Complete Summary

GUIDELINE TITLE

Clinical policy: critical issues in the sedation of pediatric patients in the emergency department.

BIBLIOGRAPHIC SOURCE(S)

Mace SE, Brown LA, Francis L, Godwin SA, Hahn SA, Howard PK, Kennedy RM, Mooney DP, Sacchetti AD, Wears RL, Clark RM, EMSC Panel (Writing Panel) on Critical Issues in the Sedation of Pediatric Patients in the ED. Clinical policy: Critical issues in the sedation of pediatric patients in the emergency department. Ann Emerg Med 2008 Apr;51(4):378-99, e1-57. [205 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Anxiety and/or pain

GUIDELINE CATEGORY

Evaluation
Management
Risk Assessment

CLINICAL SPECIALTY

Anesthesiology
Emergency Medicine
Internal Medicine
Nursing
Pediatrics

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide evidence-based recommendations for specific critical issues related to the administration of procedural sedation and analgesia to pediatric patients in hospital-based emergency departments (EDs)

TARGET POPULATION

Patients less than or equal to 18 years of age who are in a hospital emergency department (ED) and have conditions necessitating the alleviation of anxiety, pain or both

This guideline is *not* intended for patients older than 18 years of age

INTERVENTIONS AND PRACTICES CONSIDERED

1. Need for preprocedural fasting
2. Use of nitrous oxide for procedural sedation
3. Use of chloral hydrate for procedural sedation
4. Use of oral sucrose to reduce infant distress
5. Clinical indicators to establish readiness for safe postsedation discharge (considered, but no specific criteria are recommended)

MAJOR OUTCOMES CONSIDERED

- Incidence of pulmonary aspiration after sedation
- Effectiveness and safety of specific pharmacologic agents used in procedural sedation
- Adverse events related to sedation and analgesia
- Effectiveness and safety of sucrose in reducing pain and anxiety

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Multiple searches of MEDLINE and the Cochrane database were performed. Specific key words/phrases used in the searches are identified under each critical question. All searches were limited to English-language sources, human studies, and years 1976 to 2006. References obtained on the searches were reviewed by panel members (title and abstract) for relevance before inclusion in the pool of studies to be reviewed. Abstracts and articles were reviewed by panel members, and pertinent articles were selected. These articles were evaluated, and those addressing the questions considered in this document were chosen for grading. Additional articles were reviewed from the bibliographies of studies cited. Panel members also supplied articles from their own knowledge and files.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Strength of Evidence

Literature Classification Schema^

Design/ Class	Therapy*	Diagnosis**	Prognosis***
1	Randomized, controlled trial or meta-analyses of randomized trials	Prospective cohort using a criterion standard	Population prospective cohort
2	Nonrandomized trial	Retrospective observational	Retrospective cohort Case control
3	Case series Case report Other (e.g., consensus, review)	Case series Case report Other (e.g., consensus, review)	Case series Case report Other (e.g., consensus, review)

^ Some designs (e.g., surveys) will not fit this schema and should be assessed individually.

*Objective is to measure therapeutic efficacy comparing $\geq$2 interventions.

**Objective is to determine the sensitivity and specificity of diagnostic tests.

*** Objective is to predict outcome including mortality and morbidity.

Approach to Downgrading Strength of Evidence*

	Design/Class		
Downgrading	**1**	**2**	**3**
None	I	II	III
1 level	II	III	X
2 levels	III	X	X
Fatally flawed	X	X	X

*See "Description of Methods Used to Analyze the Evidence" field for more information.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

This clinical policy was created after careful review and critical analysis of the medical literature.

