CADTH

CADTH RAPID RESPONSE REPORT:
SUMMARY WITH CRITICAL APPRAISAL

Interventions for the Prevention of Sudden Infant Death Syndrome and Sudden Unexplained Death in Infancy: A Review of Guidelines

Service Line:	Rapid Response Service
Version:	1.0
Publication Date:	September 14, 2020
Report Length:	24 Pages

CADTH

Authors: Anusree Subramonian, Robin Featherstone

Cite As: Interventions for the Prevention of Sudden Infant Death Syndrome and Sudden Unexplained Death in Infancy: A Review of Guidelines .Ottawa: CADTH; 2020 September. (CADTH rapid response report: summary with critical appraisal).

ISSN: 1922-8147 (online)

About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

Questions or requests for information about this report can be directed to **Requests@CADTH.ca**

Abbreviations

AAP	American Academy of Pediatrics
NICE	National Institute for Health and Care Excellence
SIDS	Sudden Infant Death Syndrome
SUDI	Sudden Unexplained Death in Infancy

Context and Policy Issues

Sudden Infant Death Syndrome (SIDS) is defined as the sudden and unexplained death of an infant under the age of one (i.e., death for which a cause is not found even after a thorough investigation including review of clinical history, examination of death scene and a complete autopsy).[1] Sudden unexplained death in infancy (SUDI) also known as Sudden unexplained infant death is a term used to describe sudden, unexpected and unexplained death of an infant for which external risk factors may be present.[2] SUDI is a blanket term that encompasses SIDS, other unexplained infant deaths, and explained infant suffocations.[2] SIDS and SUDI are not diagnoses. Risk factors for SIDS fall under three groups: intrinsic risk factors (e.g., male sex, prematurity, exposure to cigarette smoke), extrinsic risk factors (e.g., prone or side sleep position, bed sharing, overheating) and exogenous factors (e.g., ethnicity, climate, geographical location).[3] It has been shown that racial and ethnic disparities (such as Indigenous peoples and other racial minorities) and vulnerabilities (such as low socioeconomic status, fewer social supports, those experiencing problems with housing, violence or mental illness) may contribute to increased risk of SIDS.[4,5]

In Canada, the incidence of SUDI was the highest in 1980 with a rate of 2.07 SUDI per 1,000 live births.[6] The rates of SUDI and SIDS have since decreased, especially since the 1990s. In 2018, there were ten deaths classified as SIDS in Canada.[7] A global decrease in the incidence of SIDS can be attributed to widespread “Back-to-Sleep” campaigns, which were aimed to promote placing babies in a supine position for sleeping.[8,9] Several similar risk reduction strategies, primarily focused on sleep position, have been implemented globally with the aim of reducing the incidence of SIDS and SUDI.[5,10] The “Back- to- sleep” campaign was later expanded to the “Safe -to-sleep” campaign in 2012 to involve new and evolved evidence for preventing SIDS.[11] As a result of continued research, guidelines regarding the prevention of SIDS and SUDI have been developed and updated throughout the last three decades.

A previous CADTH Summary of Abstracts report, published in 2016, briefly summarized evidence-based guidelines for the prevention of SIDS.[12] The purpose of this report is to summarize and critically appraise evidence-based guidelines that were published within the last five years regarding interventions for the prevention of SIDS or SUDI.

Research Question

What are the evidence-based guidelines regarding interventions for the prevention of Sudden Infant Death Syndrome or Sudden Unexplained Death in Infancy in the community?

Key Findings

Two evidence-based guidelines were identified regarding interventions for the prevention of Sudden Infant Death Syndrome (SIDS) and Sudden Unexplained Death in Infancy.

The American Academy of Pediatrics (AAP) guideline recommends always placing infants in the supine position (on the back) to sleep, on a firm and separate surface without any soft or loose objects in the parental room (room sharing) for the first year of life. The AAP further recommend: breastfeeding, infant immunization in accordance with existing guidelines, avoidance of prenatal and post-natal exposure to smoke, supervised and awake tummy time, and that care be taken to avoid overheating. The AAP suggests that pacifiers can be used. Home cardiorespiratory monitoring devices are not recommended to reduce the risk of SIDS, and there was no evidence to recommend swaddling as a risk reduction strategy for SIDS. The AAP guideline also recommends continuing safe sleeping campaigns, continued research and accurate media messaging.

The second guideline, developed by the National Institute for Health and Care Excellence (NICE), focused mainly on post-natal care of women and babies, and advises healthcare providers to discuss the association between co-sleeping or bedsharing and risk of SIDS with parents.

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were Sudden Infant Death Syndrome (SIDS) and infant sleep safety. Search filters were applied to limit retrieval to guidelines. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2015 and August 12, 2020.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	All infants (ages 0 to 1) in the community
Intervention	Interventions for Sudden Infant Death Syndrome and Sudden Unexplained Death in Infancy prevention (e.g., safe sleep/sleeping safely interventions, harm reduction strategies for Sudden Infant Death Syndrome and Sudden Unexplained Death in Infancy, sleep environment modifications or requirements)
Comparator	Not applicable

Outcomes	Guidelines and recommendations regarding interventions for the prevention of Sudden Infant Death Syndrome and Sudden Unexplained Death in Infancy in the community
Study Designs	Evidence-based guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2015. Guidelines with unclear methodology were excluded.

Critical Appraisal of Individual Studies

The included publications were critically appraised by one reviewer using the Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument[13] for guidelines. Summary scores were not calculated for the included guidelines; rather, the strengths and limitations of each included guideline were described narratively.

Quantity of Research Available

A total of 61 citations were identified in the literature search. Following screening of titles and abstracts, 48 citations were excluded and 13 potentially relevant reports from the electronic search were retrieved for full-text review. Four potentially relevant publications were retrieved from the grey literature search for full-text review. Of these potentially relevant articles, 15 publications were excluded for various reasons. Two evidence-based met the inclusion criteria and were included in this report.[14,15] Appendix 1 presents the PRISMA[16] flowchart of the study selection. Additional references of potential interest are provided in Appendix 5.

