Development and Validation of a Screening Tool to Identify Chronic Migraine (ID-CM)

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INTRODUCTION

- Despite its substantial economic and quality of life burden, chronic migraine (CM) remains under-diagnosed and under-treated[1-5]
- Though screening is a common strategy for improving diagnosis, there are no validated screening tools for individuals with CM

OBJECTIVE

- To develop and validate a self-administered screening tool for CM among individuals with severe headaches

METHODS

- A draft screening tool was previously developed by:
  - Reviewing existing instruments for migraine
  - Generating an item pool of candidate items and conducting a Delphi panel with headache experts
  - Completing cognitive debriefing interviews in individuals with CM to assess relevance and understandability of questions and response choices
- To determine psychometric properties and screening tool composition, the draft screening tool was administered via internet to severe headache sufferers identified through an online panel research company (Research Now)
  - Participants were sampled from four sources, three of which were from the Chronic Migraine Epidemiology and Outcomes (CaMEO) study: a prospective, web-based cohort study with a sample population of episodic and chronic migraine (n=28,677):
    1. Baseline over quota panel (n=1203): respondents who met criteria for migraine or CM and completed the CaMEO screening phase, but were not included in CaMEO
    2. Baseline screened out panel (n=4428): respondents screened negative for migraine and not enrolled in CaMEO
    3. Non-responder study completer panel (n=1065): subjects did not respond to the CaMEO baseline screener but responded to a non-responder study survey
    4. Research Now self-report of physician diagnosis of migraine panel (n=21,981): subjects recruited to supplement CaMEO sourced cases
  - Sample members reporting minimum headache frequency inclusion criteria (at least 5 days per month) were screened at baseline and stratified based on modified International Classification of Headache Disorders-3rd edition beta version (ICHD-3β) and Silberstein-Lipton CM (SL-CM) criteria into three headache type categories[6,7]:
    1. CM
    2. Episodic migraine (EM)
    3. Other severe headache (defined by reporting headache of any frequency but not meeting the modified ICHD-3β for migraine)
- A two-stage screening process was employed to detect cases using ID-CM
  - Stage 1: Screen for migraine among respondents with severe headache
  - Stage 2: Screen for CM among migraine cases
- A unique Item Response Theory (IRT) model was fit for each stage to determine ID-CM tool properties
  - Stage 1: IRT model for migraine screening based on symptoms factor
  - Stage 2: IRT model for CM screening based on "activities" and "making plans" factors, as well as headache frequency
  - Item characteristic curves (ICCs) facilitated item selection and elimination
- IRT models were also used to check initial ID-CM classification accuracy (extent to which a screening tool is able to accurately classify respondents into 2 categories)
  - Stage 1: Modified ICHD-3β migraine classification predicted in severe headache sample
  - Stage 2: SL-CM classification predicted in migraine sample
  - R[2] values for each model correspond to classification accuracy between ID-CM and ICHD-3β/SL-CM criteria

METHODS continued

- In the final phase of the study, phone interviews were conducted by clinicians to compare ID-CM to the "gold standard" (ie, clinician diagnosis)
  - Participants were sampled from the four sources with supplemental sampling from members of the CaMEO longitudinal cohort
  - Sensitivity and specificity were calculated to estimate agreement between ID-CM and clinical interview classification
- ID-CM scoring algorithm was developed using data gathered from the online survey and clinical interviews
- Psychometric analyses were conducted using M-plus version 7.1 (Los Angeles, CA) and sensitivity analyses were conducted using SAS version 9.2 (Cary, NC)

RESULTS

- The candidate screening tool item pool contained 27 items
- A draft questionnaire of 20 items was selected based on face validity and clinical judgment from the Delphi panel
- Cognitive debriefing interviews with CM patients confirmed that the 20 items were well understood and considered relevant in terms of how CM patients interpreted the questions and response choices, whether wording was appropriate, and whether instructions and formats were understandable
- Out of the 28,677 participants recruited for the study, the draft screening tool was administered to 1562 persons having CM (n=363), EM (n=416), and other severe headache (n=783), corresponding to a 5.5% response rate
- Stage 1 item pool was reduced based on initial IRT modeling
  - **Figure 1** shows the ICC supported item elimination (unilateral pain): slopes are weak and curves shifted to the extreme left of the distribution
  - **Figure 2** shows the ICC supported item selection (moderate to severe pain): slopes are strong, probability curves are strongly non-overlapping, and shifted high in the latent distribution