All articles used in the formulation of this clinical policy were graded by at least 2 panel members for strength of evidence and classified by the panel members into 3 classes of evidence on the basis of the design of the study, with design 1 representing the strongest evidence and design 3 representing the weakest evidence for therapeutic, diagnostic, and prognostic clinical reports, respectively (see Appendix A in the original guideline document and the "Rating Scheme for the Strength of Evidence" field). Articles were then graded on 6 dimensions thought to be most relevant to the development of a clinical guideline: blinded versus nonblinded outcome assessment, blinded or randomized allocation, direct or indirect outcome measures (reliability and validity), biases (e.g., selection, detection, transfer), external validity (i.e., generalizability), and sufficient sample size. Articles received a final grade (Class I, II, III) on the basis of a predetermined formula taking into account design and quality of study (see Appendix B in the original guideline document and the "Rating Scheme for the Strength of Evidence" field). Articles with fatal flaws were given an "X" grade and not used in the creation of this policy. Evidence grading was done with respect to the specific data being extracted and the specific critical question being reviewed. Thus, the level of evidence for any one study may vary according to the question, and it is possible for a single article to receive different levels of grading as different critical questions are answered. Question-specific level of evidence grading may be found in the Evidentiary Table included at the end of the original guideline document.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The panel used the American College of Emergency Physicians (ACEP) clinical policy development process including expert review; this policy is based on the existing literature; where literature was not available, consensus of panel members was used.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Clinical findings and strength of recommendations regarding patient management were made according to the following criteria:

Strength of Recommendations

Level A recommendations. Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on strength of evidence Class I or overwhelming evidence from strength of evidence Class II studies that directly address all of the issues)

Level B recommendations. Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (i.e., based on strength of evidence Class II studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of strength of evidence Class III studies)

Level C recommendations. Other strategies for patient management that are based on preliminary, inconclusive, or conflicting evidence, or, in the absence of any published literature, based on panel consensus

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, strength of prior beliefs, and publication bias, among others, might lead to such a downgrading of recommendations.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The draft was sent to all participating organizations for comments during the expert review stage of development.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the strength of evidence (Class I-III) and strength of recommendations (Level A-C) are repeated at the end of the "Major Recommendations" field.

1. **Should pediatric patients undergo a period of preprocedural fasting to decrease the incidence of clinically important complications during procedural sedation in the emergency department (ED)?**

Patient Management Recommendations

Level A recommendations. None specified.

Level B recommendations. Procedural sedation may be safely administered to pediatric patients in the ED who have had recent oral intake.

Level C recommendations. None specified.

2. **Is nitrous oxide effective and safe for providing pediatric procedural sedation in the ED?**

Note: A previous clinical policy focused on the efficacy and safety of etomidate, fentanyl/midazolam, ketamine, methohexital, pentobarbital, and propofol for achieving sedation and analgesia in pediatric patients undergoing procedures in the ED. See Appendix C in the original guideline document for the recommendations from the previous clinical policy.

Patient Management Recommendations for Nitrous Oxide

Level A recommendations. Nitrous oxide at 50% concentration can be used with concurrent local anesthesia for safe and effective procedural sedation in healthy children undergoing painful procedures.

Level B recommendations. A gas scavenging system should be used for protection of health care providers when administering nitrous oxide.

Level C recommendations

1. Nitrous oxide at 60% to 70% concentration may be used with concurrent local anesthesia for safe and effective procedural sedation in healthy children undergoing painful procedures.
2. Nitrous oxide may be combined with other sedative analgesic agents to augment sedation, but patients receiving these combinations should be carefully monitored for deepening sedation, respiratory depression, and other adverse events.

3. Nitrous oxide may be less effective in reducing procedure-related distress in younger children compared with older children.
4. Nurses trained in principles of nitrous oxide sedation, including the specific nitrous oxide administration device, may safely administer nitrous oxide to healthy children while under the supervision of an emergency physician or other appropriately trained and credentialed specialist in the ED.

3. **Can oral sucrose be used to reduce infant distress due to minor, painful procedures in the ED?**

Patient Management Recommendations

Level A recommendations. Oral sucrose can be used to reduce signs of distress due to minor, painful procedures in preterm and term neonates (less than 28 days old).

