VALIDATION OF THE STUDY MEDICATION SATISFACTION QUESTIONNAIRE (SMSQ). A MEASURE OF MEDICATION SATISFACTION DESIGNED FOR INDIVIDUALS TAKING PRE-EXPOSURE PROPHYLAXIS (PrEP) MEDICATION FOR HIV

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OBJECTIVES

The Study Medication Satisfaction Questionnaire (SMSQ) status version is a new self-completion measure designed specifically for studies investigating the value of medication for the prevention of HIV (pre-exposure prophylaxis: PrEP) where participants do not have HIV. Adapted from the HIV Treatment Satisfaction Questionnaire (HIVTSQ)[1,2,3] the SMSQs includes all aspects of treatment included in the HIVTSQ (e.g. convenience, side effects), however removes all mention of the medication being a treatment for HIV. The current SMSQ is designed for adults but an SMSQ for teenagers with HIV (not all of whom are yet aware of their HIV status) is now being developed. The objective of the present poster is to report on the psychometric evaluation of the SMSQ for adults.

METHODS

Design: Data were from week 18 of the ÉCLAIR trial (NCT02076178): a phase IIa, randomized, two-arm, double-blind placebo-controlled clinical trial evaluating safety, tolerability and acceptability of cabotegravir long acting (LA) injectable formulation. Participants (n=112) included healthy men (including men who have sex with men) not at high risk of acquiring HIV, randomly assigned (5:1) to receive cabotegravir (mean age 35.35 [SD 11.81] or placebo (mean age 33.90 [SD 11.57]). By week 18, participants (n=91) had received a once-daily oral cabotegravir (30mg) or placebo tablet for 4 weeks, (n=21) and two intra-muscular injections of cabotegravir LA (800mg) or saline placebo (each at weeks 5 & 17).

Measures: Study Medication Satisfaction Questionnaire (SMSQ)

The SMSQ is an 11-item measure that includes a range of medication satisfaction topics.

Items are rated from 6 to 0. Higher scores indicate greater satisfaction (e.g. 6 'very satisfied' to 0 'very dissatisfied').

The questionnaire also includes an open text box item for participants to note any aspects of the study medication causing either satisfaction or dissatisfaction, not covered by the questionnaire.

Analytic Approach: Data structure and underlying construct/s were explored using exploratory factor analysis (EFA).
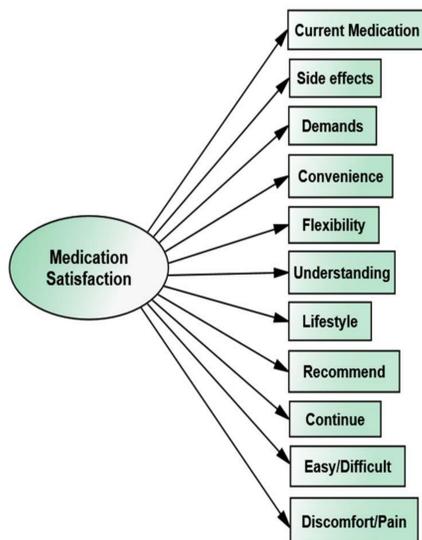

Figure 1: Item content and factor structure of the SMSQ as revealed by EFA

Exploratory factor analysis was conducted in two stages. Initial analyses were carried out using a principal components analysis (data reduction, retaining as much information as possible). Components were considered for retention using three decision rules: Kaiser's criterion (eigenvalues >1), inspection of the Scree plot and Horn's parallel analysis. Once the number of components had been identified, a fixed factor EFA (principal axis factoring [PAF]) was run (examining data structure and underlying construct/s). Factor loadings focused on identifying the 'cleanest' factor structure (item loadings >0.40, no or few item cross-loadings [>0.32], and no factors with fewer than three items).

Cronbach alpha was used to assess internal consistency reliability (>0.7).