Figure 1. Representative IRT Model Supporting Item Selection: Unilateral Pain
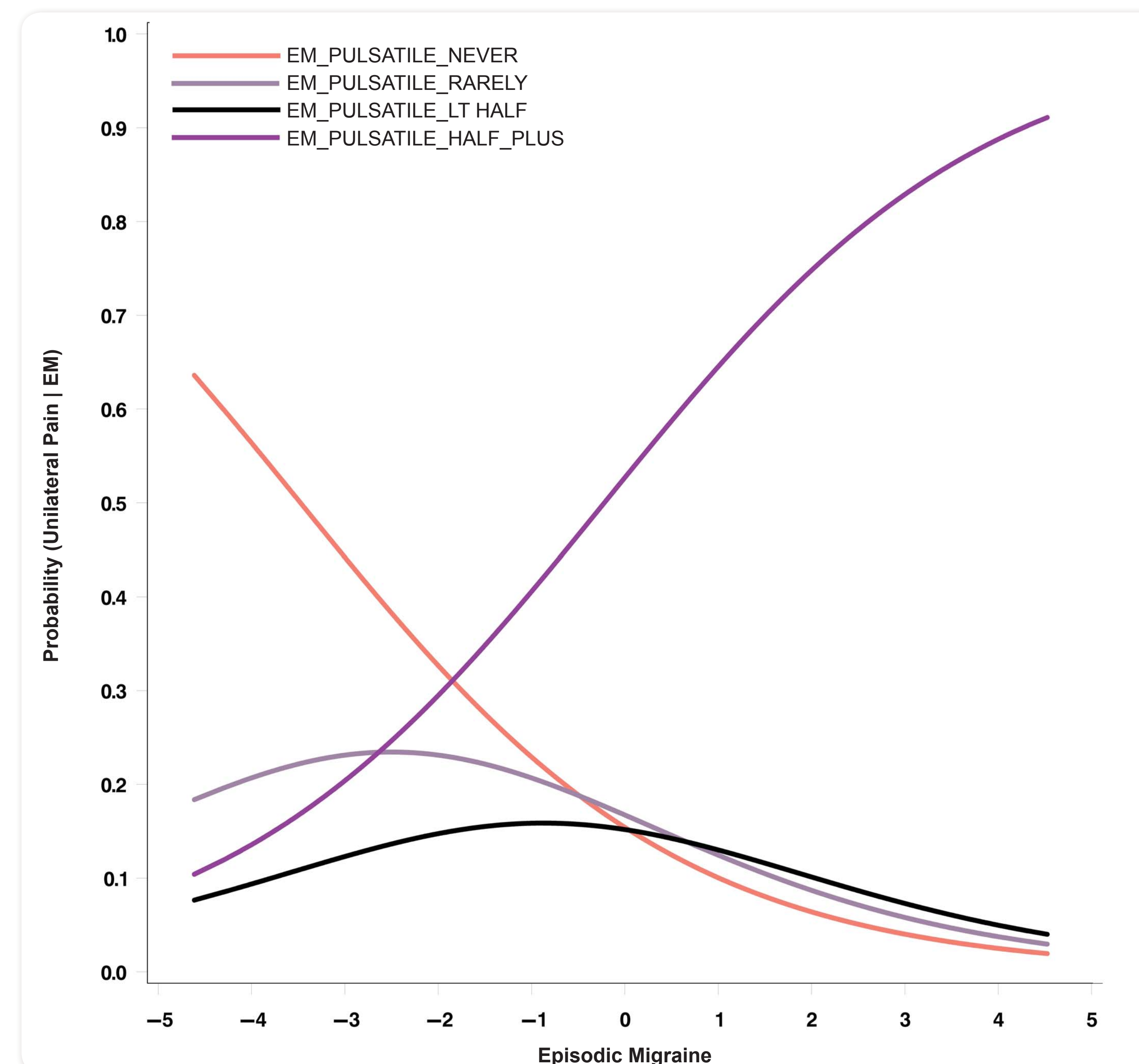
RESULTS continued

