30 minutes after procedure, mean (SD): 0.7 (0.8)
Refusal of pacifier		
1 Single arm	56	69.9% refused pacifier at 7-day follow-up.

Table 22. Summary of adverse events from single-arm studies of frenotomy with laser for tongue-tie and/or other tie types (specified)

№ of Studies	N at Follow-up	Summary of Findings
Explicitly reported that no complications occurred		
2 Single arm	157	No complications were reported following procedure.
Crying		
1 Single arm	25	56% participants were crying and 44% were not crying after the procedure.
Pain		
1 Single arm	22	82% reported local pain.
Reoccurrence/reattachment		
1 Single arm	22	9% reported recurrence of lip-tie.
Temporary hypergranulation of wound tissue		
1 Single arm	146	0.7% reported temporary hypergranulation of wound tissue.

Table 23. Summary of adverse events comparing frenotomy with unspecified methods to no frenotomy (i.e., sham, breastfeeding support, or delayed frenotomy) for tongue-tie only

№ of Studies	N at Follow-up	Summary of Findings
Bleeding		
2 RCTs	194	0.6% to 100% reported bleeding.
Crying		
1 RCT	25	100% infant crying lasting a few seconds following procedure.
Salivary duct damage		
1 RCT	169	0.6% reported salivary duct damage following procedure.
Accidental cut to tongue and salivary		
1 RCT	169	0.6% reported an accidental cut to tongue and salivary duct damage following procedure.
Need for repeat procedure		
1 RCT	99	4.0% of participants needed a repeat procedure.

Table 24. Summary of adverse events from single-arm studies of frenotomy with unspecified methods for tongue-tie only

№ of Studies	N at Follow-up	Summary of Findings
Explicitly reported that no complications occurred		
2 Single arm	145	No complications were reported following procedure.
Need for repeat procedure		
1 Single arm	158	4% of participants needed a repeat procedure.

Table 25. Summary of adverse events from single-arm studies of frenotomy with unspecified methods for tongue-tie and/or other tie types (specified and unspecified)

№ of Studies	N at Follow-up	Summary of Findings
Explicitly reported that no complications occurred		
1 Single arm	84	No complications were reported by 99% of the sample (1 unsure).
Apnea, ALTE/BRUE, or other breathing difficulties		
1 Single arm	16	4 out of 16 participants who experienced complications (25%) reported apnea, ALTE/BRUE, or other breathing difficulties.
Bleeding		
1 Single arm	16	3 out of 16 participants who experienced complications (19%)reported bleeding.
Feeding		
1 Single arm	16	7 out of 16 participants who experienced complications (44%)reported poor feeding.
Grayish black stools		
1 Single arm	16	1 out of 16 participants who experienced complications (6%) reported grayish black stools.
Hypernatremia, hypothermia and 20% weight loss		
1 Single arm	16	1 out of 16 participants who experienced complications (6%) reported severe hypernatremia, hypothermia, and 20% weight loss.

Table 25. Summary of adverse events from single-arm studies of frenotomy with unspecified methods for tongue-tie and/or other tie types (specified and unspecified) (continued)

Pain		
1 Single arm	16	3 out of 16 participants who experienced complications (19%) reported pain.
Pallor/anemia		
1 Single arm	16	2 out of 16 participants who experienced complications (13%) reported pallor/anemia.
Scarring		
1 Single arm	16	2 out of 16 participants who experienced complications (13%) reported excess scarring.
Ulcer		
1 Single arm	16	1 out of 16 participants who experienced complications (6%) reported ulcer.
Unsettledness		
1 Single arm	16	1 out of 16 participants who experienced complications (6%) reported unsettledness.
Weight loss		
1 Single arm	16	3 out of 16 participants who experienced complications (19%) reported weight loss.

Table 26. Summary of adverse events from single-arm studies of frenotomy with unspecified methods for unspecified ties

№ of Studies	N at Follow-up	Summary of Findings
Unplanned visits		
1 Single arm	414	27% reported unplanned visits after the procedure (total of 132).
Need for repeat procedure		
1 Single arm	414	23% had a repeat frenulotomy performed and 3.1% had more than 2 frenulotomies performed.

HTCC Coverage and Reimbursement Determination

Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are evidence-based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards[2]:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms[3]:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.

Based on Legislative mandate: RCW 70.14.100(2).

