Headache
© 2017 The Authors Headache: The Journal of Head and Face Pain
published by Wiley Periodicals, Inc. on behalf of American Headache Society
ISSN 0017-8748
doi: 10.1111/head.13028
Published by Wiley Periodicals, Inc.

Research Submissions

Family Impact of Migraine: Development of the Impact of Migraine on Partners and Adolescent Children (IMPAC) Scale

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Objective.—To describe the development of the Impact of Migraine on Partners and Adolescent Children (IMPAC) scale.

Background.—Although existing data and clinical experience suggest that the impact of migraine is pervasive and extends beyond the individual with migraine, no validated tools exist for assessing the impact of migraine on the family.

Methods.—The Chronic Migraine Epidemiology and Outcomes (CaMEO) Study is a longitudinal study of people with migraine in the United States. The Family Burden Module (FBM) of the CaMEO Study contained an item pool of 53 questions derived through literature review, clinician input, and patient focus groups pertaining to the following concepts: impact of migraine on family interpersonal relationships, activities, well-being, finances, and health-related quality of life. Respondents with migraine (ie, probands) were categorized into 4 groups based on household composition: migraine probands with partners/spouses and children (M-PC), migraine probands with partners/spouses only (M-P), migraine probands with child(ren) only (M-C), and migraine probands without a partner/spouse or child(ren) (M-O). The IMPAC scale was developed in 3 steps: (1) exploratory factor analysis and item reduction, (2) bifactor analysis, confirmatory factor analysis, and scoring, and (3) reliability and construct validity analyses.

Results.—The analysis of data from 13,064 respondents to the FBM meeting criteria for migraine yielded a 12-item IMPAC scale, with 4 items applying to all of the groups, 4 more items applying to the groups with partners (M-P and M-PC), and 4 additional items to the groups with children (M-C and M-PC). Item responses can be summed and converted into a scoring system assessing mild (<0.5 SD below mean; IMPAC scale Grade I), moderate (0.5 SD below to <0.5 SD above mean; Grade II), severe (0.5-<1.5 SD above mean; Grade III), and very severe (≥0.5 SD above mean; Grade IV) family impact. Test information curves relating to the IMPAC scale for each household type indicated adequate reliability across a large range of family burden severity (from ∼1 SD below to ∼3 SD above mean) and IMPAC scores showed moderate-to-large correlations with other validated tools (range, ± 0.38-0.52), providing support for construct validity.

Conclusions.—We developed a questionnaire to assess family burden attributed to migraine that is brief, robust, and psychometrically sound, with a simple scoring algorithm that can be applied to various household compositions. This questionnaire may be valuable in research settings to provide quantifiable data on the impact of migraine on family

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Accepted for publication November 29, 2016.

dynamics and in clinical settings to facilitate conversations about family burden as a target and a motivation for better treatment.

Key words: migraine, chronic migraine, impact, family, adolescents, scale

Abbreviations: AMPP American Migraine Prevalence and Prevention, AMS American Migraine Study, CaMEO Chronic Migraine Epidemiology and Outcomes, CFA confirmatory factor analysis, CFI comparative fit index, CM chronic migraine, EFA exploratory factor analysis, EM episodic migraine, FBM Family Burden Module, GAD-7 7-item Generalized Anxiety Disorder Assessment, *ICHD-2 International Classification of Headache Disorders, 2nd edition*, *ICHD-3b International Classification of Headache Disorders, 3rd edition (beta version)*, IMPAC Impact of Migraine on Partners and Adolescent Children, M-C migraine probands with child(ren), MIDAS Migraine Disability Assessment Scale, M-O migraine probands only (no partner/child[ren]), M-P migraine probands with partner, M-PC migraine probands with partner and child(ren), MSQ Migraine-Specific Quality of Life Questionnaire, PHQ-9 9-item Patient Health Questionnaire, RMSEA root mean square error of approximation, TLI Tucker-Lewis index

(*Headache* 2017;57:570-585)