Figure 2. Representative IRT Model Supporting Item Selection: Migraine Screener Moderate to Severe Pain
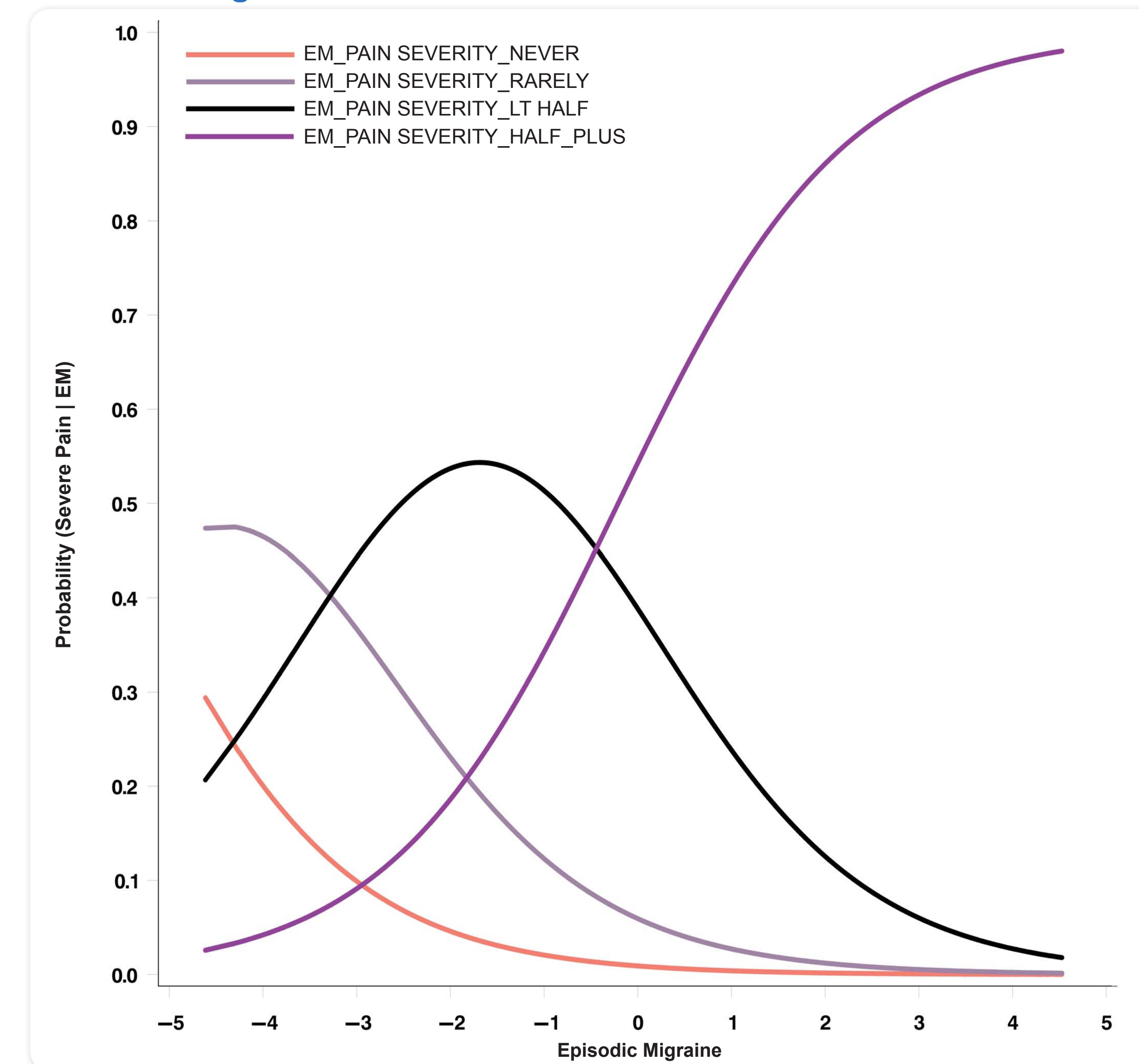
- Stage 2 item pool was not reduced, all items demonstrated strong loadings and predictive value
- After the ID-CM item pool was reduced, additional IRT models were used to check initial screener classification accuracy:
  - Stage 1 items compared to modified ICHD-3β migraine classification
  - Stage 2 items compared to SL-CM classification
- N=2923 received an invite to participate in the clinical interview phase of the study
  - The clinical interview sample at time of publication of this poster was n=111 (3.8% usable response rate), and was composed of n=32 EM cases, n=44 CM cases, and n=35 severe other headache
- ID-CM had a sensitivity of 82% and specificity of 87% when compared to clinical interview classifications (**Table 1**)

Table 1. Results Comparing ID-CM with the Gold Standard in Identifying Chronic Migraine

| Parameter	CM Defined by Clinical Interview
Sensitivity	82%
Specificity	87%
Negative Predictive Value	77%
Positive Predictive Value	90%

RESULTS continued

- The questions to be included in the ID-CM are presented in **Table 2**
- The preliminary scoring algorithm to classify CM is presented in **Figure 3**

