Effects of Pacifier Use on Breastfeeding and Health Outcomes
A Focused Practice Question

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Key Messages

The Region of Peel – Public Health should share the following key messages with parents and caregivers of healthy term infants and young children:

1. When mothers have initiated and established breastfeeding,[1] and are motivated[2] to continue breastfeeding, pacifier use has no impact on breastfeeding duration in the first six months of life.

2. Health Canada's safety tips:

   - Check the pacifier every day for breakdown (e.g. holes, tears caused by age, heat or certain foods) and ensure the nipple is securely attached to the handle. Dispose of the pacifier if it is damaged.
   - Replace a pacifier every two months.
   - Use a teething ring if the baby begins to chew on the pacifier.
   - Never tie or hang a pacifier around the baby's neck to avoid strangulation.
   - Never dip pacifiers in honey or other sweeteners as this increases the risk of tooth decay. Giving your baby honey can increase the risk of botulism in the first year of life.

3. Pacifier use increases the risk of ear infections in young children. Other factors (e.g. family history of acute otitis media, child care outside the home or exposure to smoking) pose a risk for ear infections. Having more than one risk factor further increases the overall risk.

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[1] Signs that breastfeeding is established may be determined through conversations with the mother.
[2] Women motivated to breastfeed are mothers who have initiated breastfeeding and intend to exclusively breastfeed.

Issue & Context

The Region of Peel – Public Health (ROP-PH) achieved Baby-Friendly Initiative (BFI) designation in 2009. Family Health division staff promote the Breastfeeding Committee for Canada Integrated 10 Steps Practice Outcome Indicators for Hospitals and Community Health Services. (1) Originally developed by the World Health Organization and the United Nations Children's Fund (UNICEF), the Ten Steps have been updated. Step 9 now states "Counsel mothers on the use and risks of feeding bottles, teats and pacifiers." (2) (p.21)

In 2015, the ROP-PH conducted a research review to examine the association between pacifier use and breastfeeding exclusivity or duration among healthy term infants. (3) At that time, there was insufficient evidence to recommend against pacifier use in healthy term infants whose mothers are motivated to breastfeed. It was recommended that parents of breastfeeding infants make an informed decision about pacifier use. However, the effect of pacifier use on other health outcomes was not examined. (3)

Public health nurses providing direct service have identified that parents enquire about various infant and child health outcomes associated with pacifier use. Parents need reliable information to weigh the benefits and risks of pacifier use when making an informed decision, including its effect on breastfeeding, safety, infection, and oral health and development.

The aim of this research review is to examine the association between pacifier use and breastfeeding or health outcomes to inform Family Health key messaging.

Literature Review Question

The research questions are:

1. What is the association between pacifier use and the initiation, amount and duration of breastfeeding among healthy term infants?

2. What health outcomes are associated with pacifier use in infants and young children?

The PECO includes:

- Population: full term infants and children up to four years of age

- Exposure: pacifier use

- Comparator: none; restricted or no pacifier use

- Outcomes:

    o Breastfeeding initiation, amount and duration

    o Safety including sudden infant death syndrome (SIDS), pacifier disintegration, aspiration, choking, and strangulation

    o Infection including *Candida albicans* (i.e. oral thrush) and acute otitis media (i.e. ear infection)

    o Oral health including dental caries, dental malocclusion, and palate shape, and development, including speech

Literature Search

The librarian specialists conducted two literature searches to identify published literature reporting on the effects of pacifier use on breastfeeding and other health outcomes.

The 2015 search strategy (3) was repeated to identify literature on pacifier use and breastfeeding from January 2014 to December 2017. New search terms were used to capture literature reporting on pacifier use and safety, infection, and oral health and development outcomes. The search strategies were implemented in the Cochrane Databases of Systematic Reviews, Global Health, Healthstar, Medline, Medline In-Process & Other Non-Indexed Citations, and CINAHL. Limits included meta-analyses, systematic reviews, syntheses, and guidelines. The pacifier use and health outcomes search strategy was limited to literature in English and no date limit was used (see Appendix A).

A search for grey literature in government (i.e. Health Canada) and organizational websites (i.e. National Institute for Health and Care Excellence, World Health Organization, Breastfeeding Committee for Canada, Infant Toddler Safety Association, and Canadian Dental Association) was conducted. A hand search of previously appraised textbooks used by Family Health staff was also completed.

Relevance Assessment

Two reviewers independently screened titles and abstracts for potential relevance. Conflicts on whether a document should be reviewed in full text were discussed until consensus was reached. Documents were assessed using the following criteria:

- Inclusion: pacifier use and breastfeeding (i.e. initiation, amount and duration), safety (i.e. SIDS, pacifier disintegration, aspiration, choking and strangulation), infection (i.e. *Candida albicans* and acute otitis media), and oral health (i.e. dental caries, dental malocclusion and palate shape) and development (i.e.

speech) outcomes; infants and young children up to four years of age; guidelines, systematic reviews and textbooks; and settings similar to Canada

- Exclusion: preterm infants, infants with a cleft palate, comparative studies on pacifier designs, and data duplication

Results of the Search

Results from the two searches were merged as some findings addressed both research questions. The search yielded 55 articles of published and grey literature. After removing duplicates and screening titles and abstracts, 16 articles were reviewed in full text. The group excluded five textbooks as higher-level evidence (i.e. guidelines and systematic reviews) was available. Nine documents were selected for critical appraisal (see Appendix B).

Critical Appraisal

Two guidelines (2,4) and seven systematic reviews (5-11) were critical appraised. Tools used included the AGREE II Guideline Appraisal Tool (12) and the Health Evidence Tool for systematic reviews. (13)

Two reviewers critically appraised the articles independently. Conflicts in ratings were discussed until consensus was reached. Articles were included if it was rated as moderate in quality (i.e. 4/7 for guidelines or 5/10 for systematic reviews) or higher and a clear description of methodology was provided.

Four systematic reviews (5-8) were excluded due to poor quality ratings. One guideline was excluded due to an insufficient description of methods. (4) A total of four articles were included in this research review, including one guideline (2) and three systematic reviews. (9-11)

Description of Included Evidence

This research review includes the following evidence (see Appendix C):

Guideline

World Health Organization. (2018): *Protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services: the revised Baby-Friendly Hospital Initiative* (2)

The objective of this strong quality guideline (7/7) was to provide recommendations where facilities, providing maternity and newborn services, protect, promote, and support optimal breastfeeding practices. Twenty-two systematic reviews were included as evidence informing recommendations. Studies were limited to facilities providing maternity and newborn services. Participants received advice or practiced on one of the Ten Steps (1989) and were compared to participants who received usual care or did not practice the intervention. (14)

Systematic Reviews

Buccini et al. (2016): *Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding* (9)

The objective of this strong quality systematic review (8/10) was to assess the association between pacifier use and exclusive breastfeeding duration within the first six months of life. Forty-six studies included in the systematic review were of randomized controlled trial (RCT) (n=2), longitudinal (n=20), and cross-sectional (n=24) designs. Forty of the 46 studies were included in a meta-analysis. Authors assessed study quality using the Effective Public Health Practice Project Quality Assessment Tool. Twelve studies were strong in quality, 14 were moderate and 20 were weak. Study weaknesses included design, adjusting for confounding factors, and data collection methods. Included RCTs overlap with one systematic review (15) reported in the guideline. (2)

Callaghan et al. (2005): *Association between pacifier use and breast-feeding, sudden infant death syndrome, infection and dental malocclusion* (10)

The objective of this moderate quality systematic review (6/10) was to critically review literature related to pacifier use for full term infants and young children. Twenty included studies were of RCT (n=2), cohort (n=12) and case-control (n=6) designs. Participants were healthy term infants and children up to 16 years of age. Studies focusing on preterm infants and those with serious or congenital illness were not included; however, some studies included these participants in their total population. Pacifier use was

defined and measured differently across studies. Breastfeeding, SIDS, infection and dental outcomes were explored. Authors assessed study quality using a checklist but did not report those findings.

Uhari et al. (1996): *A meta-analytic review of the risk factors for otitis media* (11)

The objective of this moderate quality systematic review (6/10) was to conduct a meta-analysis of studies reporting on acute otitis media risk factors. Of the 22 included studies, two observational studies reporting on pacifier use and acute otitis media were included in a meta-analysis. Authors did not describe the quality of included studies. There is no overlap in studies included by Callaghan, 2005. (10)

Synthesis of Findings

This research review concludes the following:

1. Breastfeeding

a) Duration of Breastfeeding

There is mixed evidence of an association between infant use of a pacifier and duration of breastfeeding.