Summary of Study Characteristics

Two evidence-based guidelines[14,15] were included in this report. One guideline[15] provided broad recommendations for post-natal care of women and babies up to eight weeks after delivery and infant sleeping guidelines for children up to one year after birth. Recognizing that not all infant caregivers are “parents”, when the term “parent” was used in the included guidelines we retained this term in our reporting. The characteristics and recommendations relevant to the current report are summarized below. Additional details regarding the characteristics of the included guidelines are provided in Appendix 2.

Study Design

Two evidence-based guidelines for the prevention of SIDS and SUDI were identified.[14,15] One guideline was developed by the American Academy of Pediatrics (AAP).[14] The guideline was published in 2016 as an update of its previous version which was published in 2011.[17] The second guideline was developed by the National Institute of Health and Care Excellence (NICE).[15] The NICE guideline was developed in 2006, updated in 2014, and amended in 2015 to include a post-publication change.

The AAP guideline[14] was developed by a task force, who conducted a systematic literature search focusing on articles published since 2011 (since the previous update).[4] The team also consulted a statistician. The draft version of the guideline was submitted to the relevant committees and the final draft was approved by the AAP executive committee. The

guideline developers used the Strength of Recommendation Taxonomy (SORT) tool to determine the strength of recommendations. There were three levels of recommendation based on the availability and quality of evidence, as follows. Level A recommendations were based on good-quality patient-oriented evidence; Level B recommendations were based on inconsistent or limited-quality patient-oriented evidence; and Level C recommendations were based on evidence from consensus, disease-oriented evidence, usual practice, expert opinion, or case series.[14] The quantity and quality of evidence were not reported.

The NICE guideline[15] was developed by a multidisciplinary team who conducted systematic literature searches of multiple databases in 2014 (date limits for the searches were not specified). The development team identified 13 relevant studies through the searches, and an additional study was identified by the topic-specific committee members. The authors used a modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach for rating the quality of evidence. The method for assigning the strength of recommendations was not explicitly reported, however the strength of recommendation was indicated in the wording of each individual recommendation. For the recommendations relevant to the current report, the term "association" was used based on the nature of evidence found. A cause effect relationship between co-sleeping and SIDS was not identified; for this reason, the guideline developers refrained from using the term "risk" while making recommendations.[18] The guideline was finalized after public consultation.

Country of Origin

The AAP guideline[14] was developed in the USA and the NICE guideline[15] was developed in the UK. Both guidelines provided recommendations that could be applied globally.

Patient Population

The patient population of the guidelines[14,15] was infants under the age of one year. The intended users of the AAP guidelines[14] are anyone who is taking care of infants. Some recommendations are specifically aimed at health policy makers, researchers, and professionals who care for infants. Although the intended users of the NICE guidelines[15] are not clearly defined, the recommendations are for health care professionals caring for infants.

Interventions and Comparators

The AAP guideline[14] considered several interventions for the preventions of SIDS and SUDI. They included: sleep position, sleep surface, breastfeeding, infant sleep location, bedding, prenatal and post-natal exposures, overheating, immunization, pacifier use, home monitor use, tummy time, swaddling, potential toxicants, hearing screens along with educational interventions, media messages, and research.

The NICE guideline[15] provided recommendations regarding co-sleeping.

Outcomes

The outcome considered in the AAP guideline[14] was the incidence of SIDS and SUDI. The relevant outcome considered in the NICE guideline was the incidence of SIDS.[15]

Summary of Critical Appraisal

The evidence-based guidelines[14,15] were critically appraised using AGREE II checklist.[13] A summary of the critical appraisal is described below, and additional details regarding the AGREE II evaluation of the included guidelines are provided in Appendix 3.

The two included guidelines[14,15] described their objectives and the health questions covered clearly. The population of interest and the target users of the guideline were also reported (or implied) by both guidelines. The AAP guidelines were developed by task force of clinical experts.[14] The NICE guidelines were developed by a multidisciplinary team including clinical experts of various specialties and lay members.[15] The developers of the NICE guideline[15] finalized the recommendations after consulting with the public whereas the AAP guideline[14] did not seek the views and preferences of the indented users of the guideline from the community (caregivers of infants). regarding the developed recommendations. There were no conflicts of interest for the development teams, and the funding sources did not appear to have influenced the development and reporting of the recommendations.[14,15]

As for the rigor of development, both guidelines[14,15] employed a systematic search for evidence which was reported in evidence documents that accompanied the guidelines.[4,18] The methods for formulating the recommendations, and the clinical evidence supporting each recommendation, were described. The guidelines were planned to be updated regularly (every five years for the AAP guideline and three years for the NICE guideline, or as needed) The evidence identified, quality of evidence, and summary of evidence were described in detail in the evidence document of the NICE guideline.[18] The quantity of evidence identified, criteria for selecting the evidence, and quality assessment of the evidence were not reported for the AAP guideline.[14]

Recommendations from both guidelines were reported with clarity.[14,15] The specific recommendations were unambiguous and easily identifiable. Recommendations regarding co-sleeping were provided in a subsection in the NICE guideline.[15] While several risk factors of SIDS, such as sleep position, sleep surface, breastfeeding, or overheating, were not addressed, it should be noted they were not considered within scope for the guideline update. The recommendations from AAP guideline[14] had greater applicability to the current report as the guideline described potential barriers and facilitators to following the recommendations and offered clear advice on use of tools to aid in implementing the recommendations. However, neither of the guidelines considered cultural values or exogenous risk factors associated with vulnerable populations, in development of the recommendations. As Indigenous communities, other ethnic and racial minorities, and vulnerable families may be at increased risk of SIDS,[5,17] recommendations that consider cultural values and practices could be beneficial. Lastly, although the included guidelines were developed in UK and the US, the recommendations could be applicable to Canadian settings, given the nature of recommendations.

Summary of Findings

The recommendations from the included guidelines[14,15] are summarized below. Appendix 4 presents additional details on recommendations.

