

Non-Inferiority Study to Compare Instructional Videos for Breath-Actuated Inhaler Technique

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Background

- Previous studies show 87% of patients make at least one error in inhaler technique
- Use of videos is an effective educational method to explain the correct inhaler technique to children
- Little evidence exists regarding breath-actuated inhaler education efficacy
- The University of Maryland School of Pharmacy (UMSOP) video was created in response to mismatched instructions and demonstrations in manufacturer instructional videos on inhaler technique and to simplify instructions for patients with low health literacy

Objectives

Primary

- Demonstrate the non-inferiority of a UMSOP breath-actuated inhaler instructional video's ability to teach children the correct inhaler technique as compared to the manufacturer's videos for ProAir RespiClick and Qvar RediHaler

Secondary

- Determine children's preferences among the video instructional material

Methods

Study Design

- Prospective convenience sample study conducted at the UMSOP, regional libraries, and health fairs
- Participants recruited using online advertisements and in-person flyers
- Both parental consent and participant assent were obtained, participants were paid \$20
- Randomized 1:1:1 to watch instructional videos (UMSOP video, ProAir RespiClick, or Qvar RediHaler)
- After watching video 1, participants verbalize all steps they recalled and then demonstrated inhaler technique using placebo breath-actuated inhaler and were scored by a blinded researcher using Breath-Actuated Device Assessment Tool (viewable via Study Tools QR code, supp. 1)
- This tool was used to determine if participants received or lost a dose of medication
- After technique scoring, participants answered 6 questions (Qualtrics Survey, supp. 2)
 - Likeability ranked using a 5-point Likert faces handout (supp. 3)
 - Inhaler Steps Cue Sheet (supp. 4) provided for participants to identify which steps, if any, were hard to understand
 - Research team documented verbatim qualitative feedback on video impressions
- Participants watched remaining 2 videos and answered feedback questions after each
- Participants age and race/ethnicity were completed by the caregiver at the end of the visit

Eligibility Criteria	
Inclusion	Exclusion
<ul style="list-style-type: none"> • Children 5 to 11 years old 	<ul style="list-style-type: none"> • Asthma diagnosis • Used an inhaler within the last year • Unable to speak or understand English • Lactose allergy



Statistical Analysis

- Goal sample size (each group = 37, a total of 111) to provide 80% power using a one-sided test at the 0.025 significance level
- An ANOVA and Fisher's exact test were run to assess the associations between age and gender and three videos
- A two-sample t-test for the noninferiority was performed to evaluate the primary objective
- Friedman ANOVA was used to assess any difference in likeability scores for the three videos

Contact and Disclosures

- Anyelis N. Rosario, PharmD Candidate, anyelis.rosario@umaryland.edu
- No financial disclosures

Results

Table 1. Demographic Summary

Demographic	n=26
Age, n (IQR)	7 (6,9)
Female, n (%)	14 (53.8)
Race/Ethnicity, n (%)	
Asian	3 (11.5)
Black or African American	4 (15.4)
Multi-racial*	6 (23.1)
White, non-Hispanic	8 (30.8)
Prefer not to say	5 (19.2)

*Participants were able to designate more than one identifier. IQR: Interquartile range

Figure 1. Blinded Evaluator Score as Percent Correct for Total Participants by Video

