Title: Evaluation of pain alleviating strategies during allergy shots (Subcutaneous immunotherapy): A randomized controlled study (**P**ain **P**erception with **A**llergy **S**hot **T**echniques: PPAST)

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Rationale and Purpose

Subcutaneous Immunotherapy (allergy injections) is a potentially disease-modifying therapy that is effective for the treatment of allergic rhinitis/conjunctivitis, allergic asthma and stinging insect hypersensitivity. Pain, which results from the irritation of nearby nerves is a common concern of patients, particularly in children, during or after the injections. This can be a stressful and negative experience for the children. There are various techniques available to minimize pain in general. However, there is a lack of published research on how to use these techniques in children receiving allergy injections. The purpose of this study is to evaluate and compare the efficacy of the standard of care method (Ethyl Chloride/Pain Ease Spray) and three non-pharmacological pain control devices (Buzzy Bee I, Buzzy Bee II and Shot Blocker) in decreasing the perception of pain during subcutaneous allergy injection in a pediatric allergy/immunology clinic setting.

Objective

- Evaluate and compare the effectiveness of utilizing various techniques to reduce the perception of pain during subcutaneous allergy injections in children

Possible Risks and Benefits

Risk Assessment

- The risks associated with study participation are consistent with standard of care risks. Potential risk for the study participants may be possible allergic reaction/skin irritation from the cold spray or ice pack or an increased level of anxiety.

Benefits Assessment

- The potential benefit associated with this research study includes a better understanding of study participant's response to their assigned distraction technique. This study may help identify which technique is more beneficial to use in children receiving subcutaneous immunotherapy to decrease the perception of pain and reduce anxiety related to immunotherapy treatment.

Study Design and Duration

This is a randomized controlled study. Approximately 100 children, age 4 – 17 years, who are currently receiving subcutaneous immunotherapy, will randomly select a blinded envelope which assigns the distraction technique to be utilized during their study participation. There will be 25 envelopes assigned to each study group for a total of 100 envelopes. Each envelope will contain a paper with a colored sticker for the associated group assignment and number sequence.

The distribution of group assignment by number sequence and color is as follows:

- Interventional Groups
  1. Shot Blocker® # 1-25 (RED)
  2. Buzzy I (vibrating only) # 26-50 (GREEN)
  3. Buzzy II (vibrating and ice wings) # 51-75 (BLUE)
- Control Group
  4. Ethyl Chloride/Pain Ease Spray # 76-100 (YELLOW)

The three interventional groups are currently marketed distraction devices. The control group is the current clinical standard of care option for pre-allergy injection application.

The study consists of two visits. Both visits will be conducted during the participants routine clinic visit for allergy injections. At the first visit the investigator will assess eligibility. An overview of the study requirements will be provided to parent/child and consent/assent will be obtained.

During the second visit, the child will be randomized to a distraction technique or standard of care group to be utilized with the allergy injection(s) administered at this visit. Adherence with institutional allergy injection guidelines will be maintained. Prior to the application of the distraction method, the investigator will interview the parent to collect data related to demographic information and their child's current allergy health and treatment regime. The child's pain perception will be assessed before and after the allergy injection. The parent's perception of their child's pain will be assessed after the allergy injection. The investigator will provide information on the application of the randomized method and will provide instruction on the completion of the pain scales and questionnaires. The investigator and study staff will not indicate a method preference or guide the child or parent with their pain level responses. After completion of the second visit, the child's study participation is complete.

