Inclusion Criteria
- All children treated at TCH undergoing procedural sedation outside of the operating room with nitrous oxide.

Exclusion Criteria
- Children not receiving nitrous oxide for their sedation for a procedure.

Background
Nitrous oxide is an ideal medication for procedural sedation as it is safe and painless to administer with a rapid onset and recovery. There are very few reported major side effects with the use of nitrous oxide. (1) Currently, the administration of nitrous oxide requires standard fasting requirements. This evidence review will determine the safety reported in recent studies of administering nitrous oxide without fasting requirements.

Critically Analyze the Evidence
The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. The table below defines how the quality of evidence is rated and how a strong versus a weak recommendation is established.

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<tr>
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PICO Question 1: In pediatric patients receiving 30-70% nitrous oxide without additional sedatives or narcotics for procedural sedation outside the OR, does a standard NPO policy (no solids for at least 6-8 hours, no clear liquids for at least 2 hours) compared to no fasting restriction significantly decrease the incidence of adverse events?

Recommendation(s): Strong recommendation with low quality evidence that patients receiving 30-70% nitrous oxide without additional sedatives or narcotics for procedural sedation outside the OR should not have fasting requirements prior to the procedure. (1-6)

A review of the limited literature evidence suggests that fasting restrictions have little to no effect on the incidence of adverse events during or after procedural sedation with 30-70% nitrous oxide. (1-4) Two observational studies, one controlled-crossover study, and one retrospective review were found that compared the incidence of adverse events with or without fasting prior to the use of 20-70% nitrous oxide for procedural sedation, and none of the studies showed a significant difference in adverse events related to NPO status. (1-4) Babl et al. compared the incidence of adverse events in emergency department patients receiving 50-70% nitrous oxide for minor procedures who met fasting guidelines versus those who did not. The study found no association between preprocedural fasting status and emesis. (6) Heinrich et al. demonstrated a very low incidence of adverse events (1% with nausea or dizziness) in patients receiving 50% nitrous oxide for minor surgical procedures without a fasting period. (5) In a controlled-crossover design, Kupietzky et al. compared the incidence of vomiting between the same patients in sessions with NPO instructions versus sessions without fasting restrictions for dental procedural sedation with 50% nitrous oxide. One non-fasted patient vomited (0.5% of sedation experiences), however this did not create a statistically significant difference between the groups with a sample size of 113 patients. (4) Pasaron et al. described a large review (1,058 patients) of non-fasted patients receiving 20-60% nitrous oxide via a nasal hood for minor surgical procedural sedation. There were no associations between complications and fasting status. (1) In addition, two sedation guidelines do not require fasting prior to nitrous oxide sedation. (5-6) Given that no studies indicated that fasting significantly decreased the incidence of adverse events during
procedural sedation with nitrous oxide, the recommendation is made to not require fasting prior to sedation with 30-70% nitrous oxide alone.

**Critical Points of Evidence**

**Evidence Supports**

- Patients receiving 30-70% nitrous oxide without additional sedatives or narcotics for procedural sedation outside the OR should not have fasting requirements prior to the procedure. – Strong recommendation, low quality evidence

**References**

Clinical Standards Preparation
This clinical standard was prepared by the Evidence-Based Outcomes Center (EBOC) team in collaboration with content experts at Texas Children’s Hospital. Development of this clinical standard supports the TCH Quality and Patient Safety Program initiative to promote clinical standards and outcomes that build a culture of quality and safety within the organization.

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No relevant financial or intellectual conflicts to report.

Development Process
This clinical standard was developed using the process outlined in the EBOC Manual. The literature appraisal documents the following steps:

1. Review Preparation
   - PICO questions established
   - Evidence search confirmed with content experts

2. Review of Existing External Guidelines
   - Guideline for the Use of Nitrous Oxide for Pediatric Dental Patients – American Academy of Pediatric Dentistry; Sedation in Children and Young People – National Institute for Health and Care Excellence (NICE)

3. Literature Review of Relevant Evidence
   - Searched: PubMed, Cochrane Library, EMBASE

4. Critically Analyze the Evidence
   - 4 nonrandomized studies

5. Summarize the Evidence
   - Materials used in the development of the clinical standard, literature appraisal, and any order sets are maintained in a Nitrous Oxide Administration and Fasting evidence-based review manual within EBOC.

Evaluating the Quality of the Evidence
Published clinical guidelines were evaluated for this review using the AGREE II criteria. The summary of these guidelines are included in the literature appraisal. AGREE II criteria evaluate Guideline Scope and Purpose, Stakeholder Involvement, Rigor of Development, Clarity and Presentation, Applicability, and Editorial Independence using a 4-point Likert scale. The higher the score, the more comprehensive the guideline.

This clinical standard specifically summarizes the evidence in support of or against specific interventions and identifies where evidence is lacking/inconclusive. The following categories describe how research findings provide support for treatment interventions.

- **Evidence Supports** provides evidence to support an intervention.
- **Evidence Against** provides evidence against an intervention.
- **Evidence Lacking/Inconclusive** indicates there is insufficient evidence to support or refute an intervention and no conclusion can be drawn from the evidence.

The GRADE criteria were utilized to evaluate the body of evidence used to make practice recommendations. The table below defines how the quality of the evidence is rated and how a strong versus weak recommendation is established. The literature appraisal reflects the critical points of evidence.

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Recommendations
Practice recommendations were directed by the existing evidence and consensus amongst the content experts. Patient and family preferences were included when possible. The Content Expert Team and EBOC team remain aware of the controversies in fasting with nitrous oxide administration in children. When evidence is lacking, options in care are provided in the clinical standard and the accompanying order sets (if applicable).

Approval Process
Clinical standards are reviewed and approved by hospital committees as deemed appropriate for its intended use. Clinical standards are reviewed as necessary within EBOC at Texas Children’s Hospital. Content Expert Teams are involved with every review and update.
Disclaimer

Practice recommendations are based upon the evidence available at the time the clinical standard was developed. Clinical standards (guidelines, summaries, or pathways) do not set out the standard of care and are not intended to be used to dictate a course of care. Each physician/practitioner must use his or her independent judgment in the management of any specific patient and is responsible, in consultation with the patient and/or the patient’s family, to make the ultimate judgment regarding care.

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