RCTs and observational studies reporting on pacifier use and its effect on duration of breastfeeding were found. Results from RCTs may differ from observational studies (e.g. cohort and cross-sectional) as participants are randomized to control and intervention groups to reduce error and bias. (16) A causal relationship between infant use of a pacifier and breastfeeding duration cannot be determined based on

observational study designs. (2) While RCTs have strong internal validity, it can be challenging to applying the findings to the general population including women less motivated to breastfeed (15) or families where the pacifier is introduced before breastfeeding is established. (9)

A guideline (2) citing a systematic review including two randomized controlled trials (15) concluded that infant use of a pacifier within the first six months of life made "little or no difference" in breastfeeding rates among women motivated to breastfeed.[3] (14) (p.8) Among healthy breastfeeding infants, pacifier use had no effect on the proportion of infants exclusively or partially breastfeeding at four months of age (risk ratio [RR] for exclusive breastfeeding: 1.01, 95% confidence interval [CI]: 0.94 to 1.09; RR of partial breastfeeding: 0.99, 95% CI: 0.97 to 1.02). The outcome was analyzed on an intention-to-treat basis where possible. (15)

A secondary analysis of the RCTs (15) by Buccini (2016) (9) confirmed that RCTs suggest there is no association between pacifier use and reduced exclusive breastfeeding duration for infants under three months of age (odds ratio [OR]: 1.06, 95% CI: 0.82 to 1.37). (9)

In contrast, two systematic reviews suggest that pacifier use may negatively affect the duration of partial and exclusive breastfeeding. (9,10)

The systematic review by Buccini (2016) (9) stated that observational studies "strongly suggest that pacifier use may be a risk factor for the premature early [sic]

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[3] Women motivated to breastfeed are mothers who have initiated breastfeeding and intend to exclusively breastfeed. (15)

discontinuation of exclusive breastfeeding" (9) (p.16) in infants under six months of age (OR for longitudinal studies: 2.28, 95% CI: 1.78 to 2.93; OR for cross-sectional studies: 2.78, 95% CI: 2.44 to 3.15) (9)

The systematic review by Callaghan (2005) (10) reported on single studies, as a meta-analysis was deemed inappropriate due to high heterogeneity. The authors concluded that pacifier use increased the risk for shorter duration of any breastfeeding (e.g. exclusive or partial) (range of RR, OR or hazard ratio [HR] from 1.22 [95% CI: 1.03 to 1.44] to 2.87 [95% CI: 1.97 to 4.19]). Authors also reported that infant use of a pacifier increased the odds of a shorter duration of exclusive and partial breastfeeding 35 to 53% and 18%, respectively, compared to infants not using a pacifier (range of OR for exclusive breastfeeding: 1.35 [95% CI: 1.05 to 1.74] to 1.53 [95% CI: 1.15 to 2.05]; OR for partial breastfeeding: 1.18, 95% CI: 1.04 to 1.34). (10)

b) Initiation and Amount of Breastfeeding

No evidence was found assessing the relationship between infant use of a pacifier and the initiation and amount of breastfeeding.

A guideline (2) advises that "proper guidance and counselling of mothers and other family members enables informed decision making on the use or avoidance of pacifiers… until successful establishment of breastfeeding." (2) (p.21)

The guideline (2) also states that "if pacifiers replace suckling and reduce the number of times an infant stimulates the mother's breast physiologically, this can lead to a

reduction of maternal milk production." (2) (p.21) No references were provided to support either statement within the guideline.

2. Safety

a) Sudden Infant Death Syndrome

Infants under one year of age using a pacifier during sleep have a reduced risk of sudden infant death syndrome.

The reduction in the odds of SIDS ranged from 57 to 81 per cent compared to infants not using a pacifier during sleep (range of OR: 0.43 [95% CI: 0.24 to 0.78] to 0.19 [95% CI: 0.08 to 0.46]). (10) No direction was provided in the event a pacifier falls out of an infant's mouth during sleep.

The systematic review cautions that "most clinicians… are reluctant to actively promote the use of pacifiers in the absence of adequate knowledge regarding actual mechanisms related to pacifier use and SIDS." (10) (p.157)

b) Pacifier Disintegration, Aspiration, Choking and Strangulation

No evidence was found assessing the relationship between infant or young child use of a pacifier and pacifier disintegration, aspiration, choking or strangulation.

Health Canada (17) provides pacifier safety tips that can be shared with parents or caregivers.

3. Infection

a) *Candida albicans*

No evidence was found assessing the relationship between infant use of a pacifier and *Candida albicans* (i.e. oral thrush).

b) Acute Otitis Media

Young children's use of a pacifier is associated with increased risk of acute otitis media.

Young children's use of a pacifier increased the risk of acute otitis media by 24 per cent compared to young children not using a pacifier (RR: 1.24, 95% CI: 1.06 to 1.46). Exposure to more than one risk factor increases the overall risk of acute otitis media due to a synergistic effect. (11)

Reported risk factors for acute otitis media in young children include the following in descending order of risk effect:

1. Family history of acute otitis media
2. Daycare outside the home
3. Parental smoking
4. At least one sibling
5. Pacifier use (11)

4. Oral Health and Development

a) <u>Dental Caries</u>

There is insufficient evidence to determine an association between child use of a pacifier and dental caries.

One cohort study (18) cited in a systematic review (10) reported that children approximately five years of age with a history of pacifier use for 24 months increased the risk for dental caries nearly four times compared to children not using a pacifier (RR: 3.5, 95% CI: 1.5 to 8.2, p=0.003).

b) <u>Dental Malocclusion, Palate Shape and Speech</u>

No evidence was found assessing the relationship between young child use of a pacifier and dental malocclusion, palate shape or speech.

Applicability and Transferability

Applicability and Transferability Meeting

Internal stakeholders[4] participated in a facilitated discussion on August 13, 2018. The purpose of the discussion was to determine the applicability and transferability of the research review's findings to Peel's local context and review the draft relevance to practice statements. Questions adapted from the National Collaborating Centre for

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[4] Stakeholders included Breastfeeding management and public health nurse (PHN), Oral Health supervisor and health promoter, Healthy Babies Healthy Children PHN and family visitor, and Multichannel Contact Centre PHN. A Reproductive Health PHN did not attend the meeting; however, the PHN's written responses to the questions (see Appendix D) were received.

Methods and Tools' applicability and transferability tool were used to guide the discussion (see Appendix D).

Key points from the facilitated discussion include:

- **Social acceptability:** Stakeholders acknowledged that parents and caregivers view pacifiers as helpful in soothing their infants (e.g. with restlessness or sleep, settling in transit, or giving mothers a break from cluster feeding). Parents and caregivers may need to learn additional soothing techniques for settling infants. The ROP-PH Why Babies Cry pamphlet and website may be an opportunity to share the additional techniques.

- **Political acceptability:** The issue of infant nutrition, safety and well-being is within the scope of the ROP-PH strategic program priority Nurturing the Next Generation. (19)

  The first draft relevance to practice statement (see p.19) aligns with BFI's Step 9, which states "Counsel mothers on the use and risks of feeding bottles, teats and pacifiers." (2) (p.21) Examining evidence on pacifier use and other health outcomes to inform key messaging also fulfills the Breastfeeding Committee for Canada assessors' recommendation received in 2014.

- **Reach:** Community stakeholders should be informed of the ROP-PH's messaging about pacifier use to optimize client reach and ensure consistency. Community stakeholders include child care centres, EarlyON Centres,

physicians, and community partners (e.g. hospitals and Peel Children's Aid Society).

- **Target population characteristics:** This research review's findings and messaging about pacifier use applies to parents of healthy term infants. Preterm infants have additional indications for pacifier use.

- **Resources:** Staff working in many programs in the ROP-PH (e.g. Healthy Start, Teen Prenatal Supper Club, Healthy Babies Healthy Children, Breastfeeding, Multichannel Contact Centre and Oral Health) discuss pacifier use with parents and caregivers, which reinforces the need for consistent messaging. Staff can work collaboratively to ensure there is uniform messaging across their programs and materials for staff, parents and caregivers (e.g. pamphlets, website or nursing practice standards). Existing technology should also be leveraged to promote messaging (e.g. Smart televisions displayed in the Breastfeeding and Oral Health clinics).