The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

3. Factors for Consideration - Importance

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

Clinical committee findings and decisions

Efficacy considerations

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
    - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
    - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next step: Cover or no cover

If not covered, or covered unconditionally, the chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next step: Cover with conditions

If covered with conditions, the committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
    - Refer to evidence identification document and discussion.
    - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
    - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.
2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
    - What are the known conditions/criteria and evidence state
    - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Clinical committee evidence votes

First voting question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Discussion document: What are the key factors and health outcomes and what evidence is there? (Applies to the population in the PICO for this review)

Safety outcomes	Importance of outcome	Safety evidence/ confidence in evidence
Bleeding		
Scarring		
Repeat surgery		
Decreased feeding		
Irritability/crying		
Reoccurrence		
Swelling		
Ulcers		
Pain		
Accidental cut/damage		

Efficacy – effectiveness outcomes	Importance of outcome	Efficacy / Effectiveness evidence
Breastfeeding sefl-efficacy		
Breastfeeding pain		
Breastfeeding effectiveness		
Infant weight gain		
Infant Breastfeeding Assessment Tool (IBFAT)		
Gastroesophageal Symptom Questionnaire for Infants (GSQ-I)		

Cost outcomes	Importance of outcome	Cost evidence
Cost		

Cost-effectiveness		

Special population / Considerations outcomes	Importance of outcome	Special populations/ Considerations evidence
Age		
Sex		
Comorbidity		
Adolescents		
Pregnant individuals		

For safety:

Is there sufficient evidence that the technology is safe for the indications considered?

No relevant studies	Low Risk Safe	Moderate Risk	High Risk Unsafe
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

For efficacy/ effectiveness:

Is there sufficient evidence that the technology has a meaningful impact on patients and patient care compared to the evidence-based alternative(s)?

No relevant studies	Less Less effective	Equivocal	More More effective at least in some
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

For cost outcomes/ cost-effectiveness:

Is there an accepted scale for cost effectiveness for treatments for this disease? If so, how does this treatment compare with evidence-based alternatives?

No relevant studies	Less Less cost effective	Equivocal	More More cost effective at least in some

	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is *insufficient* to make a conclusion about whether the health technology is *safe, efficacious, and cost-effective*;
- Evidence is *sufficient* to conclude that the health technology is *unsafe, ineffectual, or not cost-effective*
- Evidence is *sufficient* to conclude that the health technology is *safe, efficacious, and cost-effective for all indicated conditions*;
- Evidence is *sufficient* to conclude that the health technology is *safe, efficacious, and cost-effective for some conditions or in some situations*

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is:

Not covered	Covered unconditionally	Covered with conditions

Discussion item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Medicare Coverage

A Medicare NCD is not applicable for this topic due to the patient population being children. Therefore, there is no NCD.

Clinical Practice Guidelines

[see pages ES-14 of final report]

Title/Organization Guideline Quality[a]	Year Published	Excerpts of Findings	Rating/Quality of Evidence Narrative Assessment Used
American Academy of Otolaryngology—Head and Neck Surgery Foundation[16] Quality rating: NA	2020	**For frenotomy:** A survey of expert pediatric otolaryngologists agreed that frenotomy in infants with ankyloglossia can lead to an improvement in breastfeeding, not all infants with ankyloglossia need a frenotomy, and there are more common conditions which may impede breastfeeding. The Academy recommends further study to refine evidence.	Based on 2 systematic reviews. Quality of evidence assessment not performed.
American Academy of Pediatric Dentistry[83] Quality rating: NA	2022	**For surgical interventions on the frenulum:** Recognizes that difficulties with breastfeeding may have another cause and not all infants with ankyloglossia require surgical intervention. Recommends a team-based approach to treatment planning. The Academy supports further research in the causative association between ankyloglossia and difficulties in breastfeeding.	Based on a nonsystematic review of the literature. Quality of evidence assessment not performed.
American Academy of Pediatrics[84] Quality rating: NA	2024	**For frenotomy:** It is unclear if release of a tight lingual frenulum in neonates improves breastfeeding. Because symptoms of ankyloglossia overlap those of other breastfeeding difficulties, a team partnership is necessary. Frenotomy may decrease maternal nipple pain. Further research is necessary.	Based on a nonsystematic review of the literature. Quality of evidence assessment not performed.
The Academy of Breastfeeding Medicine[85] Quality rating: NA	2021	**For surgical tongue-tie release:** If there is the presence of a restrictive sublingual frenulum, frenotomy can be an effective way to increase maternal comfort and milk transfer and may prevent premature breastfeeding cessation. The Academy urges more research on “a clear definition of ‘tongue-tie’ in distinction from the normal sublingual frenulum,” optimal surgical methods, and long-term outcomes.	Based on a nonsystematic review of the literature. Quality of evidence assessment not performed.

Title/Organization Guideline Quality[a]	Year Published	Excerpts of Findings	Rating/Quality of Evidence Narrative Assessment Used
International Board of Lactation Consultant Examiners[86] Quality rating: NA	2017	Members of the International Board of Lactation Consultant Examiners should not diagnose tongue-tie but may refer parents to a clinician who can diagnose.	Overview of International Board of Lactation Consultant Examiners scope of practice, clinical competencies, code of conduct, and advisory opinions. Quality of evidence assessment not performed.