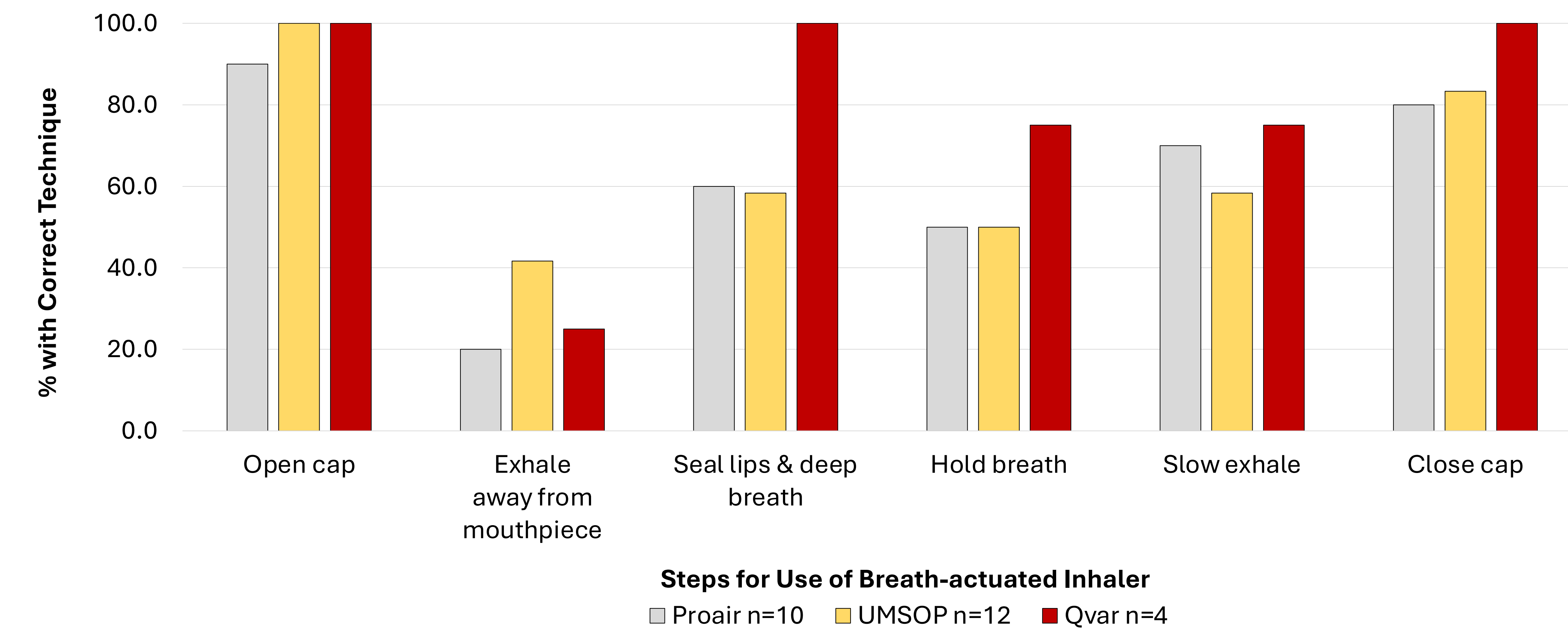


Table 2. Comparison of Age and Gender Across Videos

Characteristic	UMSOP (n=12)	Proair (n=10)	Qvar (n=4)	p value
Age(year), mean (SD)	7.4 (2.2)	7.5 (1.6)	8.8 (1.9)	0.5
Age(year), n(%)				0.3
5-6	6 (50)	3 (30)	1 (25)	
7-9	3 (25)	6 (60)	1 (25)	
10-11	3 (25)	1 (10)	2 (50)	
Gender, n (%)				0.9
Female	6 (50)	6(60)	2(50)	
Male	6 (50)	4 (40)	2 (50)	

