Evidence-Based Clinical Practice Guideline for the Management of Acute Dental Pain: Temporary pharmacologic management of toothache in children with no immediate access to definitive dental treatment.

GRADE Certainty of the Evidence

High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect.
Low	Our confidence in the effect estimate is limited.
Very Low	We have very little confidence in the effect estimate.

GRADE Interpretation of Strength of Recommendations

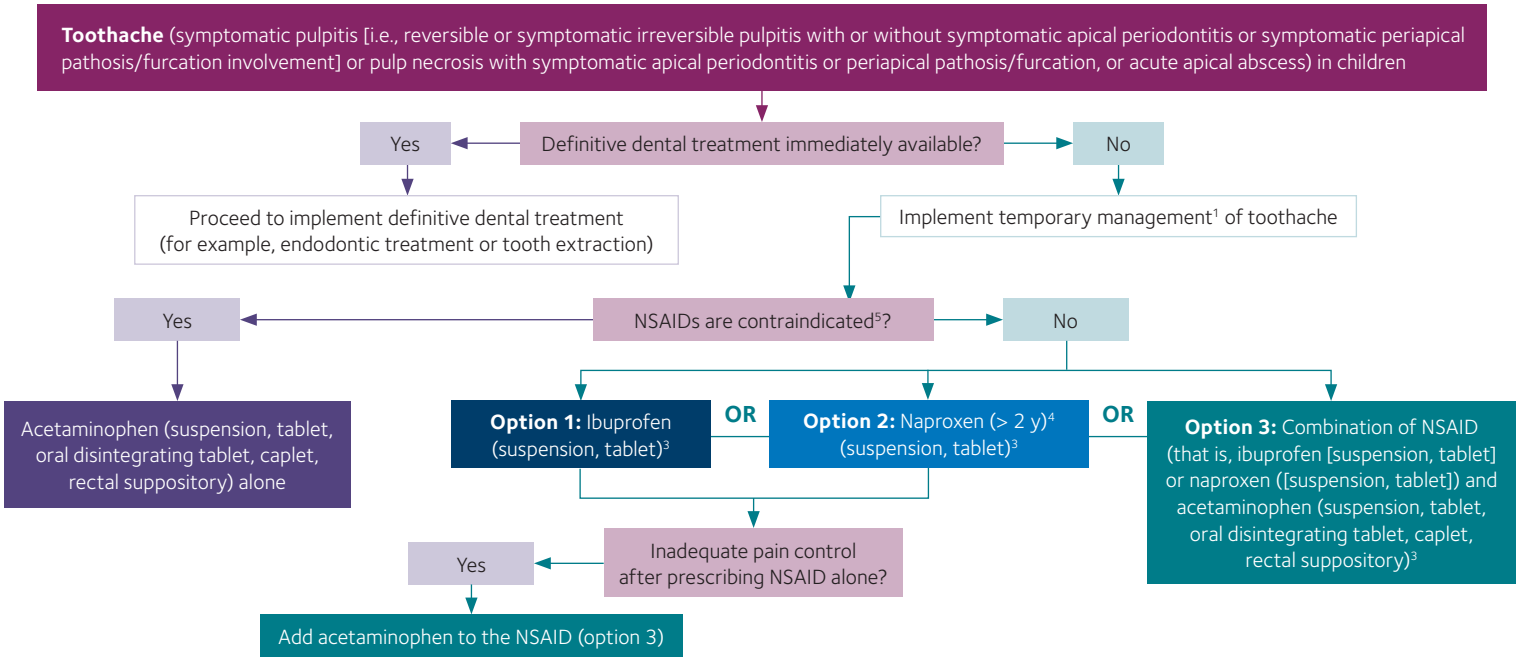
Implications	Strong Recommendations	Conditional Recommendations
For Patients	Most individuals in this situation would want the recommended course of action and only a small proportion would not.	The majority of individuals in this situation would want the suggested course of action, but many would not.
For Clinicians	Most individuals should receive the intervention.	Recognize that different choices will be appropriate for individual patients and that you must help each patient arrive at a management decision consistent with his or her values and preferences.
For Policy Makers	The recommendation can be adapted as policy in most situations.	Policy making will require substantial debate and involvement of various stakeholders.

Guideline Panel Recommendations

1. For the **temporary** management[1] of **toothache** (symptomatic pulpitis [i.e., reversible or symptomatic irreversible pulpitis with or without symptomatic apical periodontitis or symptomatic periapical pathosis/furcation involvement] or pulp necrosis with symptomatic apical periodontitis or periapical pathosis/furcation, or acute apical abscess) prior to definitive dental treatment in children[2], the guideline panel suggests the use of ibuprofen (suspension, tablet) alone[3], naproxen[4] (suspension, tablet) alone[3] **OR** either of the two in combination with acetaminophen[3] (suspension, tablet, oral disintegrating tablet, caplet, rectal suppository) over the use of acetaminophen alone (conditional, very low certainty).

    1.1. If pain control using NSAIDs alone is inadequate, the guideline panel suggests the addition of acetaminophen[3] (conditional, very low certainty).

    1.2. When NSAIDs are contraindicated[5], the guideline panel suggests the use of acetaminophen alone (conditional, very low certainty).