Inclusion & Exclusion Criteria

Inclusion Criteria

- Children aged 4-17 years on injection immunotherapy
- A minimum of three allergy injection injections prior to enrollment at Visit 1

- Child accompanied by parent or legal guardian

Exclusion Criteria
- Children with a known pain or sensory disorders
- Developmental delays lacking necessary cognitive ability
- Administration of any form of pain analgesic within eight hours of randomization at Visit 2

Study Procedures

Visit 1:

Children aged 4-17 years who present to receive their injection(s) in the allergy clinic will be screened by the Principal Investigator or Co-Investigator for study inclusion and exclusion criteria. During their routine post-allergy injection 30-minute wait time, the investigator and the research coordinator will provide the parent and child with an overview of the study design, the risk and benefits assessment and study requirements. The investigator will advise the parent/child of the pain analgesic administration exclusion for the randomization visit. After obtaining parental permission and child assent, the child will be considered enrolled in the study. A subject ID will be assigned. A visible mark placed on the child's allergy injection chart will indicate the child is ready to be randomized at their next routine allergy injection visit.

Visit 2:

At a future allergy injection clinic visit the parent and the child will be asked if the child took any pain-relieving medicines, like Tylenol or Advil, within eight hours before coming to the clinic. If the participant needed this kind of medicine, the allergy shot appointment will be the same as before the study.

Study visit 2 will be completed at another routine allergy shot appointment. Preferably the next scheduled allergy injection visit.

If the participant did **not** take any pain relieving medicine within the previous eight hours, visit 2 will continue. The participants study group assignment will be determined. The envelopes identifying the four group assignments will be coded by number and color. The child will be presented with a basket containing all the envelopes. The investigator will instruct the child to select one envelope from the basket. The envelope selected at random by the child will determine the distraction method to be utilized prior to the allergy injection(s). The possible group assignments, one of three currently marketed distraction devices or the control group utilizing the current standard of care option, are listed below and are further detailed in Attachments I – III.

The four study groups are:
- Interventional Groups
  1. Shot Blocker®
  2. Buzzy I (*with ice pack-wings)*
  3. Buzzy II (*without ice pack-wings)*
- Control Group
  4. Ethyl Chloride/Pain Ease Spray

Before applying the assigned distraction method:

- Prior to randomization, the investigator will interview the parent to obtain the information needed to complete the Parent Demographic-Health-Treatment Questionnaire (Attachment V). The investigator will review the responses for any indicator of study ineligibility, ie, analgesic medication window.
- The investigator or study staff will review the Wong-Baker FACES Pain Rating Scale with the child. The child will be given a Wong-Baker FACES Pain Rating Scale form and asked to circle the face which most closely matches their current level of pain awareness prior to any intervention. (Attachment IV-a)
- The investigator or study staff will review the Numeric Pain Rating Scale (Attachment IV-b) with the parent. The parent will be instructed to circle the number on the scale which most closely matches their perception of their child's pain level immediately after receiving the allergy injection.

Application of the distraction method and administration of the allergy injection:

- The investigator will apply the assigned distraction method per method specifications to the injection site area (subcutaneous region of the back of the upper arm).
- The investigator will administer the subcutaneous allergy injection(s) within the time frame specified for the assigned distraction device utilized or per the standard of care guidelines for the Pain Ease Spray, as appropriate. If the child's treatment plan includes more than one injection, the assigned group technique will be utilized for all injections at the visit.

Post allergy injection procedures:

- Immediately following the allergy injection, the child will be provided with a second Wong-Baker FACES Pain Rating Scale form and be asked to circle the face which most closely matches their post-injection level of pain awareness.
- Immediately following the allergy injection, the parent will be reminded to circle the number on the Numeric Pain Rating Scale which most closely matches their perception of the child's post-injection pain level.
- The participant and parent will then complete the routine 30 minute wait time for post allergy injections.

Study participation is complete at the end of Visit 2.

Prohibited Medications

Analgesic medications administered within eight hours of Visit 2 are prohibited.

Adverse Event (AE)

An AE is any unfavorable and unintended sign, symptom temporally associated with the use of the study technique and does not imply judgment about causality.

AE's associated with the randomized intervention will be collected at Visit 2. The AE's relationship to the distraction technique will be assessed using the following guidelines for causality and grading severity. AE's related to the allergy injection will not be captured in this study.