Level B recommendations

1. Effective doses for neonates range from 0.1 mL of 24% to 2 mL of 50% sucrose (with the most commonly studied dose being 2 mL of 24% sucrose).
2. Oral sucrose can be used in combination with sucking (i.e., a pacifier) to improve its efficacy.
3. Oral sucrose may be safely administered to full-term neonates and infants.

Level C recommendations

1. Sucrose appears to be less effective in infants between 1 month and 6 months of age.
2. Effective doses for infants between 1 month and 6 months of age may range from 0.75 mL of 50% to 2 mL of 75% sucrose.
3. Effective doses for very-low-birth-weight, preterm infants may be as low as 0.05 mL of 24% sucrose.
4. Oral sucrose should be given approximately 2 minutes before an invasive procedure.
5. Oral sucrose may be safely given to low-birth-weight, preterm neonates.

4. **Is chloral hydrate effective and safe for providing procedural sedation in children in the ED?**

Note: This critical question about chloral hydrate was included for completeness because of its use in some practice settings. A previous clinical policy focused on the efficacy and safety of etomidate, fentanyl/midazolam, ketamine, methohexital, pentobarbital, and propofol for achieving sedation and analgesia in pediatric patients undergoing procedures in the ED. These recommendations about the safety and efficacy of chloral hydrate do not imply superiority to the

above medications. See Appendix C of the original guideline document for the recommendations from the previous clinical policy.

Patient Management Recommendations for Chloral Hydrate

Level A recommendations

1. Chloral hydrate may be used to provide effective procedural sedation in pediatric patients undergoing painless diagnostic studies. However, children receiving chloral hydrate should be properly monitored and managed by appropriately trained personnel due to the risk of respiratory depression and hypoxia.
2. Chloral hydrate should not be considered a first-line agent in children older than 48 months because of decreased efficacy as compared with younger children.

Level B recommendations. None specified.

Level C recommendations

1. Chloral hydrate has the potential for resedation and may produce residual effects up to 24 hours after administration.
2. Chloral hydrate may be used safely and effectively in properly monitored children who have congenital cardiac anomalies and are undergoing painless diagnostic procedures.
3. Chloral hydrate should not be used in children with neurodevelopmental disorders due to an increased incidence of adverse effects and decreased efficacy as compared with healthy children.
4. Pediatric patients receiving chloral hydrate should not be intentionally fasted because of increased procedural sedation failure rates.

5. **What clinical indicators support safe discharge after pediatric procedural sedation in the ED?**

Patient Management Recommendations

Level A recommendations. None specified.

Level B recommendations. None specified.

Level C recommendations. No universally applicable, evidence-based set of clinical indicators has been established. Emergency physicians, in conjunction with their institutions, should develop criteria for safe discharge.

Definitions

Strength of Evidence

Literature Classification Schema^

Design/ Class	Therapy*	Diagnosis**	Prognosis***
1	Randomized, controlled trial or meta-analyses of randomized trials	Prospective cohort using a criterion standard	Population prospective cohort
2	Nonrandomized trial	Retrospective observational	Retrospective cohort Case control
3	Case series Case report Other (e.g., consensus, review)	Case series Case report Other (e.g., consensus, review)	Case series Case report Other (e.g., consensus, review)

^ Some designs (e.g., surveys) will not fit this schema and should be assessed individually.

*Objective is to measure therapeutic efficacy comparing $\geq$2 interventions.

**Objective is to determine the sensitivity and specificity of diagnostic tests.

*** Objective is to predict outcome including mortality and morbidity.

Approach to Downgrading Strength of Evidence*

	Design/Class		
Downgrading	**1**	**2**	**3**
None	I	II	III
1 level	II	III	X
2 levels	III	X	X
Fatally flawed	X	X	X

*See "Description of Methods Used to Analyze the Evidence" field for more information.