Guidelines

Recommendations regarding sleep position

The AAP guideline[14] recommends that infants be placed in a supine position for every sleep until the first birthday (recommendation strength: Level A).[14] Additionally, evidence showed that this sleeping position did not increase risk of choking and aspiration, even in infants with gastroesophageal reflux. This recommendation is also applied to preterm infants. Skin to skin care is recommended for all mothers and newborns as soon as possible after birth, after which the baby should be placed in a supine position in the bassinet. Once an infant is able to roll from supine to prone position during sleep, the infant can remain in the assumed position.[4]

Recommendations regarding sleep surfaces

The AAP guideline[14] recommends that infants be placed to sleep on a firm sleep surface (recommendation strength: Level A).[14] The firm sleep surface can be covered by a fitted sheet and should be devoid of any other objects (e.g., pillows, cushions, other bedding). The AAP also recommends a crib, bassinet, play yard, or portable crib that conforms to the safety standard of the Consumer Product Safety Commission Newer cribs are preferred due to this safety standard. There was insufficient evidence to provide a recommendation regarding bedside sleepers attached to the side of a caregiver's bed. The AAP recommends against placing an infant on adult-sized beds for sleep due to risk of entrapment. Additionally, the AAP recommends that sitting devices such as car seats and strollers not be used for the routine sleep of infants at home.[14]

Recommendations regarding infant sleep location

Both included guidelines[14,15] provide recommendations regarding co-sleeping or bed sharing (parent and infant sharing a sleep surface). The AAP guidelines recommend that infants sleep in the parents' room (room sharing) but on a separate designated infant sleep surface.[14] This practice should ideally be continued for the first year, and at least for the first six months of the baby's life(recommendation strength: Level A).[14] The AAP guideline cited evidence from case control studies and case series where bed-sharing (co-sleeping) was associated with increased the risk of SIDS, SUDI, or accidental injury to the infant. If the infant is brought to the adult bed for feeding or comforting, they should be placed back in the separate sleep surface afterward. The guideline did not identify adequate evidence in order to make a recommendation regarding the safety or risk of devices intended to make bed sharing safe. The AAP guideline also notes that surfaces such as armchairs and couches are "extremely dangerous places" for infants, however no recommendation specific to these surfaces was made.[14]

The NICE guidelines recommend that healthcare providers discuss the association between co-sleeping and SIDS with parents and other infant caregivers.[15] There was evidence that the association between co-sleeping and SIDS was likely to be greater with other risk factors such as caregiver (or their partner) smoking, recent alcohol consumption, drug usage, and low birth weight and premature infants. Due to the lack of causal evidence, the NICE guideline used the term "association" in the recommendation and refrained from stronger recommendations.[15]

Recommendations regarding the use of bedding

The AAP guideline[14] provides recommendation regarding the use of bedding. The AAP guideline recommends keeping the infant's sleep surface devoid of soft objects and loose bedding to lower the risk of suffocation, and SIDS (recommendation strength: Level A).[14] Based on evidence suggesting that bumper pads are a factor contributing to entrapment and strangulation, the AAP guideline advises against the use of bumper pads for infants.[14]

Recommendations regarding the use of pacifier

The AAP guideline[14] recommends considering offering pacifiers to infants during bedtime and naptime (recommendation strength: Level A).[14] This recommendation was based on evidence of a protective effect of pacifier use on the incidence of SIDS; the protective effect was observed even after the pacifier fell out infants' mouths during sleep. There was inadequate evidence regarding finger sucking on the incidence of SIDS.[4]

Recommendations regarding breastfeeding

The AAP guideline[14] recommends breastfeeding as breastfeeding was associated with lower risk of SIDS (recommendation strength: Level A).[14] The AAP guideline also noted that the protective effect of breastfeeding "increases with exclusivity", while any amount of breastfeeding had a protective effect against SIDS compared to no breastfeeding.[14]

Recommendations regarding swaddling

The AAP guideline found insufficient evidence to recommend swaddling to reduce the risk of SIDS (recommendation strength: Level C).[14] It was noted that, if swaddled, infants should always be placed in a supine position.

Recommendations regarding tummy time

The AAP guideline[14] provides a recommendation regarding "tummy time" (the practice of placing a baby in a prone position). The AAP guideline recommends placing babies in the prone position while awake with supervision to facilitate achieving motor milestones and to mitigate development of positional plagiocephaly (recommendation strength: Level B).[14]

Recommendations regarding prenatal and post-natal exposures (including smoking and alcohol)

The AAP guideline[14] provides recommendations regarding various prenatal and post-natal exposures. Specifically, the AAP guideline recommends that pregnant women obtain regular prenatal care (recommendation strength: Level A).[14] The guideline advises against smoking, illicit drug use, and alcohol use during pregnancy and after birth (recommendation strength: Level A).[14] As described earlier, the NICE guidelines also recommend advising parents about the higher risk of SIDS associated with co-sleeping when parental smoking, drug use, and recent alcohol use are present.[15] The NICE guideline did not make recommendations specific to these exposures other than in relation to co-sleeping.[15]

Recommendations regarding heating, ventilation and fans

The AAP guidelines[14] identified evidence showing an increased risk of SIDS associated with overheating of infants. They recommend avoiding overheating and head covering in infants (recommendation strength: Level A).[14] Infants should be dressed appropriately for

the sleeping environment. The guideline notes the lack of adequate evidence to recommend use of fans to prevent overheating.[4]

Recommendations regarding immunization

The AAP guideline[14] recommends that infants be immunized according to the vaccine guidelines by AAP and the Centers for Disease Control and Prevention (CDC) recommendations (recommendation strength: Level A).[14] There was no evidence suggesting immunization causes SIDS, and there was evidence that suggested vaccination may be protective against SIDS.[4,14]

Recommendations regarding use of home monitoring devices

The AAP guideline[14] recommends against the use of home cardiorespiratory monitoring devices as a strategy to reduce SIDS risk (recommendation strength: Level A). There was no evidence suggesting that the use of home cardiorespiratory monitoring devices decreased the risk of SIDS or of Brief Resolved Unexplained Events (BRUEs). BRUEs were previously thought to be precursors to SIDS, however there was also no evidence of this.[4]

Recommendations regarding use of other commercial devices

The AAP guidelines recommend avoiding the use of commercial devices that are inconsistent with safe sleep guidelines (recommendation strength: Level B).[14] Examples of such devices include wedges and position devices, which have a potential for suffocation and entrapment.

