Comfort Promise: Single Dose Anxiolysis
Clinical Pathway Synopsis

Objective of Clinical Pathway

To provide care standards for patients requiring a brief procedure with minimal discomfort. The Comfort Promise: Single Dose Anxiolysis Clinical Pathway provides decision-making support and guidance to determine whether to use a single-dose anxiolytic as part of the Comfort Promise⁺ bundle.

Background

Medical experiences, particularly experiences when pain is anticipated, can manifest feelings of fear, confusion, and anxiety in children.[1-3] When these feelings are not addressed or managed appropriately, the medical traumatic stress evoked can have long-lasting consequences.[1-3] The sequelae of unmanaged pain can lead to medical care avoidance into adulthood.[2,4,5]

Pain-reducing measures, known as the Comfort Promise bundle, were implemented at Children's Mercy to help prevent the potential long-term psychological effects of medical trauma during needle-based procedures.[6] The Comfort Promise bundle consists of four strategies, which include numbing the skin, positioning, distraction, and administering oral sucrose or breastfeeding to be offered as standard of care for children requiring routine needle procedures.[6-12] However, there are instances in which the standard Comfort Promise bundle is insufficient and requires an alternative or supplemental approach.

The Comfort Promise: Single Dose Anxiolysis Clinical Pathway provides guidance when an alternative or supplemental approach to the Comfort Promise bundle is needed. The pathway outlines the criteria for using single dose anxiolysis and the processes to follow.

Target Users

- Physicians (Ambulatory Clinics, Primary Care, Anesthesiology, Fellows, Residents)
- Advanced Practice Providers
- Clinical Psychologists
- Nurses
- Pharmacists
- Child Life Specialists

Target Population

Inclusion Criteria

- Patients ≥ 2 years of age requiring a brief procedure with minimal discomfort
- Patients classified as ASA I or ASA II: A normal healthy patient or a patient with mild systemic disease (ASA Physical Status Classification System[13])

Exclusion Criteria

- Patients < 2 years of age
- Patients who have sleep apnea
- Patient with a history of a prior procedure requiring > 1 dose of an anxiolytic (*contact the Procedural Sedation Unit*)

- Patients scheduled for procedures where sedation is indicated

AGREE II

Two international guidelines informed the Comfort Promise: Single Dose Anxiolysis Clinical Pathway Committee.[14,15] See **Appendix Table 1** for the AGREE II summary of *Reducing Pain and Distress Related to Needle Procedures in Children with Cancer: A Clinical Practice Guideline*[14] and **Appendix Table 2** for the AGREE II summary of *Reducing Pain During Vaccine Injections: Clinical Practice Guideline*.[15]

Practice Recommendations

Please refer to the two international clinical practice guidelines for evaluation and intervention recommendations specific to the standard Comfort Promise bundle.[14,15] The Comfort Promise: Single Dose Anxiolysis Committee relied on expert consensus to develop recommendations for instances in which the standard Comfort Promise bundle was insufficient.

Additional Questions Posed by the Clinical Pathway Committee

No additional clinical questions beyond those addressed in the two international clinical practice guidelines were posed for formal literature review.[14,15]

Recommendation Specific for Children's Mercy

Children's Mercy adopted the practice recommendations made by the two international clinical practice guidelines for the standard Comfort Promise bundle.[14,15] Additions include:

- Referring to Child Life for further assessment when the standard Comfort Promise bundle is insufficient
- Administering a benzodiazepine medication in a clinic or hospital setting only, particularly if being administered for the first time

Measures

Use of the Comfort Promise: Single Dose Anxiolysis Clinical Pathway

Value Implications

The following improvements may increase value by reducing healthcare costs and non-monetary costs (e.g., missed school/work, loss of wages, stress) for patients and families and reducing costs and resource utilization for healthcare facilities.