AE Relationship to Study Distraction Technique Guide

Relationship to Study Distraction Technique	Comment
Definitely	An event that follows a reasonable temporal sequence from administration of the study distraction technique; that follows a known or expected response pattern to the suspected study distraction technique; that is confirmed by stopping the use of the study distraction technique; and this is not explained by any other reasonable hypothesis.
Probably	An event that follows a reasonable temporal sequence from administration of the study distraction technique; that follows a known or expected response pattern to the suspected study technique; that is confirmed by stopping the use of the study distraction technique; and that is unlikely to be explained by the known characteristics of the subject's clinical state or by other interventions.
Possibly	An event that follows a reasonable temporal sequence from administration of the study distraction technique; that follows a known or expected response pattern to that suspected study distraction technique.; but that could readily have been produced by a number of other factors.
Unrelated	An event that can be determined with certainty to have no relationship to the study distraction technique.

AE Severity Grading

Severity (Toxicity Grade)	Description
Mild (1)	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
Moderate (2)	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate Instrumental activities of daily living (e.g., preparing meals, using the telephone, managing money)
Severe (3)	Severe or medically significant but not immediately life threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living (e.g., bathing, dressing, feeding self, using toilet, taking medications)

Discontinuation and Replacement of study participants

A child has the right to withdraw from study participation prior to the completion of Visit 2. Early withdrawal participants will be replaced one to one.

Participant ID assignment

The study participants will receive a Participant ID at Visit 1 which will be used for all data collection. The Participant ID used will range from 001 to 100. If a study participant withdraws before the completion of Visit 2, the Participant and associated group assignment will be replaced. Replacement Participant ID's will be sequential beginning with the number 101.

Data Collection

Medication administration data collected will be limited to the participant's current immunotherapy vial and dosing, distraction method utilized, site of the application method and, if applicable, antihistamine use and pain medication use. Demographic data collected will be age, race and gender. Symptom and health data point collection will target allergy injection reactions and the presence of allergic rhinitis, asthma and atopic dermatitis. (Refer to Attachment V).
Pain perception data will be collected from both the child and parent using facial and numeric pain scales (Refer to Attachment IV).
All data collected will be entered into an EXCEL data collection tool and stored on password protected, secure computers. The data will accessible only to the investigators and research coordinators in the study.

Data Analysis

Quantitative component data collected and evaluated for this study will include the number of patient participants within the allergy department, randomized interventions used, diagnoses including allergic rhinitis, asthma and atopic dermatitis, immunotherapy medication and dose, antihistamine and pain medication utilization, patient and parental pain scores, adverse reactions, age, race, and gender.
Quantitative component data collected for this study will be extracted into Microsoft Excel spreadsheets and analyzed using Excel functions. Target population demographic characteristics will be analyzed using descriptive statistics by the principal investigator with the level of significance set at <0.05.
All information collected as part of evaluating the impact of this study will be aggregated data from the project participants and will not include any potential patient identifiers. Participant confidentiality will be assured by coding the participants using individual identification numbers for any analysis activities occurring outside of the electronic health record. This information will be stored in accordance with Nemours IRB policies and procedures. The Excel files containing codified data without protected health information (PHI) will be stored in password protected files at Nemours, on a password protected desktop computer in a locked office space accessible only by the principal investigator and study designees. The risk to patients participating in this project will be no different from the risks of patients receiving standard care.

Informed Consent Process

- Children who meet study criteria will be identified by Principal Investigator or Co-Investigator in the allergy clinic.
- Parents/guardians and child will be given an overview of the study, participation requirements, and complete information on being a voluntary participant in a research study. They will be given an opportunity to read the consent form, have questions answered and decide if they want their child to participate.
- If both the parent and child are interested in participating in the study, one parent/legal guardian will be asked to sign a Parental Permission and Consent Form.
- Children between the ages of 7 and 17 who verbalize understanding and are agreeable to the Assent information and study expectations will be asked to sign a Child Assent or Adolescent Assent Form.
- The Principal Investigator, Co-Investigator or Research Coordinator obtaining consent will witness the parent and child signatures, will sign both documents and provide copies of the signed consent/assent to the parent and child.