Content validity was checked using the open-text item of the SMSQ.
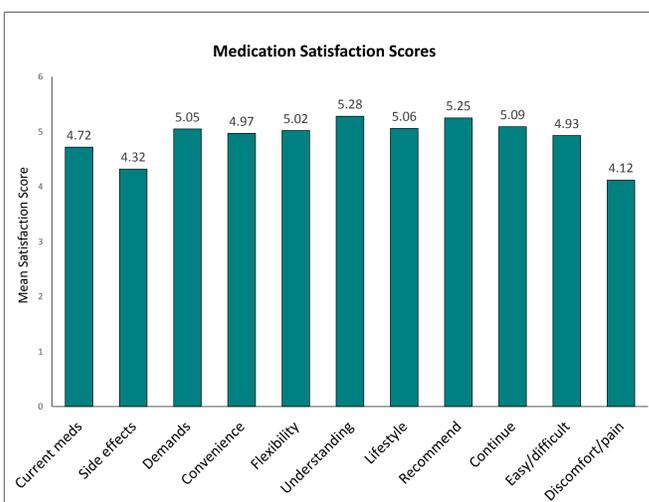
RESULTS

Descriptive data: Mean medication satisfaction scores demonstrated a high level of satisfaction across all aspects of the medication (Figure 2).

The highest level of satisfaction was noted for understanding of the medication, followed by a willingness to recommend the medication to others.

The aspect of the medication that received the lowest mean satisfaction score was discomfort or pain.

Figure 2: Medication satisfaction mean scores (Week 18)

RESULTS

Exploratory Factor Analysis: Exploratory factor analysis of the 11-item SMSQ revealed a clean one-factor structure (Table 1, Figure 1) explaining 65% of the variance in medication satisfaction. All items loaded >0.65. Internal consistency reliability was high (alpha=0.95).

Table 1: Factor matrix for PAF forced one-factor solution for the SMSQs: Data taken at Week 18

Item Number	Aspect of medication	Factor Matrix	Communalities	Alpha if Item Deleted
1	Current meds	0.908	0.824	0.941
3	Demands	0.886	0.786	0.942
7	Lifestyle	0.853	0.728	0.943
4	Convenience	0.852	0.726	0.944
2	Side effects	0.834	0.696	0.944
10	Easy/difficult	0.810	0.656	0.944
9	Continue	0.798	0.637	0.945
11	Discomfort/pain	0.756	0.571	0.948
8	Recommend	0.739	0.546	0.948
5	Flexibility	0.733	0.538	0.948
6	Understanding	0.657	0.431	0.950
N=112				
Percentage of total variance = 64.89				
Scale Item N = 11				
Alpha = 0.950				

Exploring the easy/difficult item as a potential alternative to the demands, convenience and flexibility items: In order to explore the easy/difficult item as a potential alternative to the demands, convenience and flexibility items, a series of EFA analyses were run including Item 10 (easy/difficult) but dropping all possible combinations of Item 3 (demands), 4 (flexibility), and 5 (convenience). Overall the easy/difficult item was a stronger loading item than the demands, convenience and flexibility items, however no one combination demonstrated a superior solution. In each run, loadings were >0.63, explained variance was >60 percent, and alpha was >0.91.

It was therefore concluded that two potential options are available. If a more detailed analysis of aspects of medication satisfaction are required, the 11-item version should be chosen. However, if brevity is paramount, an 8-item version (removing Item 3: demands, Item 4: convenience and Item 5: flexible) can also be used.

Content Validity: Content analysis of the free text data revealed comments centered around three themes: pain and discomfort, side effects and time between injections (Table 2). The only topic not directly addressed within the questionnaire was a comment expressing difficulty responding to efficacy-related questions when there was a possibility the treatment was a placebo.

Table 2: Extracts taken from the free text box: Are there any other aspects of the study medication, causing either satisfaction or dissatisfaction, that have not been covered by the questionnaire?

Theme	Extract
Pain or discomfort	'The discomfort experienced is only for a short amount of time compared to the duration of the shot periods.'
	'Injection site pain seems to be determined by the skill of the injector.'
Side effects	'Soreness in joints during week of injection.'
	'Swelling, tenderness and pain.'
Time between Injections	'Very satisfied that only have to receive injection every 12 weeks'
	'The medication administration is usually painless, which is great. Also, only having to have it every 3 months is very appealing.'

CONCLUSIONS

The SMSQ is an up-to-date appropriate measure of medication satisfaction for individuals at risk of HIV infection taking PrEP medication. Psychometric analyses identified a strong, reliable one-factor structure. The questionnaire is easy to complete and simple to score. All items can be summed to produce a total medication satisfaction score. Additionally each item can be used individually to examine specific aspects of medication satisfaction and can be reported separately. Two versions of the SMSQ are available. For a more detailed analysis of medication satisfaction the full 11-item version is recommended. When brevity is paramount, an 8-item short-form (excluding demands, convenience and flexibility) can be used.

REFERENCES

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ENQUIRIES & ACKNOWLEDGEMENTS