Stakeholder feedback on the draft relevance to practice statements included:

- *Breastfeeding:* More detail is needed to describe "establishing breastfeeding." Currently, the nursing practice standards state that pacifiers should not be introduced until breastfeeding is established after the first four to six weeks of life. Recognizing that breastfeeding can be established sooner, the need for individualized counselling was discussed. It was decided that "established

breastfeeding" should be individualized and determined through conversations with the mother.

- *Safety:*

  o *SIDS:* Researchers caution that clinicians are reluctant to inform parents that pacifiers reduce the risk of SIDS as there is limited knowledge of the mechanisms. (11) Promoting pacifier use during sleep may have unintended consequences. For instance, use of a pacifier at night may reduce the frequency of night time feeds. Informing parents and caregivers about pacifier use to reduce the risk of SIDS may also increase their concern about infant safety.

  o *Pacifier Disintegration, Aspiration, Choking and Strangulation:* There was agreement that Health Canada's pacifier safety tips (17) should be shared with parents and caregivers.

- *Infection:* There was agreement that parents will be interested to learn that pacifier use is one of several factors increasing the risk for acute otitis media. A synergistic effect when multiple risk factors are present is also relevant to parents and caregivers.

- *Oral health and development:* There was agreement that parents and caregivers should receive Health Canada's messaging about avoiding pacifiers dipped in honey as it increases the risk for botulism in infants less than one year of age. (20)

In summary, stakeholders acknowledged that pacifiers can help parents and caregivers soothe their infants. There may be an opportunity for parents and caregivers to learn additional soothing techniques. Stakeholders agreed that messaging about pacifier use by healthy term infants and young children should be clearly stated to avoid confusion. Collaborating with internal and external stakeholders ensures messaging is consistent across a variety of settings in Peel.

Next steps include contacting Health Canada and the Canadian Dental Association to learn about their message development processes.[5]

Relevance to Practice

The following messaging can be shared with families to support informed decision-making about whether and when to offer a pacifier to their healthy term infant or young child:

Breastfeeding

1. When mothers have initiated and established breastfeeding,[6] and are motivated[7] to continue breastfeeding, pacifier use has no impact on breastfeeding duration in the first six months of life.

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[5] Health Canada's development process was clear and its messaging was included. Canadian Dental Association's development process was unclear and its messaging was excluded.
[6] Signs that breastfeeding is established may be determined through conversations with the mother.
[7] Women motivated to breastfeed are mothers who have initiated breastfeeding and intend to exclusively breastfeed. (15)

Safety

2. Share Health Canada's safety tips with parents and caregivers:

- Check the pacifier every day for breakdown (e.g. holes, tears caused by age, heat or certain foods) and ensure the nipple is securely attached to the handle. Dispose of the pacifier if it is damaged.

- Replace a pacifier every two months.

- Use a teething ring if the baby begins to chew on the pacifier.

- Never tie or hang a pacifier around the baby's neck to avoid strangulation. (17)

- Never dip pacifiers in honey or other sweeteners as this increases the risk of tooth decay. (21) Giving your baby honey can increase the risk of botulism in the first year of life. (20)

Infection

3. Pacifier use increases the risk of ear infections in young children. Other factors (e.g. family history of acute otitis media, child care outside the home or exposure to smoking) pose a risk for ear infections. Having more than one risk factor further increases the overall risk.

References

(1) Breastfeeding Committee for Canada. Integrated 10 Steps Practice Outcome Indicators for Hospitals and Community Health Services. 2012; Available at: http://www.breastfeedingcanada.ca/documents/2012-05-14_BCC_BFI_Ten_Steps_Integrated_Indicators_Summary.pdf. Accessed Aug 1, 2018.

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(21) Health Canada. Oral Health for children. 2018; Available at: https://www.canada.ca/en/public-health/topics/oral-health/caring-your-teeth-mouth/children.html. Accessed Sept 11, 2018.

Appendix A: Search Strategy

Question 1: Pacifier Use and Breastfeeding

Databases: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to December 13, 2017>, Global Health <1973 to 2017 Week 48>, Ovid Healthstar <1966 to November 2017>, Ovid MEDLINE(R) <1946 to December Week 1 2017>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <December 13, 2017>
Search Strategy:

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1    exp infant/ (1366976)
2    infant*.ti,ab. (625438)
3    1 or 2 (1652740)
4    exp pacifiers/ (564)
5    pacifier*.ti,ab. (1716)
6    soother*.ti,ab. (97)
7    dummy.ti,ab. (7949)
8    teether*.ti,ab. (28)
9    4 or 5 or 6 or 7 or 8 (9839)
10   exp breast feeding/ (71811)
11   breastfeed*.ti,ab. (41025)
12   breast feed*.ti,ab. (29755)
13   breastfed.ti,ab. (10659)
14   breast fed.ti,ab. (13933)
15   10 or 11 or 12 or 13 or 14 (99998)
16   3 and 9 and 15 (750)
17   remove duplicates from 16 (461)
18   review*.ti,pt,ab. (5299001)
19   meta analys*.ti,pt,ab. (235803)
20   synthes*.ti,pt,ab. (1142518)
21   guideline*.ti,pt,ab. (481413)
22   18 or 19 or 20 or 21 (6675131)
23   17 and 22 (88)
24   limit 23 to yr="2014 -Current" (21)
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Database: CINAHL
Implemented December 15, 2017

	Search ID#	Search Terms	Search Options	Actions
☐	S24	S21 AND S16	Limiters - Published Date: 20140101-20181231; Exclude MEDLINE records Search modes - Boolean/Phrase	View Results (9) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S23	S21 AND S16	Limiters - Published Date: 20140101-20181231 Search modes - Boolean/Phrase	View Results (15) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S22	S21 AND S16	Search modes - Boolean/Phrase	View Results (41) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S21	S17 OR S18 OR S19 OR S20	Search modes - Boolean/Phrase	View Results (388,650) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S20	AB guideline*	Search modes - Boolean/Phrase	View Results (74,576) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S19	AB synthes*	Search modes - Boolean/Phrase	View Results (27,195) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S18	AB "meta analys*"	Search modes - Boolean/Phrase	View Results (27,533) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S17	AB review*	Search modes - Boolean/Phrase	View Results (311,710) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text

☐	S16	S8 AND S9 AND S15	Search modes - Boolean/Phrase	View Results (222) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S15	S10 OR S11 OR S12 OR S13 OR S14	Search modes - Boolean/Phrase	View Results (21,895) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S14	AB "breast fed"	Search modes - Boolean/Phrase	View Results (736) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S13	AB breastfed	Search modes - Boolean/Phrase	View Results (1,762) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S12	AB "breast feed*"	Search modes - Boolean/Phrase	View Results (2,169) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S11	AB breastfeed*	Search modes - Boolean/Phrase	View Results (8,030) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S10	(MH "Breast Feeding+")	Search modes - Boolean/Phrase	View Results (17,739) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S9	S3 OR S4 OR S5 OR S6 OR S7	Search modes - Boolean/Phrase	View Results (1,510) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S8	S1 OR S2	Search modes - Boolean/Phrase	View Results (217,272) View Details

				Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S7	AB teether*	Search modes - Boolean/Phrase	View Results (2) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S6	AB dummy	Search modes - Boolean/Phrase	View Results (906) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S5	AB soother*	Search modes - Boolean/Phrase	View Results (17) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S4	AB pacifier*	Search modes - Boolean/Phrase	View Results (317) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S3	(MH "Pacifiers")	Search modes - Boolean/Phrase	View Results (402) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S2	AB infant*	Search modes - Boolean/Phrase	View Results (54,349) View Details Edit Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL Plus with Full Text
☐	S1	(MH "Infant+")	Search modes - Boolean/Phrase	View Results (198,343) View Details Edit

Question 2: Pacifier Use and Other Health Outcomes

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to December 7, 2017>, Global Health <1973 to 2017 Week 48>, Ovid Healthstar <1966 to November 2017>, Ovid MEDLINE(R) <1946 to November Week 5 2017>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <December 08, 2017>