Recommendations regarding potential toxicants and hearing screens

The AAP guidelines[14] sought evidence regarding toxicants (e.g., nitrites in drinking water, antimony, phosphorus, or arsenic released from mattresses), however no evidence substantiating a causal relation was identified.[4] Additionally, based on available evidence, the AAP guideline advises against the use of newborn hearing screens (i.e., hearing tests) as a valid screening tool for risk of SIDS.[4]

Recommendations regarding educational interventions

The AAP task force found that intervention campaigns for SIDS, especially regarding infant sleep position, were “extremely effective”.[4] There was evidence for the effectiveness of primary care based educational interventions in changing practice. The guideline recommends continuing the “Safe to Sleep” campaign. It is recommended that pediatricians and other primary care providers actively participate in this campaign(recommendation strength: Level A)[14] Healthcare professionals, staff in newborn nurseries and Neonatal Intensive Care Units (NICUs), and childcare providers should endorse and model recommendations for SIDS risk reduction among infants from their birth.[4]

Recommendations regarding media messages and other recommendations for policy makers and researchers

The AAP guidelines[14] recommend that research and surveillance on the risk factors of SIDS be continued, along with future research on the pathophysiologic mechanisms of SIDS and other sleep-related infant deaths, with the ultimate aim of eliminating these deaths altogether (recommendation strength: Level C).[14]

The AAP guidelines also recommend that the media and manufacturers follow safe sleep guidelines in advertising and messaging (recommendation strength: Level A).[14]

Limitations

The main limitation of this report was the limited quantity of guidelines identified. Only two systematically developed guidelines, that were published in 2016[14] and 2015,[15] were identified. The evidence-based guidelines were developed in USA[14] and UK;[15] no guidelines that were developed in Canada were identified. However, the recommendations could be generalizable to Canadian settings given the commonalities in practice. The recommendations provided by the guidelines were not inclusive of cultural values and exogenous risk factors associated with vulnerable population. As Indigenous communities, other ethnic and racial minorities, and vulnerable families are at increased risk of SIDS,[5] recommendations inclusive of cultural values and practices could be beneficial.

Conclusions and Implications for Decision or Policy Making

Two evidence-based guidelines regarding interventions for the prevention of SIDS and SUDI in the community were identified and summarized in this report.[14,15] A previous CADTH report,[12] published in 2016, found recommendations that are consistent with the current report. These recommendations focused on providing education to parents and caregivers regarding interventions for prevention of SIDS. Interventions included sleep positions, sleep surfaces, sleep location (co-sleeping), pacifier use, smoke exposure, breastfeeding and immunization. The current report builds on the previous report, and reflects recent guidelines based on current evidence.

The two included guidelines, developed by the AAP and NICE,[14,15] provided recommendations regarding co-sleeping or bed-sharing. Specifically, the NICE guideline[15] recommends that healthcare professionals discuss this association between co-sleeping and SIDS with the parents or carers of infants. The AAP guideline recommends room sharing but recommends against co-sleeping for infants. The AAP guidelines[14] further recommend always placing infants in a supine position for sleep, on a firm sleep surface (separate from but close to the caregivers' sleep surface) that is devoid of bedding and soft objects. The AAP guidelines also recommend: breastfeeding; optional pacifier use; avoidance of overheating, smoke exposure, and parental use of alcohol and illicit drugs; vaccination in accordance with other guidelines; and supervised and awake tummy time. Home cardiorespiratory monitoring devices are not recommended to reduce risk of SIDS There was no evidence to recommend swaddling as a risk reduction strategy for SIDS. The AAP guideline recommends continuing "safe sleeping" campaigns and calls for healthcare providers to participate in and endorse these campaigns. They recommend that media messaging and manufacturers follow safe sleep guidelines in advertising, and healthcare professionals actively endorse recommendations for SIDS reduction among infants from their time of birth. Most of the recommendations were supported by evidence described as "good quality" and "patient-oriented" by the guideline developers.

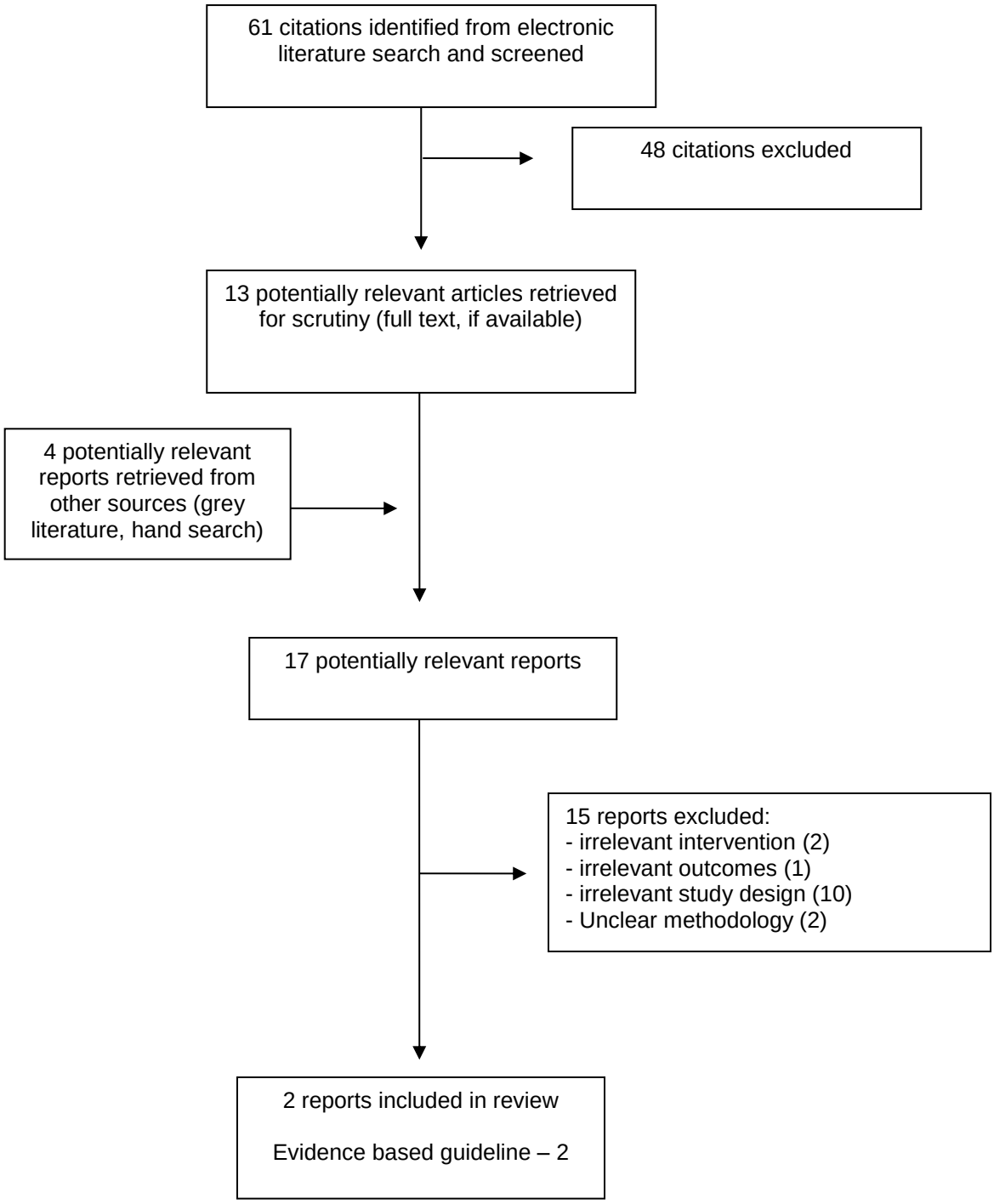
Overall, the recommendations from AAP[14] and NICE[15] were of good quality, supported by evidence and developed with sound methodology and are generalizable to Canadian settings. These recommendations are consistent with Canadian guidelines that were published in 2011,[19] and with infant sleep safety guidelines used in other industrialized countries (such as Italy, Denmark, New Zealand and Australia) that were either not considered evidence-based or published prior to 2015.[20] Focus on research and