SD: Standard deviation

Figure 2. Likeability Score as Percentage of Participants by Video

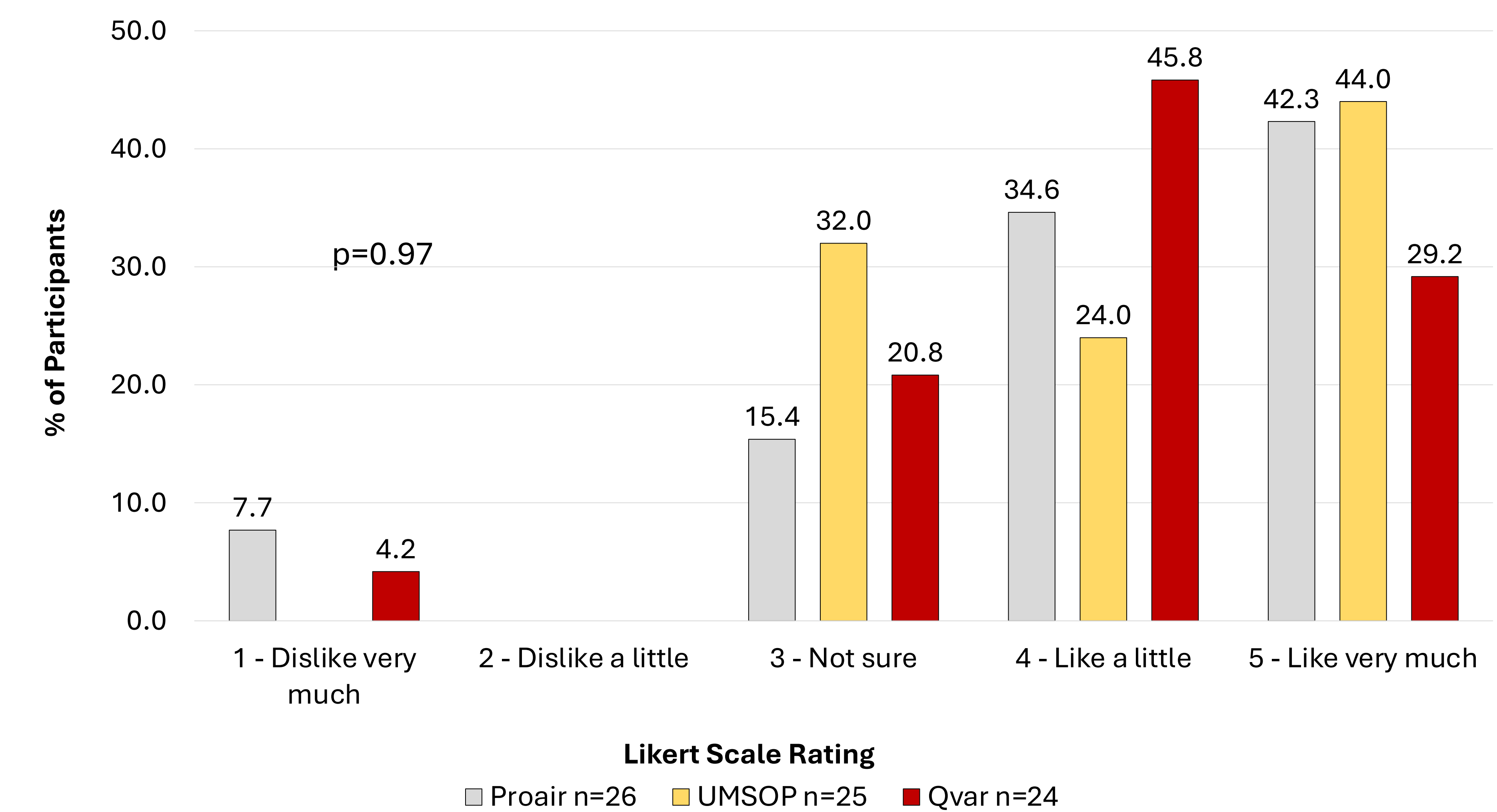


Table 3. Non-inferiority Test

Non-inferiority margin	Video, mean total score (SD)		Adjusted p value ¹
1	UMSOP (n=12)	Proair (n=10)	0.3
	3.8 (1.8)	3.9 (1.8)	
	UMSOP (n=12)	Qvar (n=4)	1.0
2	UMSOP (n=12)	Proair (n=10)	0.02
	3.8 (1.8)	3.9 (1.8)	
	UMSOP (n=12)	Qvar (n=4)	0.3
	3.8 (1.8)	4.8 (1.0)	

¹Adjusted p value: Bonferroni's correction was applied

- Only 23% (6/26) had a perfect score on the breath-actuated device assessment tool
- 19.2% (5/26) held the breath-actuated device upside down while using it and based on the device mechanism would impact the dose delivery
- 3.9% (1/26) tipped the mouthpiece toward the floor after opening the cap potentially resulting in partial loss of the dose
- 19.2% (5/26) breathed out into the mouthpiece before inhaling which would impact the dose delivery
- 80% (8) Proair, 75% (9) UMSOP, and 50% (2) of Qvar potentially lost the dose due to errors in technique

Interim Summary

- UMSOP video is non-inferior to Proair. More patients are needed to determine if the UMSOP video is non-inferior to Qvar. It was clear that watching a video one time is not enough education to teach most children the correct technique for this device.
- There was no statistical difference in likeability for the 3 videos despite our video removing kid-centric effects such as cartoons and children singing.
- Enrollment continues with the goal of reaching the power estimate. In the future, the team will evaluate the health literacy differences in the 3 videos.