Strength of Recommendations

Level A recommendations. Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on strength of evidence Class I or overwhelming evidence from strength of evidence Class II studies that directly address all of the issues)

Level B recommendations. Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (i.e., based on strength of evidence Class II studies

that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of strength of evidence Class III studies)

Level C recommendations. Other strategies for patient management that are based on preliminary, inconclusive, or conflicting evidence, or, in the absence of any published literature, based on panel consensus

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, strength of prior beliefs, and publication bias, among others, might lead to such a downgrading of recommendations.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriately treating pain and anxiety decreases patient suffering, facilitates medical interventions, increases patient/family satisfaction, improves patient care, and may improve patient outcome.

POTENTIAL HARMS

- Nitrous oxide may be combined with other sedative analgesics to augment sedation, but patients receiving these combinations should be carefully monitored for deepening sedation, respiratory depression, and other adverse events. A gas scavenging system should be used for protection of health care providers when administering nitrous oxide.
- Chloral hydrate has the potential for resedation and may produce residual effects up to 24 hours after administration. Proper monitoring is necessary due to the risk of respiratory depression and hypoxia. Chloral hydrate should not be used in children with neurodevelopmental disorders due to an increased incidence of adverse effects and decreased efficacy as compared with healthy children. Chloral hydrate should not be considered a first-line agent in children older than 48 months because of decreased efficacy as compared with younger children. Pediatric patients receiving chloral hydrate should not be intentionally fasted because of increased procedural sedation failure rates.

Refer to the original guideline document for further discussion concerning the safety of nitrous oxide, chloral hydrate, and sucrose as well as the safety of fasting versus nonfasting before procedures.

CONTRAINDICATIONS

CONTRAINDICATIONS

Chloral hydrate should not be used in children with neurodevelopmental disorders due to an increased incidence of adverse effects and decreased efficacy as compared with healthy children.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This policy is not intended to set standards for individual institutions or practitioners and cannot address every topic about pediatric procedural sedation but does give data for answering key management issues using an evidence-based approach.
- Recommendations offered in this policy are not intended to represent the only diagnostic and management options that the emergency physician should consider. The panel clearly recognizes the importance of the individual physician's judgment. Rather, this guideline defines for the physician those strategies for which medical literature exists to provide support for answers to the crucial questions addressed in this policy.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Mace SE, Brown LA, Francis L, Godwin SA, Hahn SA, Howard PK, Kennedy RM, Mooney DP, Sacchetti AD, Wears RL, Clark RM, EMSC Panel (Writing Panel) on Critical Issues in the Sedation of Pediatric Patients in the ED. Clinical policy: Critical issues in the sedation of pediatric patients in the emergency department. Ann Emerg Med 2008 Apr;51(4):378-99, e1-57. [205 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Apr

GUIDELINE DEVELOPER(S)

American College of Emergency Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

Emergency Medical Services for Children Program, Maternal and Child Health Bureau, Health Resources and Services Administration, US Department of Health and Human Services

GUIDELINE COMMITTEE

Emergency Medical Services for Children (EMSC) Panel (Writing Committee) on Critical Issues in the Sedation of Pediatric Patients in the Emergency Department

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Sharon E. Mace, MD, Chair, American College of Emergency Physicians (ACEP); Lance A. Brown, MD, MPH (ACEP); Lisa Francis, BSN, RN (Society of Pediatric Nurses); Steven A. Godwin, MD (ACEP); Sigrid A. Hahn, MD (ACEP); Patricia Kunz Howard, PhD, RN, CEN (Emergency Nurses Association); Robert M. Kennedy, MD (American Academy of Pediatrics); David P. Mooney, MD (American Pediatric Surgical Association); Alfred D. Sacchetti, MD (ACEP); Robert L. Wears, MD, MS, Methodologist (ACEP); Randall M. Clark, MD (American Society of Anesthesiologists)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

American Pediatric Surgical Association - Medical Specialty Society
Emergency Nurses Association - Medical Specialty Society
Society of Pediatric Nurses - Medical Specialty Society

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Emergency Physicians Web site.

Print copies: Available from the American College of Emergency Physicians, P.O. Box 619911, Dallas, TX 75261-9911, or call toll free: (800) 798-1822.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on May 6, 2008. The information was verified by the guideline developer on June 3, 2008.

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