recommendations inclusive of various cultural practices and addressing Indigenous populations and other minorities as well as vulnerable families is needed.

References

1. Willinger M, James LS, Catz C. Defining the sudden infant death syndrome (SIDS): deliberations of an expert panel convened by the National Institute of Child Health and Human Development. *Pediatr Pathol.* 1991;11(5):677-684.
2. Duncan J, Byard R. *Sudden infant death syndrome: an overview.* Adelaide (AU):: University of Adelaide Press; 2018.
3. Filiano JJ, Kinney HC. A perspective on neuropathologic findings in victims of the sudden infant death syndrome: the triple-risk model. *Biol Neonate.* 1994;65(3-4):194-197.
4. Moon RY, Task Force On Sudden Infant Death Syndrome. SIDS and other sleep-related infant deaths: evidence base for 2016 updated recommendations for a safe infant sleeping environment. *Pediatrics.* 2016;138(5):11.
5. Kinney HC, Thach BT. The sudden infant death syndrome. *N Engl J Med.* 2009;361(8):795-805.
6. Müller-Nordhorn J, Schneider A, Grittner U, et al. International time trends in sudden unexpected infant death, 1969-2012. *BMC Pediatr.* 2020;20(1):377.
7. Statistics Canada. Table 13-10-0395-01 Leading causes of death, infants. 2020; https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1310039501. Accessed 2020 Sep 2.
8. Gilbert R, Salanti G, Harden M, See S. Infant sleeping position and the sudden infant death syndrome: systematic review of observational studies and historical review of recommendations from 1940 to 2002. *Int J Epidemiol.* 2005;34(4):874-887.
9. Hauck FR, Tanabe KO. SIDS. *Clin Evid.* 2009;2009:0315.
10. Moon RY, Horne RSC, Hauck FR. Sudden infant death syndrome. *The Lancet.* 2007;370(9598):1578-1587.
11. Eunice Kennedy Shriver National Institute of Child Health and Human Development. Key moments in safe to sleep® history: 2004–2013. Rockville (MD): US Department of Health and Human Services; 2013: https://safetosleep.nichd.nih.gov/safesleepbasics/moments/2004-2013. Accessed 2020 Sep 8.
12. Interventions for the prevention of sudden infant death syndrome: guidelines. *(Rapid response report: summary of abstracts)*. Ottawa (ON): CADTH; 2016: https://cadth.ca/sites/default/files/pdf/htis/june-2016/RB0989%20Guidelines%20for%20SIDS%20Final.pdf. Accessed 2020 Sep 8.
13. Agree Next Steps Consortium. The AGREE II Instrument. [Hamilton, ON]: AGREE Enterprise; 2017: https://www.agreetrust.org/wp-content/uploads/2017/12/AGREE-II-Users-Manual-and-23-item-Instrument-2009-Update-2017.pdf. Accessed 2020 Sep 8.
14. Task Force On Sudden Infant Death Syndrome. SIDS and other sleep-related infant deaths: updated 2016 recommendations for a safe infant sleeping environment. *Pediatrics.* 2016;138(5):11.
15. National Institute for Health and Care Excellence. Postnatal care up to 8 weeks after birth. *(Clinical guideline CG37)* 2006; https://www.nice.org.uk/guidance/cg37. Accessed 2020 Aug 25.
16. Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *J Clin Epidemiol.* 2009;62(10):e1-e34.
17. Moon RY. SIDS and other sleep-related infant deaths: expansion of recommendations for a safe infant sleeping environment. *Pediatrics.* 2011;128(5):e1341-1367.
18. National Institute for Health and Clinical Excellence. Addendum to clinical cuideline 37, postnatal care. Routine postnatal care of women and their babies. *(Clinical guideline addendum 37.1 - methods, evidence and recommendations)* 2014; https://www.nice.org.uk/guidance/cg37/evidence/full-guideline-addendum-485782238. Accessed 2020 Aug 25.
19. Public Health Agency of Canada. Joint statement on safe sleep: preventing sudden infant deaths in Canada. [2009]; https://www.canada.ca/en/public-health/services/health-promotion/childhood-adolescence/stages-childhood/infancy-birth-two-years/safe-sleep/joint-statement-on-safe-sleep.html. Accessed 2020 Sep 3.
20. Doering JJ, Salm Ward TC, Strook S, Campbell JK. A comparison of infant sleep safety guidelines in nine industrialized countries. *J Community Health.* 2019;44(1):81-87.

Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Guidelines

Table 2: Characteristics of Included Guidelines

Country, intended users, target population	Intervention and practice considered	Major outcomes considered	Evidence collection, selection, and synthesis	Evidence quality assessment	Recommendations development and evaluation	Guideline validation
American Academy of Pediatrics (AAP) Guideline, 2016[14]						
US **Intended users:** All who care for infants**.** Some recommendations were specifically intended for health policy makers and researchers. **Target population:** Infants (children less than one year of age) **Note:** This guideline was developed as an update to the 2011 AAP guideline.[17]	• Sleep position • Sleep surfaces • Infant sleep location • Breastfeeding • Use of bedding • Pacifier use • Prenatal and post-natal exposure to smoking, alcohol consumption and illicit drugs • Overheating, ventilation and fans • Immunization • Home monitoring devices • Tummy time • Swaddling • Potential toxicants • Newborn hearing screens • Educational and research interventions • Media messages	Incidence of SIDS and SUDI	Literature searches were conducted using PubMed. Articles published since 2011 were considered. Expert consultation of a statistician was sought.	Not reported	Task force members evaluated the evidence and developed the guidelines. Strength of the recommendations were reported in 3 levels based on the availability and quality of evidence using SORT Level A: Recommendations were based on good-quality patient-oriented evidence Level B: Recommendations were based on inconsistent or limited-quality patient-oriented evidence. Level C: Recommendations were based on evidence from consensus, disease-oriented evidence, usual practice, expert opinion, or case series.	Draft version of the technical report was submitted to relevant committees of the AAP. Final version submitted to AAP Executive Committee for approval.
National Institute for Health and Care Excellence (NICE) Guideline, 2015[15]						
UK **Intended Users:** Healthcare professionals	This guideline considered interventions for routine and essential care for	Incidence of SIDS	Literature searches were conducted using	Modified GRADE approach, covering categories	Guidelines were developed by a standing committee of healthcare professionals, methodologists, and lay	Guidelines were finalized after public consultation.

Country, intended users, target population	Intervention and practice considered	Major outcomes considered	Evidence collection, selection, and synthesis	Evidence quality assessment	Recommendations development and evaluation	Guideline validation
Target Population: Infants (Children less than one year of age) **Note:** The NICE guideline was developed in 2006, updated in 2014, and amended in 2015 to include a post-publication change.	women and babies in the babies' first 6-8 months of life. Relevant to this report, bed-sharing or co-sleeping was considered		multiple electronic databases (e.g., PubMed, CINAHL, EMBASE, CDSR, HTA database). Searches were conducted on February 20, 2014. One study was identified by committee topic specific members. Twelve case control studies and 2 two patient level meta-analysis were included.	such as risk of bias, indirectness, inconsistency, imprecision and other considerations.	members from a range of discipline and places. Strength of recommendation: For the recommendations relevant to the current report, the term "association" was used based on the nature of evidence found. "Association" denotes a statistical relationship while acknowledging that it cannot be definitively stated as a risk factor.[18] A cause-and-effect relationship between co-sleeping and SIDS was not identified; for this reason, the wording "risk" was avoided.	

AAP = American Academy of Pediatrics; GRADE = Grading of Recommendations Assessment, Development and Evaluation; NICE = National Institute for Health and Care Excellence; SIDS = Sudden infant death syndrome; SORT = Strength of Recommendation Taxonomy; SUDI = Sudden unexplained death in infancy.

Appendix 3: Critical Appraisal of Included Guidelines

Table 3: Strengths and Limitations of Guidelines Using AGREE II[13]

Item	Guideline	
	American Academy of Pediatrics (AAP) Guideline, 2016 [14]	National Institute for Health and Care Excellence (NICE) Guideline, 2015[15]
Domain 1: Scope and Purpose		
1. The overall objective(s) of the guideline is (are) specifically described.	Yes	Yes
2. The health question(s) covered by the guideline is (are) specifically described.	Yes	Yes
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	Yes	Yes
Domain 2: Stakeholder Involvement		
4. The guideline development group includes individuals from all relevant professional groups.	Yes	Yes
5. The views and preferences of the target population (patients, public, etc.) have been sought.	No	Yes
6. The target users of the guideline are clearly defined.	Yes	Yes
Domain 3: Rigour of Development		
7. Systematic methods were used to search for evidence.	Yes	Yes
8. The criteria for selecting the evidence are clearly described.	Unclear	Yes
9. The strengths and limitations of the body of evidence are clearly described.	No	Yes
10. The methods for formulating the recommendations are clearly described.	Yes	Yes
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	Yes	Yes
12. There is an explicit link between the recommendations and the supporting evidence.	Yes	Yes
13. The guideline has been externally reviewed by experts prior to its publication.	Yes	Yes
14. A procedure for updating the guideline is provided.	Yes	Yes
Domain 4: Clarity of Presentation		
15. The recommendations are specific and unambiguous.	Yes	Yes

Item	Guideline	
	American Academy of Pediatrics (AAP) Guideline, 2016 [14]	National Institute for Health and Care Excellence (NICE) Guideline, 2015[15]
16. The different options for management of the condition or health issue are clearly presented.	Yes	No
17. Key recommendations are easily identifiable.	Yes	Yes
Domain 5: Applicability		
18. The guideline describes facilitators and barriers to its application.	Yes	No
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	Yes	No
20. The potential resource implications of applying the recommendations have been considered.	Yes	No
21. The guideline presents monitoring and/or auditing criteria.	Unclear	Yes
Domain 6: Editorial Independence		
22. The views of the funding body have not influenced the content of the guideline.	Yes	Yes
23. Competing interests of guideline development group members have been recorded and addressed.	Yes	Yes

AAP = American Academy of Pediatrics; AGREE II = Appraisal of Guidelines for Research and Evaluation II; NICE = National Institute for Health and Care Excellence.