Disclosures/Conflicts of Interest: Financial arrangements of the authors with companies whose products may be related to the present report are listed below, as declared by the authors. Richard B. Lipton, MD, has received grant support from the National Institutes of Health, the National Headache Foundation, and the Migraine Research Fund. He serves as a consultant, serves as an advisory board member, or has received honoraria from Alder, Allergan, American Headache Society, Autonomic Technologies, Boston Scientific, Bristol-Myers Squibb, CogniMed, CoLucid, Dr. Reddy's Laboratories, Eli Lilly, eNeura Therapeutics, Merck, Novartis, Pfizer, and Teva. Dawn C. Buse, PhD, has received grant support and honoraria from Allergan, Avanir, Eli Lilly, Novartis, NuPathe, Zogenix, the National Headache Foundation, and the American Headache Society. She is an employee of Montefiore Medical Center, which has received research support funded by Allergan, Alder, Avanir, CoLucid, Dr. Reddy's Laboratories, Endo Pharmaceuticals, GlaxoSmithKline, Labrys, Merck, NuPathe, Novartis, Ortho-McNeil, and Zogenix, via grants to the National Headache Foundation and/or Montefiore Medical Center. She is on the editorial board of *Current Pain and Headache Reports*, the *Journal of Headache and Pain*, *Pain Medicine News*, and *Pain Pathways* magazine. Aubrey Manack Adams, PhD, is a full-time employee of Allergan plc and owns stock in the company. Sepideh F. Varon, PhD, is a full-time employee of Allergan plc and owns stock in the company. Kristina M. Fanning, PhD, is an employee of Vedanta Research, which has received research funding from Allergan, Amgen, CoLucid, Dr. Reddy's Laboratories, Endo Pharmaceuticals, GlaxoSmithKline, Merck & Co., Inc., NuPathe, Novartis, and Ortho-McNeil, via grants to the National Headache Foundation. Michael L. Reed, PhD, is Managing Director of Vedanta Research, which has received research funding from Allergan, Amgen, CoLucid, Dr. Reddy's Laboratories, Endo Pharmaceuticals, GlaxoSmithKline, Merck & Co., Inc., NuPathe, Novartis, and Ortho-McNeil, via grants to the National Headache Foundation. Vedanta Research has received funding directly from Allergan for work on the CaMEO Study.

INTRODUCTION

The personal and societal burdens of migraine are well established.[1-9] However, chronic conditions, including migraine, are also associated with substantial burden on the family.[10,11] Although existing data and clinical experience suggest that the impact of migraine is pervasive and extends beyond the individual with migraine,[12-15] few studies have assessed the family impact of migraine.[12,13,16,17] Smith[13] reported a US-based telephone survey of 350 people with migraine from the late 1990s, focusing on the impact of headaches on relationships with partners and children. Most respondents (61%) stated that migraine had a significant effect on their family members, particularly relationships with their children; however, this study did not evaluate migraine impact from the perspective of partners and children. Lipton et al[12] reported similar results from a US- and UK-based telephone survey of 389 individuals with migraine and 100 of their partners. The third study of the family impact of migraine was the Migraine and Zolmitriptan Evaluation (MAZE) Study,[16] an international web-based survey conducted among 866 people with migraine and 162 people related to or living with people with migraine. Cohabitating family members reported a moderate or great effect of migraine on family life and social/leisure activities.

No prior study assessed the extent of migraine impact on the family using data from the person with migraine, their household partner, and their child(ren), or as a function of migraine headache type (episodic vs chronic migraine [CM]). The

Family Burden Module (FBM) of the Chronic Migraine Epidemiology and Outcomes (CaMEO) Study was designed to address these gaps. The CaMEO Study[17] was a US web-based longitudinal study that included 16,789 people with migraine, 4022 partners (including spouses and domestic partners), and 2140 children. Preliminary data from the CaMEO Study[17,18] have confirmed findings of substantial family impact of migraine from earlier studies.