- Decreased risk of creating long-term adverse psychological effects of trauma during brief procedures (e.g., peripheral intravenous catheter placement, blood draw, nasogastric tube placement, or immunizations) when the standard Comfort Promise bundle is insufficient
- Decreased risk of overtreatment (i.e., procedural sedation is required for a brief procedure when a single-dose anxiolytic is more appropriate)
- Decreased unwarranted variation in care

Organizational Barriers and Facilitators

Potential Barriers

- Variability of the acceptable level of risk among providers

- Challenges with pre-procedural single-dose anxiolytic obtainment and administration faced by some families

Potential Facilitators

- Collaborative engagement across care continuum settings during clinical pathway development
- Limited options for children who require a brief procedure with anticipated discomfort, and the standard Comfort Promise bundle is insufficient

Diversity/Equity/Inclusion

Our aim is to provide equitable care. These issues were discussed with the Committee, reviewed in the literature, and discussed prior to making any practice recommendations.

Order Set(s)

- There are no order set(s) associated with the Comfort Promise: Single Dose Anxiolysis Clinical Pathway

Education Materials

- Comfort for Needle Procedures
  - Explains strategies used in the Comfort Promise bundle to families
  - Available to order through the Printing Portal
  - Available in English and Spanish

Clinical Pathway Preparation

This pathway was prepared by the Evidence Based Practice (EBP) Department in collaboration with the Comfort Promise: Single Dose Anxiolysis Clinical Pathway Committee, which is composed of content experts at Children's Mercy. If a conflict of interest is identified, the conflict will be disclosed next to the committee member's name.

Comfort Promise: Single Dose Anxiolysis Clinical Pathway Committee Members and Representation

- Lucy Raab, MA, CCLS | Patient and Family Services, Child Life | Committee Chair
- Liz Edmundson, PhD, RN, NE-BC | Patient Care Services, Comfort Promise and Opioid Stewardship | Committee Member
- Katy Clarkston, MD | Gastroenterology | Committee Member
- Jennifer Schurman, PhD, ABPP, BCB | Gastroenterology | Committee Member
- Emily Weisberg, MD | Anesthesiology, Pain Management | Committee Member
- Jonathan Jerman, MD, FASA | Anesthesiology | Committee Member
- Shannon Johnson, BSN, RN, CPN | Pain Management, Nursing | Committee Member
- Ricky Ogden, PharmD, MBA, BCPS, FACHE | Pharmacy | Committee Member
- Alissa Arnold, MSN, RN, VA-BC | Procedural Sedation Unit| Committee Member
- Bobbi Schomburg, RN, BSN, CPN | Procedural Sedation Unit | Committee Member
- Sarah Dierking, MSN, RN, CPHQ | Clinical Practice and Quality | Committee Member

EBP Committee Members

- Todd Glenski, MD, MSHA, FASA | Anesthesiology, Evidence Based Practice
- Kelli Ott, OTD, OTR/L | Evidence Based Practice

Clinical Pathway Development Funding

The development of this clinical pathway was underwritten by the following departments/divisions: Patient Care Services, Pain Management, Gastroenterology, Anesthesiology, Child Life, Pharmacy, Clinical Practice and Quality, and Evidence Based Practice

Conflict of Interest

The contributors to the Comfort Promise: Single Dose Anxiolysis Clinical Pathway have no conflicts of interest to disclose related to the subject matter or materials discussed.

Approval Process

- This pathway was reviewed and approved by the Comfort Promise: Single Dose Anxiolysis Committee, Content Expert Departments/Divisions, and the EBP Department; after which they were approved by the Medical Executive Committee.
- Pathways are reviewed and updated as necessary every 4 years within the EBP Department at Children's Mercy. Content expert teams are involved with every review and update.