Search Strategy:
----
1   exp Pacifiers/ (564)
2   "pacifier*".ti,ab. (1718)
3   ("dummy" or "dummies").ti,ab. (8511)
4   "binky*".ti,ab. (4)
5   "soother*".ti,ab. (97)
6   "teether*".ti,ab. (28)
7   "risk*".ti,ab. (3187967)
8   exp Risk/ or exp Risk Assessment/ (1602648)
9   "health outcome*".ab. (62819)
10   7 or 8 or 9 (3822108)
11   1 or 2 or 3 or 4 or 5 or 6 (10371)
12   10 and 11 (1937)
13   Child, Preschool/ (1336828)
14   exp Infant/ (1366165)
15   "infant*".ti,ab. (625293)
16   13 or 14 or 15 (2377568)
17   12 and 16 (703)
18   ("review*" or "synth*" or "meta-analys*" or "guideline*").ti. (1296182)
19   17 and 18 (27)
20   remove duplicates from 19 (16)
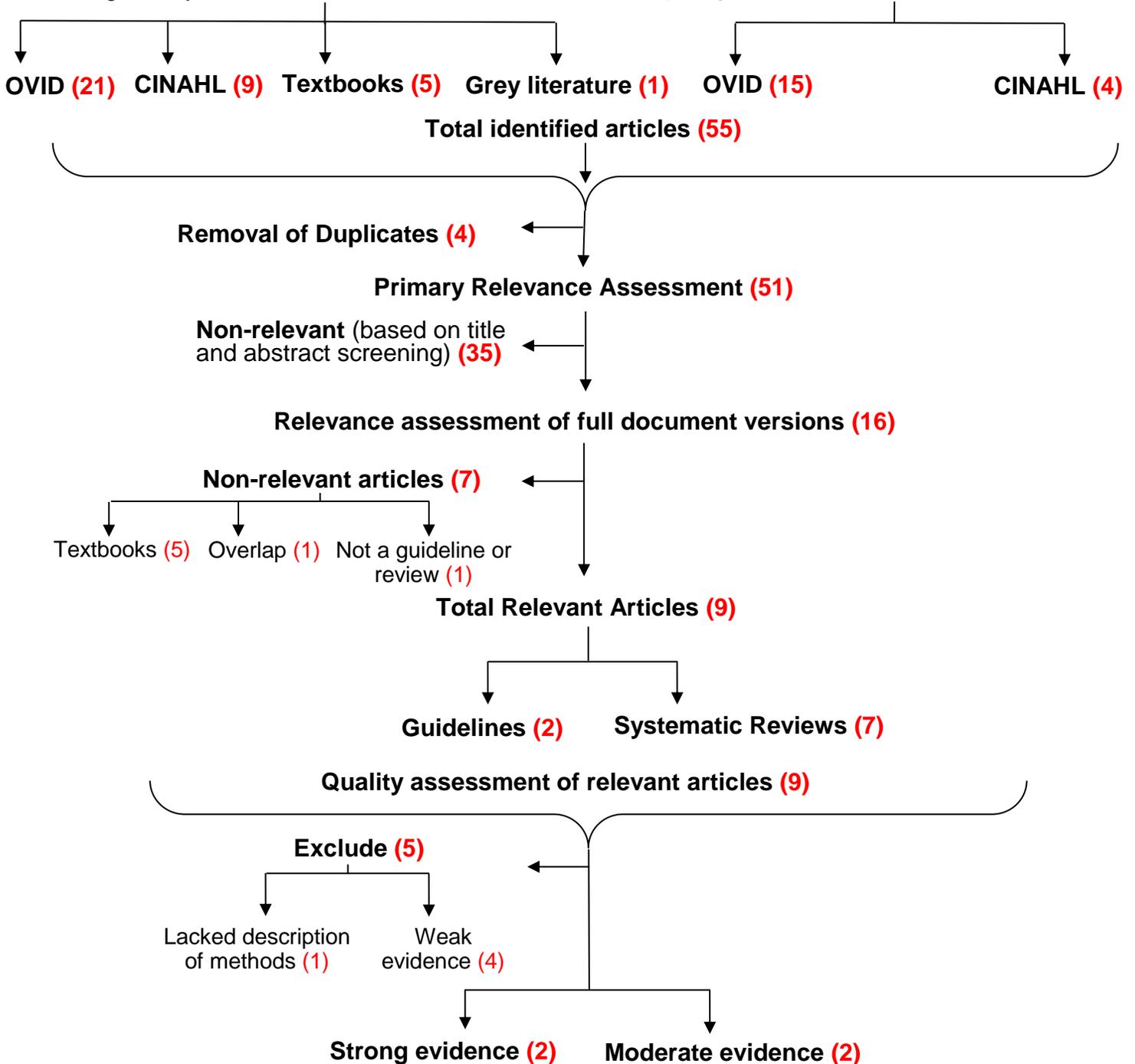21   limit 20 to english language [Limit not valid in CDSR; records were retained] (15)

Database: CINAHL
Implemented December 15, 2017

#	Search terms	Search options	Results
S15	S13 AND S14	Search modes - Boolean/Phrase	View Results (4)
S14	"review*" OR "meta-analys*" OR "guideline*"	Limiters - English Language; Exclude MEDLINE records; Search modes - Boolean/Phrase	View Results (153,505)
S13	S9 AND S10 AND S11	Limiters - English Language; Exclude MEDLINE records; Search modes - Boolean/Phrase	View Results (43)
S12	S9 AND S10 AND S11	Search modes - Boolean/Phrase	View Results (138)
S11	S1 OR S2	Search modes - Boolean/Phrase	View Results (1,330)
S10	S6 OR S7 OR S8	Search modes - Boolean/Phrase	View Results (211,664)
S9	S3 OR S4 OR S5	Search modes - Boolean/Phrase	View Results (451,793)
S8	"Infant*"	Search modes - Boolean/Phrase	View Results (159,451)
S7	(MH "Infant")	Search modes - Boolean/Phrase	View Results (90,182)
S6	(MH "Child, Preschool")	Search modes - Boolean/Phrase	View Results (108,801)
S5	"health outcome*"	Search modes - Boolean/Phrase	View Results (13,458)
S4	"risk*"	Search modes - Boolean/Phrase	View Results (442,618)
S3	(MH "Risk Assessment")	Search modes - Boolean/Phrase	View Results (43,995)
S2	"pacifier*" OR "dummy" OR "dummies" OR "binky*" OR "soother*" OR "teether*"	Search modes - Boolean/Phrase	View Results (1,330)
S1	(MH "Pacifiers")	Search modes - Boolean/Phrase	View Results (320)

Appendix B: Literature Search Flowchart

Question 1: What is the association between pacifier use and breastfeeding initiation, amount and duration among healthy term infants?

Question 2: What health outcomes are associated with pacifier use in infants and young children?

OVID (21) **CINAHL (9)** **Textbooks (5)** **Grey literature (1)** **OVID (15)** **CINAHL (4)**

Total identified articles (55)

Removal of Duplicates (4)

Primary Relevance Assessment (51)

Non-relevant (based on title and abstract screening) **(35)**

Relevance assessment of full document versions (16)

Non-relevant articles (7)

Textbooks (5)   Overlap (1)   Not a guideline or review (1)

Total Relevant Articles (9)

Guidelines (2)   **Systematic Reviews (7)**

Quality assessment of relevant articles (9)

Exclude (5)

Lacked description of methods (1)   Weak evidence (4)

Strong evidence (2)   **Moderate evidence (2)**

Appendix C: Data Extraction Tables

Guideline: World Health Organization. (2018). Protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services: the revised Baby-Friendly Hospital Initiative.