Despite mounting evidence of the effect of migraine on the family, no validated tool exists for assessing these effects. This report describes the development of the Impact of Migraine on Partners and Adolescent Children (IMPAC) scale, a brief, robust, and psychometrically sound instrument designed to measure the impact of migraine on the family using information gathered from the migraine proband. The goal was to have questions that focus on everyone with migraine, those with partners, and those with children.

METHODS

Study Design.—The CaMEO Study was conducted from September 2012 to November 2013, and consisted of web-based cross-sectional modules embedded in a longitudinal design (methods published previously[17]). Longitudinal assessments were conducted every 3 months to evaluate headache-day frequency; headache-related disability; acute, preventive, interventional, and behavioral migraine treatment use; and treatment satisfaction, among other constructs. One-time cross-sectional modules focused on perceptions of family burden, barriers to medical care, as well as self-reported comorbid health problems to assess underlying endophenotypes.

The study was approved by the Albert Einstein College of Medicine institutional review board.

Study Population.—CaMEO Study participants were recruited from a web-based panel (Research Now, Plano, TX, USA) with 2.4 million active US members. The screening and recruiting phases occurred from September through October 2012. Migraine was assessed using the American Migraine Study (AMS)/American Migraine Prevalence and Prevention (AMPP) Study diagnostic module.[19,20] This module was designed to approximate the diagnostic criteria provided by the *International Classification of Headache Disorders, 2nd edition* (*ICHD-2*) and *3rd edition (beta version)* (*ICHD-3b*) for migraine.[21] We did not confirm the following 2 criteria: ≥5 lifetime migraine events (criterion A) and duration of attack untreated from 4 to 72 hours (criterion B). In addition, we could not exclude secondary headache. CM classification was derived from Silberstein-Lipton criteria[22,23] and *ICHD-3b* criteria for CM. Respondents with CM were defined as those with ≥15 headache days per month averaged over the past 3 months, but were not assessed for *ICHD-3b* CM criterion C (ie, ≥8 days per month fulfilled migraine criteria) because this is best assessed using a daily diary or a physician interview. Respondents who met these migraine symptom criteria (ie, migraine probands) were invited to complete the FBM and participate in the longitudinal phase of the study.

The FBM.—The FBM of the CaMEO Study was sent to 19,891 migraine probands identified using the AMS/AMPP diagnostic module, including probands from the CaMEO Study population and an additional group of equally qualified respondents meeting the same study inclusion criteria, who were used only for the FBM (Fig. 1; for details, see Adams et al[17]). The FBM contained items evaluating the impact of migraine on family interpersonal relationships, social interactions, activities, well-being, finances, career, and health-related quality of life. Respondents reported their family structure (eg, married, single, living with partner, number, and ages of children) and answered questions regarding impact of migraine on their cohabitating (for >2 months) children (defined as any child, stepchild, or grandchild aged 13-29 years) and partners (defined as being in a relationship with a spouse, partner, or significant other), if applicable. Partners and children were subsequently invited by the respondent, via forwarded custom survey links, to participate in FBM surveys.

Statistical Methods.—To develop the IMPAC scale, migraine probands were classified into 4 subgroups for confirmatory psychometric models: migraine probands living with a partner/spouse and child(ren) (M-PC; n = 4640), migraine probands