Table 2. ID-CM Questions[a]

- How often was the pain moderate or severe?
- How often were you unusually sensitive to light (eg, you felt more comfortable in a dark place)?
- How often were you unusually sensitive to sound (eg, you felt more comfortable in a quiet place)?
- How often did you feel nauseated or sick to your stomach?
- In the last month (past 30 days), how often did your headaches interfere with making plans?
- In the last month (past 30 days), how often did you worry about making plans because of your headaches?
- In the last month (past 30 days), on how many days did you miss work or school because of your headaches?
- In the last month (past 30 days), on how many days did you miss family, social, or leisure activities because of your headaches?
- In the last month (past 30 days), on how many days did you have a headache of any type?
- In the last 3 months (past 90 days), on how many days did you have a headache of any type? If a headache lasted more than 1 day, count each day.
- In the last month (past 30 days), on how many days did you use over-the-counter medications to treat your headache attacks?
- In the last month (past 30 days), on how many days did you use prescription medications to treat your headache attacks?

[a]The final list of questions as well as the exact wording and formatting is pending final analysis

Figure 3. Preliminary Scoring Algorithm for Chronic Migraine
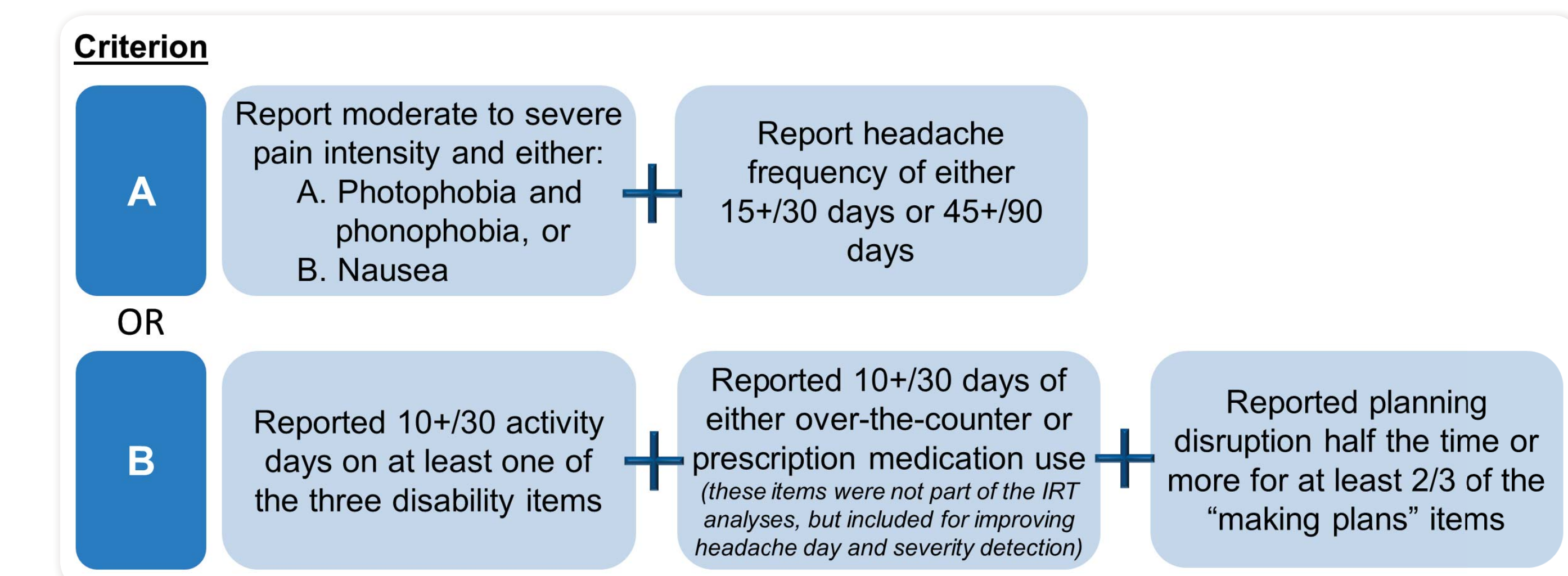
CONCLUSIONS

- A self-administered CM screening tool has been developed through existing instrument review, expert panel consensus, and psychometric work
- The ID-CM has high CM classification accuracy, ie, high capability to accurately classify respondents into CM among individuals with headaches
- Ongoing work includes reducing the ID-CM items without loss of sensitivity and specificity

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