Next step: proposed findings and decision and public comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?
2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next step: final determination

Following review of the proposed findings and decision document and public comments:

Final vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?
If yes, the process is concluded.
If no or unclear (i.e., tie), outcome chair will lead discussion to determine next steps.

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FINAL Key Questions and Background

Frenotomy and Frenectomy with Breastfeeding Support

Background

Estimates of ankyloglossia (i.e., tongue-tie) vary from <1% to about 11%, with prevalence more common among males than females.[1-3] Reasons for the wide variance in prevalence arise from unclear diagnostic methods, which may include visual inspection of the oral anatomy, assessment of functional impairment and decreased mobility, and the effect on mothers during breastfeeding (such as nipple pain).[3] Ankyloglossia may be most commonly anterior, that is, where the frenum attaches near the tip of the tongue and is visible, or less commonly posterior, where the frenulum is attached further back on the tongue and may be harder to see.[4] Of note, there is no consensus as to the definition of "posterior ankyloglossia" including whether this represents a distinct clinical entity.[5, 6] Categories of severity have been proposed that rely on free tongue length[7] and additional anatomical features (thickness, notching),[8] but the relationship between these categories and breastfeeding difficulty have not been established.[9] As a result, additional functional assessments of breastfeeding such as the LATCH index, Infant Breastfeeding Assessment Tool (IBFAT), or Frenotomy Decision Rule for Breastfeeding Infants (FDRBI) may be needed.[9] The absence of validated diagnostic criteria creates uncertainty around the threshold for management.[3]

Outcomes potentially associated with untreated ankyloglossia include breastfeeding difficulties that may result in restricted weight gain in the infant,[10-13] speech difficulties and problems with dentition,[14, 15] and maternal pain, reduced milk supply, or incomplete emptying in the mother that may result in infections.[16, 17]

Diagnosis of ankyloglossia and rates of frenotomy have increased sharply over the past 2 decades. Diagnoses of ankyloglossia in the US increased from 3,377 in 2004 to 13,200 in 2019 and lingual frenotomy to address lip-tie increased from 1,483 in 2004 to 6,213 in 2019.[18]

Policy Context

The State of Washington Health Care Authority selected frenectomy and frenotomy for breastfeeding support for a health technology assessment (HTA) because of high concerns for efficacy, and medium concerns for safety and cost.

Scope of this HTA

The analytic framework (***Figure 1***), research questions, and key study selection criteria (***Table 1***) are listed in this section.

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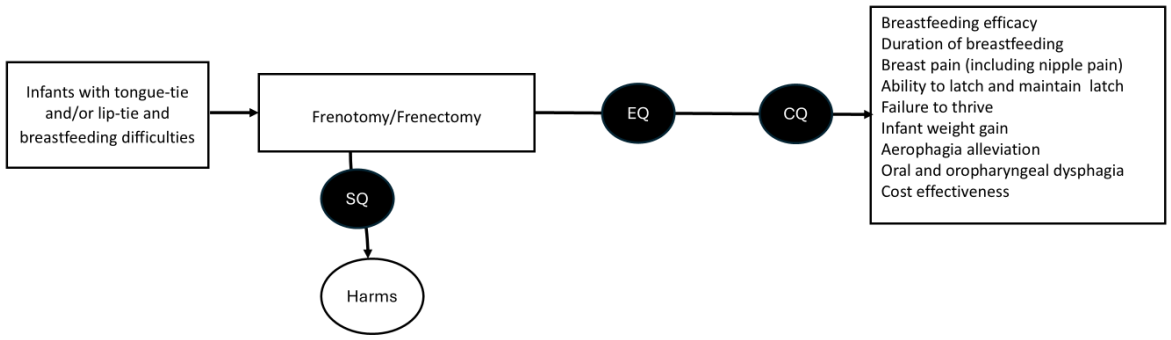
Figure 1. Analytic Framework Depicting Scope of this Health Technology Assessment



Abbreviations: CQ = cost question; EQ = efficacy question; SQ = safety question.

Research Questions

Efficacy Question. What is the effectiveness and comparative effectiveness of frenotomy or frenectomy for tongue-tie and/or lip-tie on breastfeeding outcomes?

Safety Question. What are the harms of frenotomy or frenectomy for tongue-tie and/or lip-tie as a support for breastfeeding?

Cost Question. What is the cost-effectiveness of frenotomy or frenectomy for tongue-tie and/or lip-tie for breastfeeding support?

Study Selection Criteria

Table 1 provides the study selection criteria we will use to include studies in the HTA.