General Information and Quality Rating	
Country	Switzerland
Quality Rating using AGREE II Tool	7/7 (strong quality) by two reviewers MC and EW in 2018 using the AGREE II Tool
Details of Guideline	
Objective	To provide recommendations on protection, promotion and support of optimal breastfeeding in facilities providing maternity and newborn services, as a public health intervention, to protect, promote and support optimal breastfeeding practices and improve nutrition, health and development outcomes.
Target audience	World Health Organization (WHO) member states and their partners including: • National and local policy makers • Implementers and managers of national and local nutrition programs • Administrative and health care workers involved in policy making, information sharing, education and training in hospitals, facilities providing maternity and newborn services • Health professionals of health programs and public health policy making in all settings • Health workers in facilities providing maternity and newborn services
Evidence used to develop the guideline	• 22 systematic reviews • All studies compared a group of participants who received advice on, or practiced, one of the Ten Steps to Successful Breastfeeding (1989) to a group that received a placebo or usual care, or did not practice the intervention
Search period	Inception to December 2015
Number of databases searched	Seven databases including the Campbell Collaboration, Cochrane Library, Embase, Epistemonikos, Health Systems Evidence, Medline and the WHO Global Index Medicus
Inclusion/exclusion criteria	Inclusion: • Interventions that protect, promote and support breastfeeding in facilities providing maternity and newborn services • Participants received advice on, or practiced one of the Ten Steps to Successful Breastfeeding (1989) • Co-interventions other than the practice of interest used for the control and experimental study arms
Details of Interventions Included in Guideline	
Description of relevant interventions	• Participants receiving advice on, or practicing, one of the Ten Steps to Successful Breastfeeding • Participants included preterm and full term infants
Intervention settings	Facilities providing maternity and newborn services
Outcomes	Effect of restricted or unrestricted pacifier use on breastfeeding duration among term infants
Results of the Guideline	
Relevant recommendations	**Step 9** "Counsel mothers on the use and risks of feeding bottles, teats and pacifiers." (p.21)

	Rationale
	"Proper guidance and counselling of mothers and other family members enables informed decision making on use or avoidance of pacifiers and/or feeding bottles and teats until successful establishment of breastfeeding.
	WHO Guidelines (WHO, 2017) does not call for absolute avoidance of feeding bottles, teats and pacifiers for term infants, there are a number of reasons for caution about their use including hygiene, oral formation and recognition of feeding cues."
	Reviewer comment
	WHO, 2017 is the guideline version open to stakeholder comments prior to finalizing the Implementation Guidance document (2018).
	Implementation
	"Pacifiers have long been used to soothe an upset infant. In some cases, they serve a therapeutic purpose, such as reducing pain during procedures when breastfeeding or skin-to-skin contact is not possible. However, if pacifiers replace suckling and reduce the number of times an infant stimulates the mother's breast physiologically, this can lead to a reduction of maternal milk production. The use of teats or pacifiers may interfere with the mother's ability to recognize feeding cues. If the use of a pacifier prevents the mother from observing the infant's smacking of the lips or rooting towards the breast, she may delay feeding until the infant is crying and agitated." (p.21)
Results informing recommendations	**Revision of the Ten Steps to Successful Breastfeeding**
	Step 9 on the use of feeding bottles, teats and pacifiers focuses on counselling mothers on their use, instead of completely prohibiting them. The evidence for complete prohibition of their use was found to be weak, since the systematic review conducted in the guideline development process found little or no difference in breastfeeding rates between healthy term infants who used feeding bottles, teats or pacifiers in the immediate postpartum period and those who did not (Jaafar, 2016 [cited in guideline]). (p.19)
	Details on systematic review by Jaafar, 2016
	• Examined participants who were in facilities providing maternity and newborn services.
	• Definitions for breastfeeding and partial breastfeeding:
	o Full or exclusive breastfeeding is defined as no food (solid or liquid including water) other than breast milk.
	o Almost exclusive breastfeeding allows infrequent supplemental liquids, other than milk formula.
	o Partial breastfeeding other milk supplements are regularly given along with breastfeeding (Labbok, 1990).
	• Included two randomized controlled trials (RCTs): Intervention arm participants received advice against pacifier use. Control arm participants had unrestricted pacifier use or were actively encouraged to use a pacifier in breastfed infants six months of age or younger. Control arm participants could offer pacifiers to the infant for many hours in between feeds and for no medical reason.
	• Mothers in the studies were motivated to breastfeed and were recruited immediately after birth or at two weeks of life, respectively. (p.2)
	• Studies were assessed using GRADE.
	• Outcome was analyzed on an intention-to-treat basis where possible to include all participants randomized to each group.
	• Both trials contributed to at last one of the primary outcomes (i.e. proportion of infants of infants partially or exclusively breastfed at three and four months of

age).
- Findings:
  - o Sample of three studies (Jenik, 2009; Kramer, 2001; Schubiger, 1997) included in the review involved 1,915 infants. Sample of two studies (Jenik, 2009; Kramer, 2001) included in the meta-analysis involved 1,302 healthy full term breastfeeding infants.
  - o Proportion of infants **exclusively** breastfed at **three** months (n=1,228), risk ratio (RR): 1.01, 95% confidence interval (CI): 0.96 to 1.07), two studies. (p.23) Study quality not reported.
  - o Proportion of infants **partially** breastfed at **three** months (n=1,228), RR: 1.00, 95% CI: 0.98 to 1.02, two studies. (p.23) Study quality not reported.
  - o Proportion of infants **exclusively** breastfed at **four** months (n=970), RR: 1.01, 95% CI: 0.94 to 1.09, one study, moderate-quality evidence. (p.23)
  - o Proportion of infants **partially** breastfed at **four** months (n=970), RR: 0.99, 95% CI: 0.97 to 1.02, one study. (p.23) Study quality not reported.
  - o Authors state that evidence is overall moderate-quality evidence (p.2, 15) and two included studies in the meta-analysis have a low risk of bias as per "implications to practice" section. (p.15)
- No adverse events reported by the RCTs on the provision or avoidance of pacifiers in term infants.
- None of the included studies reported data on the other primary outcomes (i.e. duration of partial or exclusive breastfeeding). (p.13)
- Unrestricted use of a pacifier did not affect the proportion of infants' exclusive or partial breastfeeding at three or four months. The studies were consistent (based on the CIs).

Details of included studies
- Jenik, 2009 (Argentina): multicenter trial evaluated pacifier use in breastfeeding infants once lactation was well-established to see whether it reduced the prevalence or duration of breastfeeding. Primary outcome was prevalence of exclusive breastfeeding at three months. Main secondary outcomes were the prevalence of exclusive and any breastfeeding and duration of any breastfeeding. (p.18) Total of 1,021 mothers highly motivated to breastfeed were recruited and randomly assigned to whether a pacifier was offered (n=528) or not offered (n=493). Only mothers who were already successfully breastfeeding at two weeks and indicated their intention to continue to do so for at least three months participated. Primary analysis was by intention-to-treat. Mothers were interviewed at one, two, three, four, fix, six, eight, 10 and 12 months after birth or until breastfeeding ended. Interviews were assessed exclusive or breastfeeding prevalence, duration of breastfeeding and whether the baby used a pacifier. Comparison between the two groups did not show any difference in baseline characteristics (i.e. infant birth weight, mode of delivery, maternal age and education, and onset of breastfeeding). (p.10) Study had low risk of bias. (p.18)
- Kramer, 2001 (Montreal, Canada): double-blind RCT. Primary outcome of interest was rate of early weaning at three months. (p.18) "Total of 281 healthy breastfeeding women intending to breastfeed their infant longer and their healthy term singleton infants were recruited in the immediate postnatal period prior to discharge from hospital… Mothers were randomized to one of two counselling interventions by a trained research nurse. Experimental group mothers (n=140) were asked to avoid pacifier use when the infant cried or fussed and to first offer the breast and if that did not work, to try carrying or

| | rocking the infant. In the control group (n=141) all options were discussed for calming the infant (e.g. breastfeeding, carrying, rocking and pacifier use)." (p.10) Mothers were asked to complete a validated behavior diary over three days while the infant was four, six and nine weeks of age. Mothers were also interviewed. Total of 258 (91.8%) of mother-infant pairs completed three months follow-up. (p.10) Study had low risk of bias. (p.18)

Overall completeness and applicability of evidence
- Findings of this review "may not apply to mothers who are less motivated or who have no desire to breastfeed their infants longer." (p.14)
- Review "provides evidence on which to base recommendations for women who are motivated to breastfeed. The WHO Ten Steps To Successful Breastfeeding of necessity needs to make recommendations taking into account all levels of motivation of women using a birthing facility." (p.14) |
|---|---|
| Comments and limitations | Guideline comments
- Observational studies suggesting an association between pacifier use and breastfeeding are not able to demonstrate a causal relationship because of "confounding, reverse causality or self-selection." (WHO, 2017 [version where external stakeholders provided comments])

Notes from Jaafar (2016) systematic review
- Mothers should decide about pacifier use based on their personal preference.
- One of the studies included in the review has contributions from an individual that may have a conflict of interest with the pacifier industry. |

Systematic Review #1: Buccini GdS, Perez-Escamilla R, Munari Palino L, Lopes Araujo C, Venancio S. (2016). Pacifier use and interruption of exclusive breastfeeding: Systematic review and meta-analysis.