Participating Sites

The study will be conducted at Nemours Children's Specialty Care in the pediatric allergy clinics locations:

- Jacksonville Downtown
- Jacksonville South
- Fleming Island

Literature Cited

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Vessey JA, Carlson KL, McGill J. Use of distraction with children during an acute pain experience. *Nursing Research*. 1994;43(6):369–372

Cohen LL, Blount RL, Cohen RJ, Schaen ER, Zaff JF. Comparative study of distraction versus topical anesthesia for pediatric pain management during immunizations. *Health Psychology*. 1999;18(6):591–598.

Attachments:

I – Shot Blocker

ShotBlocker®

ShotBlocker®

ShotBlocker instantly reduces needle pain and anxiety associated with injections.

ShotBlocker distracts and comforts patients of all ages receiving intramuscular or subcutaneous injections to lessen the perceived pain and anxiety. ShotBlocker is an innovative, patented device that is both simple and easy-to-use.

Features and Benefits

- **Simple Design** – One ShotBlocker per patient is all you need.
- **Easy to Use** – Just press ShotBlocker firmly over the injection site and give the injection through or near the opening.
- **Immediate Effect** – The contact points on the underside create an immediate distracting effect. No waiting for topical anesthetics to take effect.
- **Versatility** – Useful in intramuscular injections, subcutaneous injections and other procedures that include a painful needle poke.
- **Cost Benefit** – Less costly than anesthetic creams or freezing sprays. (Faster, too.)
- **Smiles On Your Patient's Faces** – Invented by a pediatrician to lessen the pain and anxiety experienced by his patients.
- **It Really Works!**

Product Offering

#8050 - Box of 50

#8100 - Box of 100

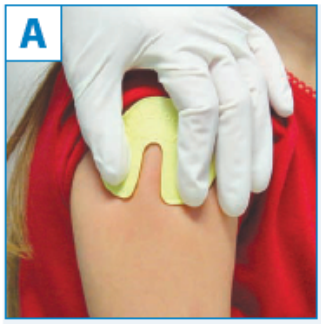
BIONIX® MEDICAL TECHNOLOGIES

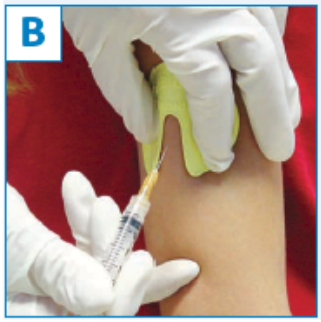
Phone 1.800.551.6810 *Fax* 1.800.455.5678 *Web* www.BionixMed.com

How ShotBlocker® Works

ShotBlocker is a novel application of the gate control theory of pain management. ShotBlocker is a flexible plastic disk that has a number of blunt contact points on its underside. When pressed firmly against the patient's skin at the injection site, ShotBlocker saturates the sensory signals distracting the patient from the pain signals caused by the needle poke.

How to Use





1. Select the injection site and prep the skin as usual.
2. Hold ShotBlocker so that the blunt contact points touch the patient's skin at the injection site.
3. Press ShotBlocker FIRMLY against the skin. (A)
   DO NOT MOVE OR REMOVE SHOTBLOCKER UNTIL THE INJECTION HAS BEEN COMPLETED.
4. Immediately administer the injection in the usual manner through or near the central opening of ShotBlocker. For subcutaneous injections, angle the needle as needed to give the injection. (B)
   IF MORE THAN 20 SECONDS ELAPSE BETWEEN THE PLACEMENT OF SHOTBLOCKER AND THE INJECTION, COMPLETELY REMOVE SHOTBLOCKER FROM THE SKIN. REPEAT THE PROCESS BEGINNING WITH STEP 2.
5. After you have completed the injection and withdrawn the needle, remove and discard ShotBlocker.