Table 1. Proposed Population, Intervention, Comparator, Outcome, Timing, and Setting for Health Technology Assessment on Frenotomy or Frenectomy with Breastfeeding Support

Domain	Included	Excluded
Population	Breastfeeding newborns with tongue-tie and/or lip-tie	• Infants with physical/anatomic comorbidities, such as hypotonia • Infants with Pierre Robin syndrome or sequence, Down syndrome, or craniofacial or airway abnormalities (i.e., cleft palate) • Infants born at less than <37 weeks of gestation
Intervention	Frenotomy, frenectomy, frenulotomy, frenulopasty, or z-plasty to improve breastfeeding using all methods (i.e., scissors, lasers)	Frenotomy, frenectomy, frenulotomy, or z-plasty done for indications other than breastfeeding support
Comparator	• EQ: All comparators including other surgical approaches, sham surgery, non-surgical interventions (i.e., lactation intervention, speech therapy, physical/occupational therapy, oral motor	• EQ: No comparator group • SQ: N/A • CQ: No comparator group

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Domain	Included	Excluded
	therapy, and stretching exercises/therapy), complementary and alternative medicine (CAM) therapies (e.g. craniosacral therapy), observation only • SQ: No comparator necessary • CQ: Any comparator	
Outcomes	• *EQ: Breastfeeding, including latch, nipple pain, nipple excoriations, nipple infections (mastitis), weight gain, aerophagia, swallowing function, failure to thrive, milk transfer, low milk supply, breastfeeding cessation/duration of breastfeeding, and other feeding issues • SQ: Any harms, including excessive bleeding, airway obstruction, pain, transient poor feeding secondary to discomfort, dysphagia, complications related to dysphagia such as aspiration pneumonia, surgical site infection, nerve damage, salivary gland damage, ranulae, scarring, soft tissue damage, oral aversion, readherence of tongue- or lip-tie, need for further surgery/revision, ED visits, hospitalizations, extension of current hospitalization. • CQ: cost effectiveness or cost-utility	• Outcomes not listed as eligible • Cost-effectiveness based on cost inputs from countries other than the U.S.
Timing	• EQ: Outcomes measured after intervention/comparator through 12 months of age • SQ: no time limitation • CQ: no time limitations	Outcomes measured after 12 months of age
Setting	Inpatient or outpatient pediatric care, operating room, newborn nursery or NICU, ENT clinic, primary care outpatient, dental office, or breastfeeding medicine clinics in countries categorized as "very high" on the 2023/2024 UN Human Development Index.[19]	Studies conducted in countries not categorized as "very high" on the 2023/2024 UN Human Development index.[19]
Study Design	• EQ: RCTs, nonrandomized controlled trials, prospective and retrospective cohort studies, cross over studies, and case control studies • SQ: Same as for EQ plus case series • CQ: cost-effectiveness or cost-utility studies	• EQ: Case reports, case-series, SRs, and qualitative studies • SQ: SRs, qualitative studies, and all study designs not already specified • CQ: Studies that use non-U.S. based cost inputs. • EQ, SQ, and CQ: Relevant SRs will be excluded but will be hand searched to identify potentially eligible primary studies
Language	• English	• Non-English
Publication Type	• Original research	• Editorial, commentaries, narrative reviews, or letters

*Dependent on the volume of captured EQ evidence, evidence synthesis and grading may be limited to validated measures.
Abbreviations: CQ =cost question; ENT = ear, nose and throat; EQ = efficacy question; N/A = not applicable; NICU = neonatal intensive care unit; RCT = randomized control trial; SQ = safety question; SR = systematic review.
Notes: [a] Countries identified as *very high* on the 2023/2024 UN Human Development Index: Andorra, Antigua and Barbuda, Argentina, Australia, Austria, Bahamas, Bahrain, Barbados, Belarus, Belgium, Brunei Darussalam, Canada, Chile, Costa Rica, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hong Kong, China (SAR), Hungary, Iceland, Ireland, Israel, Italy, Japan, Kazakhstan, Korea (Republic of), Kuwait, Latvia, Liechtenstein, Lithuania, Luxembourg, Malaysia, Malta, Montenegro, Netherlands, New Zealand, Norway, Oman, Panama, Poland, Portugal, Qatar, Romania, Russian Federation, Saint Kitts and Nevis, San Marino, Saudi Arabia, Serbia, Seychelles, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, Thailand, Trinidad and Tobago, Türkiye, United Arab Emirates, United Kingdom, United States, Uruguay.[19]

What is Excluded from this HTA

This review will not include studies published in languages other than English or studies conducted in countries less than 'very high' on the 2023/2024 United Nations Human Development Index.[19] This review will not include studies that examine frenotomies and frenectomies performed for reasons other than breastfeeding support (e.g., articulation). This review will also not include studies conducted among infants with major comorbidities, other abnormalities, or who were born at less than 37 weeks gestation. This review will exclude studies with no comparison group for the EQ.

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