1. These recommendations are applicable only to settings where definitive dental treatment is not available. Definitive dental treatment includes pulpectomy, nonsurgical root canal treatment, incision for drainage of abscess, and tooth extraction. Patients should be instructed to call if their pain fails to lessen over time or to call if the referral to receive definitive dental treatment within 2 through 3 days is not possible.
2. The guideline panel defined children as patients younger than 12 years.
3. When defining dosages, weight should be the primary directive as opposed to age.
4. The recommendation statements are based on dosing for professionally prescribed analgesics, and do not address over-the-counter indications and dosages. The recommendation for the use of naproxen in children over 2 years of age in this guideline is an off-label use. Naproxen is FDA approved for use as young as 12 years. Naproxen is also approved for prescription use only in pediatric patients with polyarticular juvenile idiopathic arthritis as young as age 2 years. Naproxen is not FDA approved in children aged from 0 through 2 years.
5. "A drug should be contraindicated only in those clinical situations for which the risk from use clearly outweighs any possible therapeutic benefit. Only known hazards, and not theoretical possibilities, can be the basis for a contraindication." (Warnings and precautions, contraindications, and boxed warnings sections of labeling for human prescription drug and biological products- content and format. U.S. Food and Drug Administration. October 2011. Accessed June 1, 2022. https://www.fda.gov/media/71866/download

Evidence-Based Clinical Practice Guideline for the Management of Acute Dental Pain: Temporary pharmacologic management of toothache in children with no immediate access to definitive dental treatment.

Guideline Panel Good Practice Statements

- The guideline panel advises clinicians to assess children's pain using suitable tools for their ages. For example, a behavioral scale (1-3 years), a Faces scale (≥ 3 years), a numerical rating scale (≥ 8 years) or a visual analog scale (≥ 8 years).
- The guideline panel advises clinicians to counsel patients and their caregivers that they should expect some pain and the analgesics should make their pain manageable. The guideline panel also recommends discussing with the patient, parent, guardian, or caregiver their past experiences, preferences, and values regarding managing acute dental pain before prescribing.
- The guideline panel reminds users of these recommendations that they only apply to settings where definitive dental treatment is not immediately available. These pharmacological strategies will alleviate dental pain temporarily until a referral for definitive dental treatment is in place.
- The guideline panel recommends clinicians thoroughly review the patient's medical and social histories and medications and supplements to avoid overdose and adverse drug-drug interactions.
- According to FDA, codeine and tramadol are contraindicated in children younger than 12 years. In addition, topical benzocaine should not be used in infants or young children due to the high risk of methemoglobinemia.

Ibuprofen

(Suspension, tablet)

Dosing based on child's age and weight

Weight		Age	Dosage
lbs	kg		mg
12-17	5.4-8.1	6-11 months	50
18-23	8.2-10.8	12-23 months	75
24-35	10.9-16.3	2-3 years	100
36-47	16.4-21.7	4-5 years	150
48-59	21.8-27.2	6-8 years	200
60-71	27.3-32.6	9-10 years	250
72-95	32.7-43.2	11 years	300

Usual oral dosage:

Infants and children up to and including 11 years of age, <50 kg: 4-10 mg/kg/dose every 6-8 hours as needed (maximum single dose 400 mg; maximum dose 40 mg/kg/24 hours).

Naproxen

(Over 2 years of age)
(Suspension, tablet)

< 60 kg	5-6 mg/kg every 12 hours as needed	Maximum daily dose of 1,000 mg/day for naproxen and 1,100 mg/day for naproxen sodium
≥ 60 kg	250-375 mg every 12 hours as needed	

Dosage expressed as 200 mg naproxen base is equivalent to 220 mg naproxen sodium. For acute pain, naproxen sodium may be preferred because of increased solubility leading to faster onset, higher peak concentration, and decreased adverse drug events.

Acetaminophen

(Suspension, tablet, oral disintegrating tablet, caplet, rectal suppository)

Dosing based on child's age and weight

Weight		Age	Dosage
lbs	kg		mg
6-11	2.7-5.3	0-3 months	40
12-17	5.4-8.1	4-11 months	80
18-23	8.2-10.8	1-2 years	120
24-35	10.9-16.3	2-3 years	160
36-47	16.4-21.7	4-5 years	240
48-59	21.8-27.2	6-8 years	320
60-71	27.3-32.6	9-10 years	400
72-95	32.7-43.2	11 years	480

Usual oral dosage:

Infants and children up to and including 11 years: 10-15 mg/kg/dose every 4-6 hours as needed (maximum 75 mg/kg/24 hours, but not to exceed 4,000 mg/24 hours).

Both short- and long-term doses of acetaminophen are associated with hepatotoxicity. For this reason, this drug has been reformulated, so the products are limited to 325 mg per dosage unit.

This project was financially supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement by, FDA/HHS or the U.S. Government [U01FD007151]

These guidelines are intended to help inform clinical decision making by prescribers and patients. They are not intended to be used for the purposes of restricting, limiting, delaying, or denying coverage for, or access to, a prescription issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

ADA American Dental Association®
America's leading advocate for oral health

Penn Dental Medicine
University of Pennsylvania

University of Pittsburgh School of Dental Medicine