General Information and Quality Rating	
Country	Brazil
Quality Rating using Health Evidence Tool	8/10 (strong quality) by two reviewers EW and AN in 2018 using the Health Evidence Tool
Details of Review	
Objective	To investigate the association between pacifier use and exclusive breastfeeding interruption in infants within six months of life
Number of primary studies included	46 studies included and 40 studies included in the meta-analysis
Types of studies included	RCTs, and case-control, cross-sectional, and cohort
Search period	Database inception to December 2014
Number of databases searched	Five databases including CINAHL, SCOPUS, Web of Science, LILACS and MEDLINE
Inclusion/exclusion criteria	Inclusion: • Studies published in English and Portuguese • Observational and experimental studies Exclusion: • Non-quantitative studies including reviews • Letters to the editor • Premature babies or newborns with congenital anomalies • Combining pacifiers and bottle nipples in the same category • No reporting on the size of association between pacifier use and exclusive breastfeeding interruption using statistics • Studies with limited data to estimate the effect size of association
Details of Interventions Included in Review	
Description of relevant interventions	Pacifier and non-pacifier use in infants less than six months of age
Terminology used	Pacifier use as an exposure defined as use versus non-use in infants less than six months of age. Exclusive breastfeeding defined as the "infant receiving only breast milk (including expressed breast milk or breast milk from a wet nurse) allowing the infant to receive oral rehydration solutions, drops, syrups (vitamins, minerals, medicines), but nothing else." (WHO, 2008)
Outcomes	Interruption of exclusive breastfeeding in the first six months of life. "Interruption" was not defined.
Results of the Review	
Main findings	• Most studies were conducted in Brazil, followed by Italy and New Zealand. • Bias risk was assessed using a modified version of the Effective Public Health Practice Project Quality Assessment Tool. • Of the 46 included studies, 12 were strong, 14 were moderate and 20 were weak in quality. "The quality items [examined] that had the more weaknesses were study design, adjusting for confounding factors, and data collection methods." (p.4) • "Studies were included regardless of methodological quality." (p.16) • Odds ratio (OR) of the pooled random effects of pacifier use and exclusive breastfeeding interruption in the first six months of life: 2.48 (95% CI: 2.16 to 2.85) and heterogeneity was high. • Random effects of meta-analysis conducted by study design type.

- "Interruption" not defined in the systematic review. Authors have used the term "interruption" to describe all study outcomes in evidence tables even if original studies did not report "exclusive breastfeeding interruption as an outcome" (e.g. Jenik, 2009; Kramer, 2001).
- Pacifier use was most commonly dichotomous (i.e. use versus non-use). Other definitions were based on frequency of pacifier use (i.e. occasional, frequent, daily, intense, and partial).
- Due to high heterogeneity, a meta-regression was conducted to determine whether study characteristics were responsible for the variability between studies. Meta-regressions showed that the study design contributed to 40.2% of the global heterogeneity. Other study characteristics such as the age of assessment of pacifier use, age of assessment of exclusive breastfeeding interruption, study quality score and setting contributed to 31.7%, 8.4%, 5.3% and 2.8% of the global heterogeneity, respectively. Findings varied across study designs.
- Regarding association between pacifier use and **duration of exclusive breastfeeding in the first three months of life**:
  - Two RCTs (captured by Jaafar, 2016) found no relationship. These studies included women "highly motivated to breastfeed" (as defined by Jaafar, 2016) (p.13)
  - "… the intervention by Kramer, 2001 (in Jaafar, 2016) led to a reduction in pacifier use or prevented the early introduction of it, but the intervention was not associated with exclusive breastfeeding duration." (p.13)
- Regarding association between pacifier use and **exclusive breastfeeding interruption** when stratifying by study design:
  - RCTs: OR: 1.06 (95% CI: 0.82 to 1.37). Heterogeneity was low, included two strong quality studies, highly limiting external validity. Overlap with Jaafar, 2016.
    - Reviewer comment: Jaafar, 2016 states the results of RCTs are the "proportion of infant being fully or partially breastfed…" and not "exclusive breastfeeding interruption."
  - Longitudinal studies: OR: 2.28 (95% CI: 1.78 to 2.93). Heterogeneity was high; included 14 studies (three strong, 10 moderate, and one weak quality). No overlap with Jaafar, 2016.
  - Cross-sectional studies: OR: 2.78 (95% CI: 2.44 to 3.15). Heterogeneity was high; included 24 studies (two strong, three moderate and 19 weak quality). No overlap with Jaafar, 2016.
- Of the 46 included studies, six longitudinal were not included in meta-analysis.
- Authors conclude that "despite the lack of an association found in the RCTs findings, observational studies strongly suggest that pacifier use may be a risk factor for the premature early discontinuation of exclusive breastfeeding." (p.16)

Discussion
- Funnel plot with pseudo 95% CI provided. "… [the] impact on exclusive breastfeeding may vary accordingly to the effectiveness of implementation of the pacifier use intervention. Both RCTs found that compliance with the pacifier use or avoidance intervention was low, so the impact of the intervention on exclusive breastfeeding might have been strongly diluted especially when using intent-to-treat analysis. To address this issue, observational analyses of RCTs have been recommended. RCTs included women highly motivated to breastfeed and one study (Jenik, 2009) had inclusion criteria for breastfeeding to be established and for the infant to be gaining weight at 15 days of life before recommending the introduction of the pacifier. This may explain in our meta-

	analysis, the RCTs provided an indication of minimal effect, or no effect, while observational studies provided an estimate of the maximal effect." (p.14) • "Despite their relatively strong internal validity, RCTs can have major external validity limitations, preventing the extrapolation of findings from RCTs to the general population that is women who are less motivated to breastfeed or to the context when the pacifier is introduced before breastfeeding is established as mentioned by Jenik (2009)." (p.14)

Comments and limitations reported	Author comments
	• One RCT (Jenik, 2009) included in Jaafar, 2016 may have a conflict of interest due to the funding source.
	• Causal pathway between pacifier use and premature interruption of exclusive breastfeeding can happen through three ways:
	    ○ Pacifier introduction leading to exclusive breastfeeding interruption where the effect of pacifier use and the pattern of use (frequency and intensity) can lead to "nipple confusion."
	    ○ Exclusive breastfeeding interruption or breastfeeding problems lead to introduction of a pacifier (i.e. reverse causality) where pacifies use could be a marker of breastfeeding difficulties reduced motivation to breastfeed (i.e. pacifier introduction and interruption of exclusive breastfeeding are based on mother's preference).
	    ○ Mothers or families that follow the recommendation to avoid pacifier use may also follow other recommendations that suggest exclusively breastfeeding for longer such as breastfeeding on demand.
	
	Reviewer comment
	Age of infants not reported in results. Systematic review participants were infants less than six months of age.

Systematic Review #2: Callaghan A, Kendall G, Lock C, Mahony A, Payne J, Verrier L. (2005). Association between pacifier use and breast-feeding, sudden infant death syndrome, infection and dental malocclusion.