ISO 9001:2008 CERTIFIED

5154 Enterprise Blvd. • Toledo, Ohio 43612
Phone: 800.551.6810 • Fax: 800.455.5678
www.BionixMed.com

BIONIX® MEDICAL TECHNOLOGIES

II – Buzzy Bee I (*with ice pack-wings*) and Buzzy Bee II (*without ice pack-wings*)

Buzzy®
DRUG FREE PAIN RELIEF

Developed by a physician, Buzzy® is a reusable device for minor aches and pains.

Buzzy® is a personal consumer use product intended to be used by a single user.

Bring with you to the doctor; or use at home for:

- STINGS
- SPLINTERS
- SHOTS

BuzzyHelps.com

Home Use Rev. 02.01.17

INDICATIONS FOR USE:
Controls pain associated with injections (venipuncture, IV starts, cosmetic procedures) and the temporary relief of minor injuries (muscle or tendon aches, splinters and bee stings). Also intended to treat myofascial pain caused by trigger points, restricted motion and muscle tension.

Fold Wings and STORE IN FREEZER. Wings must be frozen solid for best effect. Personal Buzzy® units coms with universal personal Ice Wings & Comfort Strap.

WARNINGS: For intended use only • Direct or prolonged application of ice could vasoconstrict or alter lab values.

CONTRAINDICATIONS: Do not use in the presence of unexplained calf pain. Consult a physician. • This device should not be used over swollen or inflamed areas or skin eruptions. • Do not place directly on a thermal burn • Do not use ice pack with underlying sensitivities to ice or cold (e.g. Sickle Cell Disease, Raynaud's Disease).

CAUTIONS: Store in a cool, dry place.

1

ICE WINGS:
Wings will stay frozen 10 minutes at room temperature. For best pain relief, the Wings must be frozen solid to avoid absorbing vibration.

Face the blue or smooth side of the Wings toward the skin for more numbing power. If sensitive to cold, the soft side of the wings should face the skin.

Tip: For long procedures or for medications that burn or sting, prepare additional Wings.

Store folded Wings in freezer. Gel inside Wings is a non-toxic, safe, food-grade product that may deteriorate if not stored properly.

Note: To transport, place the Wings between the Cold-To-Go bag blue ice inserts (sold separately), or between 2 commercial cold packs (sold separately) to maintain frozen temperature.

COMFORT STRAP:
Our Comfort Strap is a reusable, single-handed tourniquet, smooth and pinch free. To use, **1.** Loop the Comfort Strap around the arm, passing one end through the slit in the other. **2.** Hold the slit and pull the other end through until the desired tension is reached, then release the slitted end. **3.** To lock the Comfort Strap in position, release the tension from the long end. **4.** To release, simply pull gently on the short end and the Comfort Strap will fall away.

2

DIRECTIONS FOR USE:


Immediately before use, remove the Wings from the freezer and attach behind Buzzy® on the hook. Activate by firmly pressing button on top of Buzzy®. Press a second time to turn Buzzy® off.

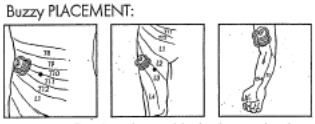
Buzzy® has an energy saving automatic shut-off after 3 minutes of constant use. Simply press the button on top of Buzzy® to reactivate vibration.

Buzzy comes with a silicone Comfort Strap to hold Buzzy in place on extremities. **1.** Loop the Comfort Strap around the arm, passing one end through the slit in the other. **2.** Hold the slit and pull the other end through until the desired tension is reached, then release the slitted end. **3.** To lock the Comfort Strap in position, release the tension from the long end. **4.** To release, simply pull gently on the short end and the Comfort Strap will fall away.

Use Buzzy® only on clean, unbroken skin. The stripes on Buzzy®, or bottom end should be closest to the procedure, and the head on Buzzy® and switch farthest away.