Review Requested

Department/Unit	Date Obtained
Comfort Promise Team	March 2025
Anesthesiology	March 2025
Child Life	March 2025
Pharmacy	March 2025
Clinical Practice and Quality	March 2025
Evidence Based Practice	February 2025

Version History

Date	Comments
March 2025	Version one – (*developed the Comfort Promise: Single Dose Anxiolysis Clinical Pathway and synopsis*)
April 2025	Version two – (*modified language to reflect collaborative decision-making amongst nursing, physicians, and Child Life regarding the use of single-dose anxiolysis as part of the Comfort Promise+ plan)*

Date for Next Review

- March 2029

Implementation & Follow-Up

- Once approved, the pathway was presented to appropriate care teams and implemented. Care measurements will be assessed and shared with the appropriate care teams to determine whether changes are needed.
- The associated policies were reviewed. These detail a process for advanced practice providers, physicians, dentists, nurses, and medical assistants to promote optimal comfort through a proactive pain management plan.
- Education was provided to all stakeholders:
    - Ambulatory clinics where the Comfort Promise: Single Dose Anxiolysis Clinical Pathway is used
    - Department of Patient Care Services, Child Life, Pharmacy, Clinical Practice and Quality
    - Providers from Anesthesiology, Gastroenterology, Pain Management, Procedural Sedation Unit, and
      resident physicians
- Additional institution-wide announcements were made via email, the hospital website, and relevant huddles.

Disclaimer

When evidence is lacking or inconclusive, options in care are provided in the supporting documents and the order set(s) and/or order panel(s) that accompany the clinical pathway.

These clinical pathways do not establish a standard of care to be followed in every case. It is recognized that each case is different, and those individuals involved in providing health care are expected to use their judgment to determine what is in the best interests of the patient based on the circumstances existing at the time.

It is impossible to anticipate all possible situations that may exist and to prepare clinical pathways for each. Accordingly, these clinical pathways should guide care with the understanding that departures from them may be required at times.

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Appendix

Table 1. AGREE II Summary for the Reducing Pain and Distress Related to Needle Procedures in Children with Cancer: A Clinical Practice Guideline[14]

Domain	Percent Agreement	Percent Justification^
Scope and purpose	97%	The aim of the guideline, the clinical questions posed and target populations **were** identified.
Stakeholder involvement	99%	The guideline **was developed** by the appropriate stakeholders and represents the views of its intended users.
Rigor of development	88%	The process used to gather and synthesize the evidence, the methods to formulate the recommendations **were** explicitly stated. The guideline developers **did not** clearly identify how the guidelines will be updated.
Clarity and presentation	100%	The guideline recommendations **are** clear, unambiguous, and easily identified; in addition, different management options are presented.
Applicability	72%	Barriers and facilitators to implementation, strategies to improve utilization, and resource implications **were addressed** in the guideline.
Editorial independence	100%	The recommendations **were not** biased with competing interests.
Overall guideline assessment	93%	
See Practice Recommendations		

Note: Four EBP Scholars completed the AGREE II on this guideline.
^Percentage justification is an interpretation based on the Children's Mercy EBP Department standards.

Table 2. AGREE II Summary for the Reducing Pain During Vaccine Injections: Clinical Practice Guideline[15]

Domain	Percent Agreement	Percent Justification^
Scope and purpose	99%	The aim of the guideline, the clinical questions posed, and the target populations **were** identified.
Stakeholder involvement	83%	The guideline **was developed** by the appropriate stakeholders and represents the views of its intended users.
Rigor of development	93%	The process used to gather and synthesize the evidence and the methods to formulate the recommendations **were** explicitly stated. The guideline developers **did not** clearly identify how the guidelines will be updated.
Clarity and presentation	99%	The guideline recommendations **are** clear, unambiguous, and easily identified; in addition, different management options are presented.
Applicability	89%	Barriers and facilitators to implementation, strategies to improve utilization, and resource implications **were addressed** in the guideline.

Editorial independence	100%	The recommendations **were not** biased with competing interests.
Overall guideline assessment	94%	
See Practice Recommendations		

Note: Four EBP Scholars completed the AGREE II on this guideline.
^Percentage justification is an interpretation based on the Children's Mercy EBP Department standards.