General Information and Quality Rating	
Country	Australia
Quality Rating	Moderate (6/10) by two reviewers EW and AN in 2018 using the Health Evidence Tool
Details of Review	
Objective	To critically review all literature related to pacifier use for full term health infants and young children.
Number of primary studies included	A total of 20 studies included on the topics of breastfeeding (10 studies published 1995-2003); sudden infant death syndrome (SIDS) (six studies published 1993-2003); infection (four studies); and dental (zero studies)
Types of studies included	RCTs, prospective cohort and case-control
Search period	1960 to 2003
Number of databases searched	15 databases searched including Medline, Embase, PubMed, CINAHL, PsycINFO, Cochrane Library, DARE, ERIC, TRIP, Best Evidence, CenterWatch, Expanded Academic Index, Australian Medical Index, Austrom., Current Contents.
Inclusion/exclusion criteria	Included criteria: • Healthy term infants and children up to age 16 years • RCTs, prospective cohort and case-control • Breastfeeding, infection and dental malocclusion outcomes Exclusion criteria: • Focus on preterm infants, those with serious illness or congenital malformations; however, some total population studies included these children • Cross-sectional and qualitative studies • Pacifier use for procedural pain and gastro-oesophageal reflux
Details of Interventions Included in Review	
Description of relevant interventions	Pacifier use defined differently by various authors including no use, less than daily, daily, occasional, part-time, often, frequent, full-time and the age at pacifier use, before five days, before two weeks, at one month, before six weeks.
Terminology used	SIDS: "the sudden death of an infant or young child which is unexpected by history, and in which a full post-mortem examination fails to demonstrate an adequate cause of death"
Outcomes	• Breastfeeding duration and exclusivity reported as RR, hazard ratio (HR), or • Death from SIDS
Results of the Review	
Main results	**Overall quality** • Methodological quality of included articles was assessed independently by groups of three or more principal investigators and clinicians using a checklist (provided in Appendix I of systematic review). • All 20 studies that were accepted met minimum set criteria, but few passed without some methodological concern. • Results of the quality assessment are not provided in the systematic review. **Breastfeeding:** (10 studies, unknown quality) • Review focuses on the evidence for a causal relationship between pacifier use and disrupted breastfeeding behaviour. "…[It] is extremely important to identify factors that disrupt breastfeeding, leading to partial rather than exclusive feeding and/or a shorter duration." (p.154) • Breastfeeding duration findings included two RCTs and eight cohort studies. • Research conducted between 1995 and 2003 from Australia, Brazil, Canada,

Italy, New Zealand, Sweden, and United States of America. Participants were from diverse cultural backgrounds and socioeconomic status.
- Pacifier use defined and measured inconsistently across studies for breastfeeding outcome.
  - Most comprehensive measure: number of times pacifier used per day, length of time for each use, and time of day pacifier was used.
  - Least comprehensive measure: question posed if pacifier used frequently or occasionally.
- Breastfeeding exclusivity and duration defined differently across studies. The difference between exclusive breastfeeding (breast milk only source of milk and infrequent supplements of water, juice or other fluids) and partial breastfeeding (a combination of breast milk and other infant or milk formulas with the addition of other supplements of water, juice, etc.) was not uniformly established.
- Completeness of follow-up was addressed by missing data not uniformly identified and explained. When comparisons were made between participants and non-participants, there was some evidence of differential loss and bias towards families in higher socioeconomic groups.
- Follow-up ranged from four weeks to breastfeeding cessation.
- Meta-analysis was not appropriate due to inconsistent definitions and measures, and relationship between pacifier use and breastfeeding was presented in different ways.
- 10 studies assessed the effects of pacifier use on breastfeeding:
  - Two studies (Kramer, 2001; Howard, 2003) were RCTs.
  - Eight studies were observational studies (Barros, 1995, Victoria, 1997; Aarts, 1999; Howard, 1999; Riva, 1999; Vogel, 2001; Binns and Scott, 2001; Levy, 20002).
  - Kramer, 2001 overlaps with Jaafar, 2016 captured in WHO, 2018.
  - Barros, 1995 and Aarts, 1999 overlap with Buccini, 2016.
- Median number of mother-infant pairs: 607 (range from 265-1,601).
- Quality of studies not reported.
- Seven of 10 studies (one RCT) and six observational studies) suggest that regardless of how pacifier use was defined, it is negatively associated with duration of breastfeeding.
- Increased risk for a **reduced "overall" duration in breastfeeding:** seven studies found a statistically significant RR, HR, and OR ranging from 1.22 (95% CI: 1.03 to 1.44) to 2.87 (95% CI: 1.97 to 4.19).
  - "Overall" was defined in any of the following ways: pacifier use at one month, part-time use at one month, full-time use at one month, often, frequent, daily use up to six weeks, daily use, before two weeks, before six weeks, before five days versus after four weeks.
- **Pacifier use (however defined) is associated with a shorter duration of exclusive breastfeeding**: range of OR from 1.35 (95% CI: 1.05 to 1.74) to 1.53 (95% CI: 1.15 to 2.05) (three cohort studies, unknown sample size, unknown quality).
- **Pacifier use (however defined) is associated with a shorter duration of partial breastfeeding**: OR: 1.18 (95% CI: 1.04 to 1.34) (one cohort study, unknown sample size, unknown quality).
- **Odds of not exclusively breastfeeding significantly increased when a pacifier was used**: OR: 1.53 (95% CI: 1.15 to 2.05) (one cohort study, unknown sample size, unknown quality).
- Data suggests that a pacifier not frequently used may not have an overall negative effect on breastfeeding.
- Two possible explanations for results:
  - Entirely plausible that pacifier use causes babies to breastfeed less.

            Innate sucking reflex of the infant is satisfied by the pacifier, decreasing or eliminating the desire for contact with the nipple and breast.
-   o Pacifier use does not cause a reduction in breastfeeding; it is simply a marker for socioeconomic, demographic, psychosocial and cultural factors that determine both pacifier use and breastfeeding.
- Quality not reported, however the following information is provided:
  - o Information on exposure and outcome, and potential confounding factors were obtained from records, interviews and surveys. The "level of contact and the frequency with the child's mother differed widely." (p.154)
  - o Multivariate analysis conducted for majority of studies, including sociodemographic, obstetric and infant covariates, as well as maternal age and education.

SIDS: (six studies, unknown quality)
- Research conducted using information from 1984 to 1999 from Norway, United Kingdom, New Zealand, Netherlands and United States of America.
- Six case-control studies included.
- Cases were infants who died of SIDS between first week and first year of life in all but one study, which included cases up to two years of age.
- Pacifier use defined and measured inconsistently. Five studies referred to pacifier use in the 'last' sleep for SIDS cases and an assigned 'reference' sleep for the control, matched to time of case's death. One study recorded usual use during day/night as 'sometimes', 'often', or 'always'.
- All studies controlled for confounding factors by matching and/or using multivariate analysis. Generally prenatal and postnatal factors, infant care practices and maternal, family and socioeconomic issues were considered.
  - o Mitchell, 1993: controlled for infant age, sex, birth weight, gestational age, maternal obstetric history, smoking, season, time of death, sociodemographic, and other SIDS risk factors
  - o Fleming, 1999: controlled for infant gestational age, birth weight, breastfeeding; maternal sociodemographic age, parity, smoking, and SIDS risk factors.
  - o Arnestad, 1997: had high recall bias because data collection occurred three to 11 years after the last/reference sleep. Does not report that confounders were controlled.
  - o L'Hoir, 1999: infant age, sex, birth weight; maternal age, parity, smoking in pregnancy, and socioeconomic status.
  - o Brook, 2000: controlled for infant, birth weight, breastfeeding, age; maternal parity, age, employment, marital status, education, cigarette smoking.
  - o Hauck, 2003: controlled for maternal education, prenatal care, marital status, age; SIDS risk factors.
- Median number of SIDS cases: 214 (range from 146-1,800).
- Five studies found **pacifier use for the last or reference sleep** was associated with reduced odds of SIDS. Range of OR effect sizes using multivariate analysis from 0.43 (95% CI: 0.24 to 0.78) to 0.19 (95% CI: 0.08 to 0.46).
  - o The five studies found significantly fewer SIDS cases used a pacifier compared with controls. Pacifier use was associated with reduced odds of SIDS (sample size not reported).
- Two studies found significant reductions in SIDS for **'usual' use of pacifiers**. However, two studies found no significant difference for usual use of pacifiers and the risk of SIDS between cases and controls.