Tip: For best results, center the bigger rounded end of Buzzy® directly next to the pain.

3

Buzzy PLACEMENT:


The Buzzy® physiologic blockade works best when placed "between the brain and the pain" in the same nerve area as the pain. On arms and shoulders, nerves run from fingers to shoulders to the spine. For the chest and back, the nerves run from the center of the chest or stomach horizontally to the back. On the thighs, the nerves run diagonally from the inner thigh around to the back to the spine.

For children: For best results, let children hold Buzzy® in advance for familiarity, and let them choose whether or not to use the ice pack.

4

For shots: Switch on to activate the vibration, and then place Buzzy® on the site of the shot. Leave for 15 seconds for surface shots - 60 seconds for deeper injections. Immediately before cleaning the site, move Buzzy® proximal (closer to the head) to the pain location, and press in place throughout cleaning and getting the shot.

For children who get their shots sitting up, a parent can put an arm around the shoulders to hold Buzzy® for them.

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For injections in the stomach: Place Buzzy® lateral to the shot (i.e., belly button, the shot, and then Buzzy®.

For Aches and Pains:
Apply directly to sore muscles for maximum of 10 minutes. Hold in place or attach with strap. Buzzy® has an energy saving automatic shut-off after 3 minutes of constant use. Simply press the button on top of Buzzy® to reactivate vibration.

For additional placement information, please visit: bzy.fyi/howto

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For finger sticks or splinter removal: Switch on to activate the vibration, and then press Buzzy® on the palm with the bottom end toward the finger. Leave in place throughout cleaning and doing the procedure.

For burning or itching: Like any cold and warm therapy application, Buzzy® can be helpful for burning or itching. For insect bites or medications that cause burning or itching, take frozen Wings and massage the vibrating Buzzy®/Wings combination directly on the site. Rub or press in place until the area feels better. Do not place Buzzy® directly on a thermal burn.

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For IVs or phlebotomy:
Switch on to activate the vibration, and then place Buzzy® proximal (above) to the pain location. Press in place or tuck under tourniquet before immediately cleaning and obtaining access. Pass any tourniquet through slot to secure Buzzy® to arm. Do not put directly on site of access.

8

CLEANING:
Buzzy® is a personal consumer product intended to be used by a single user. Buzzy® may be cleaned with alcohol based sanitation wipes. Do not autoclave. Do not immerse in liquid. Soiled wings should be disposed of and replaced.

BATTERIES:
Buzzy's batteries will last at full strength about 20 hours. For best pain relief, replace batteries when vibration weakens. Unscrew the back using a Phillips head screwdriver to remove back panel. Buzzy® is powered by 2 alkaline AAA batteries. Remove batteries if Buzzy is not being used for extended period of time.

If you are having trouble powering on your Buzzy® unit, please open up your Buzzy®, remove the batteries, bend the battery tabs inward, and replace the batteries.

9

TROUBLESHOOTING:
When used with care, Buzzy® should last years. If Buzzy® is dropped repeatedly, however, the metal that holds the batteries in place can bend. If Buzzy® fails to function after a fall, try pinching battery clip in to restore contact.

HOW TO ORDER /ADDITIONAL INFORMATION:
Please visit our website BuzzyHelps.com for a complete list of FAQ's, other pain management tips, how-to videos, accessories, replacement parts, and more!

GUARANTEE:
Previous medical history and intrinsic physiologic differences may make Buzzy® less effective for some people. If not completely satisfied, return within three months to place of purchase for a full refund, or contact us at the address below.

