Group 6-Ametop-Louis Scheepers

Primary Hypothesis: Ametop plus vapocoolant spray reduces the discomfort of intravenous insertion in pediatric patients compared to Ametop alone.

Side Hypotheses:

- **Provider Experience and IV Attempts**: Provider experience (categorized as Resident or Anesthetist) influences the number of IV attempts, with less experienced providers, such as Residents, having a higher number of attempts compared to more experienced ones like Anesthetists, within each age group.
- **Side Effects**: The use of Ametop, either alone or in combination with vapocoolant spray, results in a low incidence of side effects such as itchiness and edema in pediatric patients, with no significant difference in the frequency or severity of these side effects between the two treatment groups. Dr. Scheepers realized that this was not part of the original study and he noted that it is alright if this is more of a descriptive finding or some charts.
- **Age Groups (may not have enough data to perform test)**: There are significant differences in pain scores across different age groups in pediatric patients undergoing intravenous insertion.

Age-Based Analysis: Consideration of splitting participants by age to determine if older children respond more accurately to the scale. The study includes children aged 5 to 16 years. There are some concerns that younger children didn't fill out the "FACES" scores correctly compared to older children. For a more detailed analysis, the group could be subdivided, for instance, into 5 to 9-year-olds and 10 to 16-year-olds. Dr. Scheepers didn't have any specific age groups in mind.

Definition of Significant Difference: The 20% change relates to the improvement target over existing treatments. This 20% change was used in calculating the sample size to get the statistical power they wanted. Later on, when we are doing our hypothesis testing, it will be done under the regular 5% significance.

Statistical Analysis: T-tests.

Criteria for Observer's Scoring: The observer scores the patient's reaction to the intravenous insertion on a 3-point scale ("none", "slight", and "severe"), looking for visible signs of discomfort or pain such as crying, withdrawing, or verbal expressions of pain.

Study Design Challenges: Issues with potential inaccuracies in younger children's responses and insufficient participants in each age group for detailed analysis. Issue with the target response, the "FACES" score should match with the observer's scoring. "FACES" scores are the primary target response to look at, however, it should be validated with a similar score by the observer.

Randomization Column Meaning: "1" in the randomization column indicates the control group (Ametop alone), and "2" indicates the study group (Ametop plus vapocoolant spray).

Columns that are controlled variables:

- Elective surgery requiring IV?
- ASA I or II?
- Aged 5-16?
- Any allergies to Ametop, Pain Ease, or Tagederm adhesive?
- Ametop placed at least 30min before estimated IV start time?
- Receiving sedative pre-medication / anxiolytics?
- Needle phobia?
- Planned inhalation induction?
- Developmental delay or unable to interpret FPS-R?
- Duration of Ametop -> must be between 30 to 60 minutes
- Time between Ametop and skin puncture -> must be less than 30 minutes (the effectiveness of spray decrease over time)

Time Influence on Discomfort Outcome: It is suggested to analyze the influence of "Duration of Ametop" and "Time between Ametop and skin puncture" on discomfort outcomes, as these factors might impact the treatment's effectiveness.

Handling Withdrawn Patients in Analysis: Patients who withdrew after consent but still completed parts of the experiment create missing values in several measures. Withdrawn patients should be excluded, especially if they did not follow the procedure correctly or fully. Deciding whether to exclude withdrawn patients entirely or only in specific circumstances is crucial, as this could impact the study's outcomes.

Impact of Needle Gauge: "22" and "24" in needle gauge represent the size of the needle used for the procedure. "22" is slightly bigger than "24", which could cause varying levels of pain.

Integration of Side Effects Column: Side effects are considered but are not a primary focus of the study. Side effects, particularly itchiness and swelling, should be considered descriptive elements. Both groups received Ametop, so the comparison of side effects is not between study and control groups but more about the incidence and nature of side effects overall.

Clarification on Target Response Variable: The two measures - the observer's scoring and the patient's FPS-R score - are meant to support each other. The observer's scoring serves as a verification for the patient's self-reported pain. These measures might need to be analyzed separately but in conjunction to understand discrepancies and correlations.

What's next: Dr. Scheepers will email us references that they used in the study, the "FACES" scoring system, and the exclusion criteria.

Individual

Maggie Ruan: From the client meeting, Dr. Scheepers mentioned that we do not need to analyze by age group to see if there is any difference in pain scores as there may be various confounding variables that would affect the study and there may not have enough data points for us to perform the experiment as

well. Moreover, the durations recorded in the spreadsheet are controlled variables which we do not need to worry about in the study.

Yimin You: An important conclusion from the first discussions with Dr. Scheepers regarding the research project was the importance of accurately addressing and interpreting the various factors that may affect the result of the study. This includes understanding the impact of variables such as provider experience, age group, and duration between Ametop use and IV administration. Also, the design of this study focused on comparing the effectiveness of Ametop alone and Ametop plus vapocoolant spray in reducing discomfort at the time of IV insertion in child patients, so it was important to analyze these factors accurately. More and more, we need to integrate the different data points, such as observer scores and patient FPS-R scores, which also requires careful consideration to make sure that the considerations drawn are robust and reliable.

Runhe Guo: Dr. Scheepers mentioned that there are withdrawn patients whom we might need to exclude from the analysis, as they did not fully or correctly follow the procedure. He also raised concerns about potential inaccuracies in younger children's responses to their FPS-R scores. This is because they might perceive the assessment more as a game, thus skewing the results.

Fabiola Grace: An important conclusion drawn from this meeting involves clarifying the target response. We are utilizing two measures: the observer's scoring and the patient's FPS-R score. It is important to integrate both measures into our model and testing procedures. The primary focus is on the patient's FPS-R score; however, some patients may struggle to comprehend the scoring process, especially considering their age. Consequently, a secondary target response was introduced - a nurse observed and scored the patient's reaction. To ensure accuracy, these two measures should align, and we must proceed with caution if discrepancies arise. One potential solution is to conduct two tests: one incorporating all data and another using only a subset where the observer's scoring and the patient's FPS-R score match. To create this subset, we must also match the scales (FPS-R score is on a 10 point scale and observer's scoring is on a 3 point scale).