	- Association of SIDS for infants not using a pacifier in the last or reference sleep was greater than infants who did use a pacifier.
	- Study reports that "most clinicians… are reluctant to actively promote the use of pacifiers in the absence of adequate knowledge regarding actual mechanisms related to pacifier use and SIDS." (p.157)
	- Quality not reported, however the following information is provided:
	    ○ Exposure information obtained from records, investigation, interviews and questionnaires. Information for cases and controls were collected differently across studies. Cases dates include two days after death, two to four weeks after death, and three to 11 years after death. Controls include four days of a nominated case, one to seven weeks from the case date, and three to 11 years after the case date. The study collecting data three to 11 years after infant death [leaves it open] to claims of substantial recall bias." (p.156)
	
	Infection: (three studies, unknown quality)
	- Acute otitis media: (one cohort study, unknown quality)
	    ○ Population included 845 children attending 20 day care centres full time. "Complete follow-up" and multivariate analysis performed. (Niemela, 1995)
	    ○ The use of a pacifier increased the annual incidence of AOM from 3.6 (95% CI, 2.5, 4.9) to 5.4 episodes (4.4, 6.6) in children younger than 2 years and from 1.9 (1.4, 2.5) to 2.7 (2.2, 3.3) in children 2 to 3 years of age. (Niemela, 1995)
	    ○ It can be calculated that the use of a pacifier was responsible for 25% of the attacks in children younger than 3 years. (Niemela, 1995)
	- Respiratory symptoms, ear problems, gastrointestinal and other symptoms were examined (two cohort studies, unknown quality, unknown sample). "Ear problems" did not include acute otitis media as an outcome.
	- Authors concluded that "given the limited number of studies available and the variability of results, no meaningful conclusions could be drawn." (p.157)
	
	Oral health and development: (zero studies)
	- Dental malocclusion: None of the six studies (five cohort, one case-control study, unknown quality, unknown sample) reported a measure of association (e.g. RR) and were excluded from review.
	- Dental infection leading to dental caries: (one cohort study, unknown quality) (Ollila, 1998) included 183 children attending day care centres aged one to four years. Study had 83% follow-up (n=166) two years later and conducted multi-variate analysis.
	    ○ RR for a child (age not specified) to have caries at follow-up was more than two times greater: 2.5 (95% CI: 1.4 to 4.4, p=0.001) if the child sucked a pacifier for more than two years, compared to children who did not use a pacifier.
	    ○ Mean age of children at follow up was 4.7 years. Pacifier use for 24 months or more is associated with caries: RR: 3.5 (95% CI: 1.5 to 8.2, p=0.003).

Comments and limitations	Reviewer comments - Authors do not consistently report whether results are RR, HR, and OR for the breastfeeding outcome. - Sample of included studies are not reported. - Authors did not state participant ages when reporting results. - Quality not reported in included studies.

Systematic Review #3: Uhari M, Mantysaari K, Niemela M. (1996). A meta-analytic review of the risk factors for otitis media.

General Information and Quality Rating	
Country	Finland
Quality Rating using Health Evidence Tool	6/10 (moderate quality) by two reviewers EW and DMP using the Health Evidence Tool
Details of Review	
Objective	To conduct a meta-analysis of studies on risk factors for acute otitis media to clarify ways to prevent acute otitis media in children.
Number of primary studies included	22 studies
Types of studies included	Observational studies
Search period	1966 to 1994
Number of databases searched	One including Medline
Inclusion/exclusion criteria	Inclusion: • Original studies reporting on risk factors that had adequate control groups and reported the number of participants. • No restriction on inclusion based on diagnostic criteria. • Reporting of the instance and recurrent acute otitis media
Details of Interventions Included in Review	
Description of relevant interventions	• Population reported in the systematic review includes "children" and their ages are not reported. • Two included "follow-up" (i.e. cohort) studies reporting on pacifier use and acute otitis media include four (Larrson, 1975) and five year olds (Niemela, 1994) in their population.
Terminology used	Diagnosis varied; pneumatic otoscopy was used for diagnosis
Outcomes	Acute otitis media risk factors including positive family history, day care outside home, parental smoking, family day care versus home day care, more than one sibling, day care centre versus family care, whether the child attends day care, use of a pacifier, and whether the infant is breastfed at all, for three months or six months.
Results of the Review	

Main results	• Studies were evaluated based on study design and presentation and analysis of data. Quality of included studies was not reported in the systematic review.
	• Risk factor of acute otitis media associated with pacifier use was reported in two "follow up" studies and the pooled estimate of the RR was 1.24 (95% CI: 1.06 to 1.46, p=0.008, two "follow-up" studies, n=4,110 subjects, unknown quality).
	• Authors report that all risk factors identified in the study are considered important given that acute otitis media is common.
	   ○ Risk factors for acute otitis media are highly related to one another and the pooled estimate of the RR of an individual risk factor should be interpreted with caution because there is a synergistic effect when more than one risk factor is present.
	   ○ A small increment in the RR of the disease increases the occurrence of acute otitis media.
	• Other risk factors have a greater risk of acute otitis media compared to pacifier use. Pooled estimates of RR of acute otitis media risk factors include:
	   ○ Positive family history: RR: ~2.6 (95% CI: approximately 1.8 to 3.7, three studies, n=1,240 subjects, unknown quality)
	   ○ Day care outside the home: RR: ~2.5 (95% CI: approximately 1.4 to 4.0, six studies, n=1,972, unknown quality,)
	   ○ At least one sibling: RR: 1.92 (95% CI: 1.29 to 2.85, p=0.001, two

	studies, n=1,344, unknown quality,) o Parental smoking: RR: ~1.8 (95% CI: approximately 1.3 to 2.1, three studies, n=1,784 subjects, unknown quality)
Comments and limitations	Reviewer comment • Study was included as Callaghan, 2005 did not report conclusive findings on the association between pacifier use and otitis media. • No overlap in included studies between Callaghan, 2005 and Uhari, 1996.

Grey literature on pacifier use from organizations not critically appraised

Organization	Details
National Institute for Clinical Care and Excellence (NICE)	- Postnatal care up to eight weeks after birth guideline (2006) discussed the association between pacifier use and SIDS. - The guideline is currently being updated and is expected to be published January 2020.
Health Canada	**Pacifier safety** - Government website has a section on pacifier safety. Last updated May 2016. - Notes that there are many ways to soothe a baby other than using a pacifier. If one chooses to use a pacifier, they should follow these safety tips: - Never tie or hang a pacifier around a baby's neck to avoid strangulation - Replace a child's pacifier every two months before it begins to wear out - Check child's pacifier every day: - For changes in texture, holes, or tears that can be caused by age, heat, sunlight, or certain foods - To ensure that the nipple and the ring or handle is firmly attached - Dispose of pacifiers showing signs of wear and tear since broken or loose pieces can cause a baby to choke - Replace pacifiers with a teething ring if the baby begins to chew on the pacifier Health Canada was contacted to enquire whether references could be provided on the above safety tips. *Development process* Health Canada stated that the pacifier safety tips were developed based on incidents the Consumer Product Safety Program was made aware of over a number of years. The safety tips also correspond to hazards described in the *Pacifiers Regulations*, which were first adopted in 1974 (e-mail communication with Health Canada on August 28, 2018). **Food safety for vulnerable populations** - Infant botulism is a rare but serious form of food poisoning that can affect babies up to a year old. - In Canada, honey is the only food that has been linked to infant botulism. - You can help reduce the risk of this disease by only feeding honey to healthy children over one year of age. - Infant botulism is caused by *Clostridium botulinum* spores, which are sometimes found in both pasteurized and unpasteurized honey. When an infant ingests honey, bacteria from these spores can grow and produce toxins that could lead to paralysis. - To reduce your risk: - Do not give any type of honey to infants (babies who are less than one year old). - Never add honey to an infant's food, water, formula, or soother. **Oral Health for children** How to clean your baby's mouth up to six months of age - Use these tips when cleaning your baby's mouth… - If you think of using pacifiers or soothers, they should **never** be dipped in honey or other sweeteners, as this increases the risk of tooth decay
Breastfeeding Committee for Canada (BCC)	- Currently Step 9 states "Support mothers to feed and care for their babies being breastfed without the use of pacifiers." (2012) - BCC may update their recommendations based on WHO update (2018).

Appendix D: Applicability and Transferability Worksheet

Questions	Notes
In your experience, how are parents using pacifiers when caring for infants and young children?	
How are we currently discussing pacifier use with clients?	
How do we reach parents with messaging? How big is our reach?	
Will parents find the new/revised messages acceptable?	
Will public health staff find the new/revised messaging acceptable?	
What are the resource implications of modifying our messaging?	
Can the messages be sequenced by staff in order of importance/ priority?	
Will the proposed messages be support in the current political climate?	
Will the proposed messages enhance the stature of Peel Public Health?	
Do the messages overlap with existing programs (internally, externally?)	
Can you suggest internal and external partners with whom we should seek to collaborate?	