Appendix 4: Main Recommendations

Table 4: Summary of Recommendations in Included Guidelines

Recommendations and supporting evidence	Strength of recommendations
American Academy of Pediatrics (AAP) Guideline, 2016[14]	
Evidence based recommendations for a safe infant sleeping environment. This guideline was an update of the 2011 AAP guideline. **Sleep position** ▪ **Recommendation:** "Back to sleep for every sleep (p. 3)."[14] ▪ "To reduce the risk of SIDS, infants should be placed for sleep in a supine position (wholly on the back) for every sleep by every caregiver until the child reaches 1 year of age. Side sleeping is not safe and is not advised (p. e7)."[4] ▪ "The supine sleep position does not increase the risk of choking and aspiration in infants, even in those with gastroesophageal reflux (p. e8)."[4] ▪ "Preterm infants should be placed supine as soon as possible (p. e8)."[4] ▪ "As stated in the AAP clinical report, "skin-to-skin care is recommended for all mothers and newborns, regardless of feeding or delivery method, immediately following birth (as soon as the mother is medically stable, awake, and able to respond to her newborn), and to continue for at least an hour." Thereafter, or when the mother needs to sleep or take care of other needs, infants should be placed supine in a bassinet (p. e8)."[4] ▪ "Once an infant can roll from supine to prone and from prone to supine, the infant may remain in the sleep position that he or she assumes (p. e9)."[4] **Sleep surfaces** ▪ **Recommendation:** "Use a firm sleep surface (p. 3)."[14] ▪ "Infants should be placed on a firm sleep surface (eg, mattress in a safety-approved crib) covered by a fitted sheet with no other bedding or soft objects to reduce the risk of SIDS and suffocation (p. e9)."[4] ▪ "A crib, bassinet, portable crib, or play yard that conforms to the safety standards of the Consumer Product Safety Commission (CPSC) is recommended (p. e9)."[4] ▪ "Sitting devices, such as car seats, strollers, swings, infant carriers, and infant slings, are not recommended for routine sleep in the hospital or at home, particularly for young infants (p. e10)."[4] **Breastfeeding** ▪ **Recommendation:** "Breastfeeding is recommended (p. 4)."[14] ▪ "Breastfeeding is associated with a reduced risk of SIDS. The protective effect of breastfeeding increases with exclusivity. Furthermore, any breastfeeding is more protective against SIDS than no breastfeeding (p. e10)."[4]	**Recommendation strength: Level A** **Recommendation strength: Level A** **Recommendation strength: Level A**

Recommendations and supporting evidence	Strength of recommendations
Infant sleep location ▪ **Recommendation:** "It is recommended that infants sleep in the parents' room, close to the parents' bed, but on a separate surface designed for infants, ideally for the first year of life, but at least for the first 6 months (p. 4)."[14] ▪ "There is insufficient evidence to recommend for or against the use of devices promoted to make bed-sharing 'safe'(p. e13)."[4] ▪ "Infants who are brought into the bed for feeding or comforting should be returned to their own crib or bassinet when the parent is ready to return to sleep." (p. e13)[4] ▪ "Couches and armchairs are extremely dangerous places for infants (p. e13)."[4] ▪ Guidance for parents who fall asleep while feeding their infant: "Parents should follow safe sleep recommendations outlined elsewhere in this statement. Because there is evidence that the risk of bed-sharing is higher with longer duration, if the parent falls asleep while feeding the infant in bed the infant should be placed back on a separate sleep surface as soon as the parent awakens(p. e13)."[4] ▪ Specific circumstances in which bed-sharing should be avoided at all times: ➢ When one or both parents are smokers (even if they are not smoking in bed) ➢ When mother smoked during pregnancy ➢ When the infant is less than 4 months of age (regardless of parental smoking status) ➢ When the infant was preterm or had low birth weight ➢ When the sleep surface is soft or small (e.g., waterbeds, couches, armchairs) ➢ When soft bedding accessories are present (e.g., pillows, blankets) ➢ When there are multiple bed sharers ➢ When parent has consumed alcohol or illicit or sedating drugs ➢ Bed sharing with a non-parent ▪ "The safety and benefits of cobedding twins and higher-order multiples have not been established. It is prudent to provide separate sleep areas and avoid cobedding (sleeping on the same sleep surface) for twins and higher-order multiples in the hospital and at home (p. e14)."[4]	**Recommendation strength: Level A**
Use of bedding ▪ **Recommendation:** "Keep soft objects and loose bedding away from the infant's sleep area to reduce the risk of SIDS, suffocation, entrapment, and strangulation. (p. 5)."[14] ▪ "Bumper pads are not recommended; they have been implicated in deaths attributable to suffocation, entrapment, and strangulation and, with new safety standards for crib slats, are not necessary for safety against head entrapment (p. e15)."[4]	**Recommendation strength: Level A**
Pacifier use ▪ **Recommendation:** "Consider offering a pacifier at nap time and bedtime (p. 6)."[14] ▪ "There is insufficient evidence that finger sucking is protective against SIDS (p. e16)."[4]	

Recommendations and supporting evidence	Strength of recommendations
Prenatal and Postnatal Exposures (Including Smoking and Alcohol)	**Recommendation strength: Level A**
▪ **Recommendation:** "Pregnant women should seek and obtain regular prenatal care (p. 6)."[14]	
▪ **Recommendation:** "Avoid smoke exposure during pregnancy and after birth (p. 6)."[14]	**Recommendation strength: Level A**
▪ **Recommendation:** "Avoid alcohol and illicit drug use during pregnancy and after birth (p. 6)."[14]	**Recommendation strength: Level A**
Overheating, Fans, and Room Ventilation	**Recommendation strength: Level A**
▪ **Recommendation: "**Avoid overheating and head covering in infants (p. 6)."[14]	
▪ "On the basis of available data, the task force cannot make a recommendation on the use of a fan as a SIDS risk-reduction strategy (p. 6)."[14]	**Recommendation strength: Level A**
Immunizations	
▪ **Recommendation**: "Infants should be immunized in accordance with recommendations of the AAP and Centers for Disease Control and Prevention (p. 6)."[14]	
▪ "The evidence continues to show no causal relationship between immunizations and SIDS and suggests that vaccination may have a protective effect against SIDS (p. e18)."[4]	**Recommendation strength: Level A**
Commercial devices	
▪ **Recommendation**: "Avoid the use of commercial devices that are inconsistent with safe sleep recommendations (p. 6)."[14] ▪ "Because of the lack of evidence that [wedges and positioning devices] are effective against SIDS, suffocation, or gastroesophageal reflux and because of the potential for suffocation and entrapment risk, the AAP concurs with the CPSC and the US Food and Drug Administration in warning against the use of these products (p. e18)."[4]	**Recommendation strength: Level B**
Home Monitors	
▪ **Recommendation**: "Do not use home cardiorespiratory monitors as a strategy to reduce the risk of SIDS (p. 6)."[14]	**Recommendation strength: Level A**
Tummy time	
▪ **Recommendation:** "Supervised, awake tummy time is recommended to facilitate development and to minimize development of positional plagiocephaly (p. 7)."[14]	
Swaddling	**Recommendation strength: Level B**
▪ **Recommendation: "**There is no evidence to recommend swaddling as a strategy to reduce the risk of SIDS (p. 7)."[14]	