MMJ Labs
195 Arizona Ave NE, LW 08
Atlanta, GA 30307, U.S.A.
BuzzyHelps.com info@mmjlabs.com
877.805.2899

US Patented British Patent No. 2455695
RM-1910, 1248-064-500200, 1248-064-5001-00

Authorized European Representative
MPC INTERNATIONAL S.A.
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L-2449 LUXEMBURG
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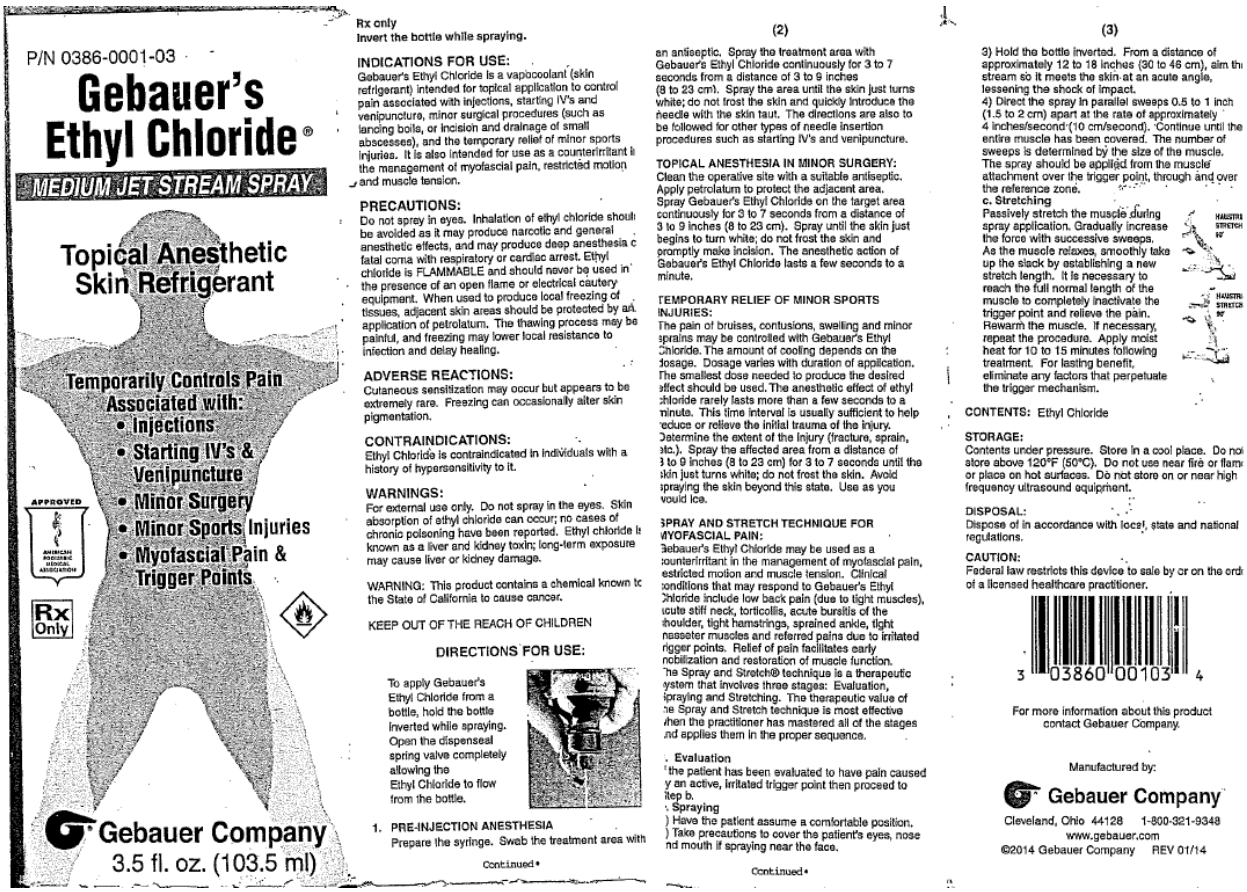
Type B Applied Part

10

III – Ethyl chloride spray



IV – Data Collection Instruments for pain rating scales – (a) facial (b) numeric

Wong-Baker FACES® Pain Rating Scale

0	2	4	6	8	10
No Hurt	Hurts Little Bit	Hurts Little More	Hurts Even More	Hurts Whole Lot	Hurts Worst