Recommendations and supporting evidence	Strength of recommendations
▪ "Infants who are swaddled have an increased risk of death if they are placed in or roll to the prone position. If swaddling is used, infants should always be placed on the back. When an infant exhibits signs of attempting to roll, swaddling should no longer be used (p. e19)."[4]	**Recommendation strength: Level C**
Educational Interventions: ▪ This guideline is specifically intended for health policy makers researchers and professionals who care for or work on behalf of infants.	
▪ **Recommendation:** "Continue the "Safe to Sleep" campaign, focusing on ways to reduce the risk of all sleep-related infant deaths, including SIDS, suffocation, and other unintentional deaths. Pediatricians and other primary care providers should actively participate in this campaign (p. 7)."[14]	**Recommendation strength: Level A**
▪ **Recommendation:** "Health care professionals, staff in newborn nurseries and NICUs, and child care providers should endorse and model the SIDS risk reduction recommendations from birth (p. 7)."[14]	**Recommendation strength: Level A**
▪ **Recommendation:** "Continue research and surveillance on the risk factors causes, and pathophysiologic mechanisms of SIDS and other sleep-related infant deaths, with the ultimate goal of eliminating these deaths altogether (p. 8)."[14]	**Recommendation strength: Level C**
Media messages	
▪ **Recommendation**: **"**Media and manufacturers should follow safe sleep guidelines in their messaging and advertising (p. 7)."[14]	
▪ "In addition, public health departments and organizations that provide safe sleep information should review, revise, and reissue this information at least every 5 years to ensure that each generation of new parents receives appropriate information. (p. e21)."[4]	**Recommendation strength: Level A**
Potential Toxicants and hearing screens	
▪ "There is no evidence substantiating a causal relationship between various toxicants to SIDS (p. e21)."[4]	**Recommendation strength: Not applicable**
▪ "Current data do not support the use of newborn hearing screens as screening tests for SIDS (p. e21)."[4]	
Evidence summary: ➢ Evidence for SIDS risk and each of the interventions were obtained from several studies. The number of studies and the quality of evidence contributing to each of the recommendations were not reported.	
National Institute for Health and Care Excellence (NICE) Guideline, 2015[15]	
Evidence based guidelines on post-natal care for woman and babies. The guidelines relevant to the current report are described below. **Co-sleeping**	Not reported The guideline uses the term "association" because of the

Recommendations and supporting evidence	Strength of recommendations
▪ **Recommendation:** "Recognize that co-sleeping can be intentional or unintentional. Discuss this with parents and carers and inform them that there is an association between co-sleeping (parents or carers sleeping on a bed or sofa or chair with an infant) and SIDS (p. 34)."[15] ▪ **Recommendation:** "Inform parents and carers that the association between co-sleeping (sleeping on a bed or sofa or chair with an infant) and SIDS is likely to be greater when they, or their partner, smoke (p. 34)."[15] ▪ ▪ **Recommendation:** "Inform parents and carers that the association between co-sleeping (sleeping on a bed or sofa or chair with an infant) and SIDS may be greater with: ➢ parental or carer recent alcohol consumption, or ➢ parental or carer drug use, or ➢ low birth weight or premature infants. [new 2014] (p. 34)." [15] **Evidence summary:** ➢ Evidence for co-sleeping (sofa or chair) was obtained from 1 patient-level meta-analysis (very low quality) and four "very low quality" studies. ➢ Evidence for co-sleeping (bed or sofa or chair) was obtained from 1 patient-level meta-analysis (very low quality) and three "very low quality" studies. ➢ Evidence for co-sleeping (bed sharing) was obtained from 2 patient-level meta-analyses (very low quality and six "very low quality" studies. ➢ Evidence for co-sleeping and smoking was obtained from 1 patient-level meta-analysis (very low quality) and five "very low quality" studies. ➢ Evidence for co-sleeping and other factors such as alcohol consumption, drug use, and breastfeeding, was insufficient.	lack of definitive causal evidence regarding co-sleeping and SIDS.

AAP = American Academy of Pediatrics; GRADE = Grading of Recommendations Assessment, Development and Evaluation; NICE = National Institute for Health and Care Excellence; NICU = Neonatal Intensive Care Unit; SIDS = Sudden infant death syndrome; SUDI = Sudden unexplained death in infancy.

Appendix 5: Further Information

Guidelines with unclear methodology

Safe Infant Sleeping Standard. Women's and Newborns Health Network. Government of Western Australia Department of Health. 2018. https://ww2.health.wa.gov.au/~/media/Files/Corporate/Policy%20Frameworks/Clinical%20Services%20Planning%20and%20Programs/Policy/Safe%20Infant%20Sleeping%20MP/Supporting/Safe-Infant-Sleeping-Standard.pdf

Safe sleeping. Clinical Guidelines (Nursing). The Royal Children's Hospital Melbourne. Updated 2020. https://www.rch.org.au/rchcpg/hospital_clinical_guideline_index/Safe_Sleeping/

Other articles of interest

Public Health Agency of Canada. (2014). Joint statement on safe sleep: Preventing sudden infant deaths in Canada. http://www.phac-aspc.gc.ca/hp-ps/dca-dea/stages-etape s/child hood-enfan ce_0-2/sids/pdf/jsss-ecss2 011-eng.pdf

Doering JJ, Salm Ward TC, Strook S, Campbell JK. A Comparison of Infant Sleep Safety Guidelines in Nine Industrialized Countries. *J Community Health*. 2019 02;44(1):81-87. PubMed: PM30019197