Instructions for Usage

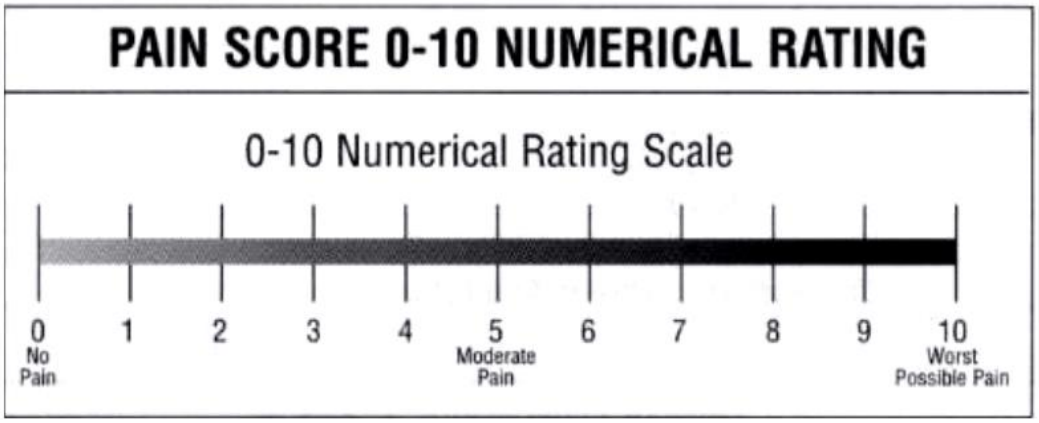
Explain to the person that each face represents a person who has no pain (hurt), or some, or a lot of pain.

Face 0 doesn't hurt at all. Face 2 hurts just a little bit. Face 4 hurts a little bit more. Face 6 hurts even more. Face 8 hurt a whole lot. Face 10 hurts as much as you can imagine, although you don't have to be crying to have this worst pain.

Ask the person to choose the face that best depicts the pain they are experiencing.

Numeric Rating Scale

PAIN SCORE 0-10 NUMERICAL RATING



Instructions: Parent/ Guardian, please circle what pain level YOU percieve YOUR child to be in just after receiving their subcutaneous Immunotherapy (allergy shots).

PPAST v1.0-Numeric Rating Scale

V – Parent Questionnaire: Demographic – Health – Treatment Questionnaire

PPAST study Source Document Worksheet – *Attachment V*
PI: Jennifer Pfieffer, MSN, APRN, PCNS-BC, CPEN

Participant ID: _____ Visit 2: ____/____/_____

Demographic – Health – Treatment Questionnaire: Parent Interview

Investigator will interview the parent to complete this questionnaire.
Questionnaire to be completed prior to administering allergy shot.

1. How old is your child? _____
2. What race / ethnicity is your child? _____
3. What gender is your child? _____
4. How long has your child been on allergy shots? (Estimate in weeks, months or years) _____
5. What is the number of allergy shots your child will receive today? _____
6. What color vial is your child on? _____
7. What is your child's dose for the allergy shot? _____
8. What kind of allergy shot is your child receiving – venom / fire ant / environment? _____
9. Has your child ever had symptoms after receiving allergy shots? _____

   If yes, explain: _____

   _____

10. Has your child taken any medication for **pain** today? _____

    If yes: What was the name and dose of the pain medication? _____

    For what reason was the medication given? _____

    What time was the medication given? _____

11. Does your child use **antihistamine** medications? _____

    If yes: What was the name and dose of this medication? _____

    How often is the medication given? _____

    What time was the medication given? _____

11. Please check the ☐ if your child has any of the following symptoms:

☐ Allergic Rhinitis ☐ Asthma ☐ Atopic Dermatitis

_____ _____:_____ ____/____/_____
Investigator Signature *Time form completed* *Date form completed*

V1.0 – 15Dec18