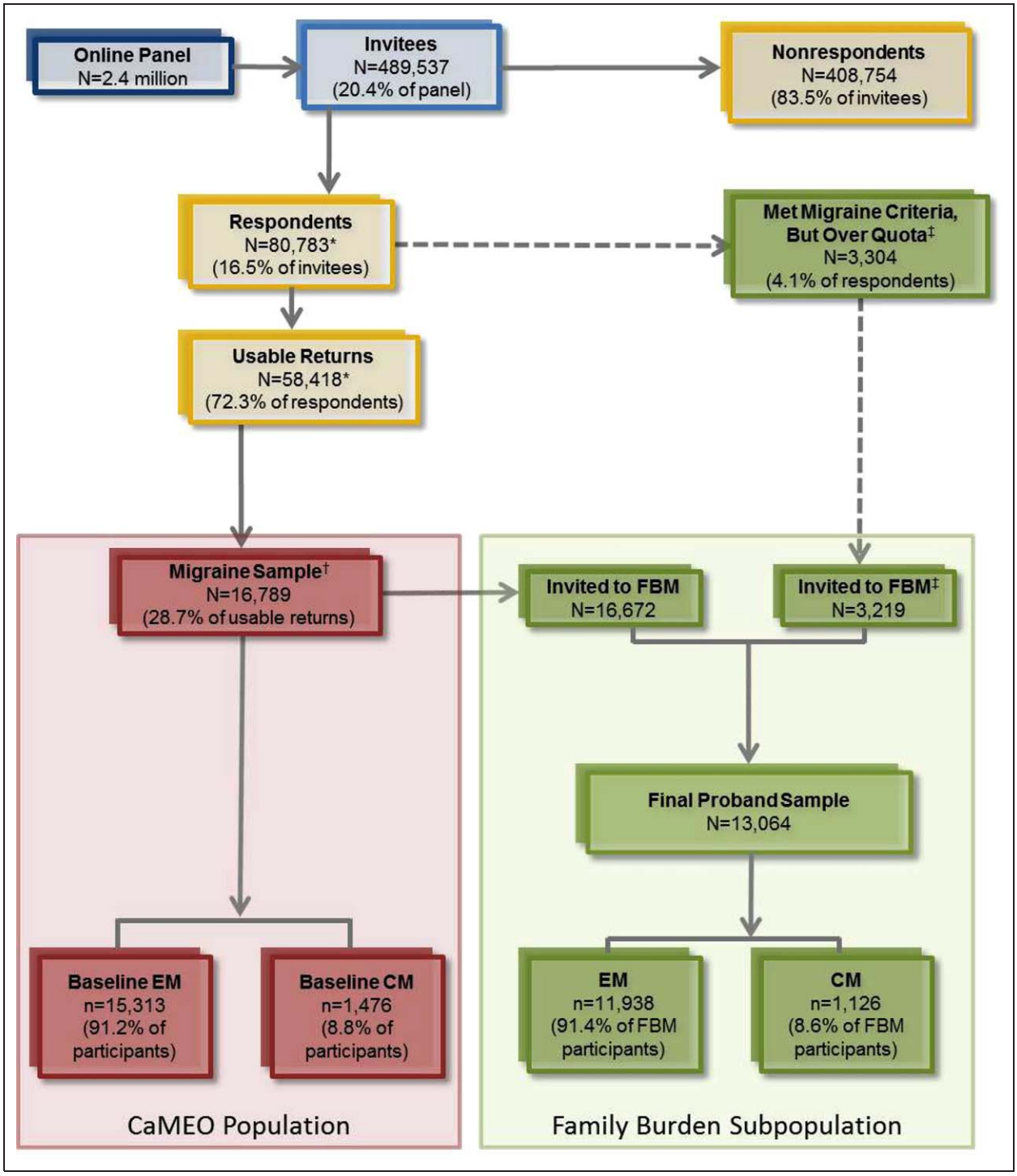

Fig. 1.—CaMEO Study flow diagram. CaMEO = Chronic Migraine Epidemiology and Outcomes; CM = chronic migraine; EM = episodic migraine; FBM = Family Burden Module. *22,365 respondents either abandoned the survey (<20% of the survey was complete and headache status could not be identified), were over quota, or had unusable data, which left 58,418 usable returns. †Baseline sampling was quota based, with the limit for the migraine sample defined as 17,000. Respondents who replied after quotas had been reached but before initiation of the next sampling wave were deemed over quota and not included. Of the quota sample, 16,789 met the following inclusion criteria: agreed to participate, screened positive for modified *International Classification of Headache Disorders*, 3rd edition (beta version) migraine, completed initial surveys in a reasonable time (10 min), were ≥18 years old, were not missing headache frequency data, and reported consistent age and sex (of the 17,000 people in the migraine sample, as defined by the quotas, 211 [1.2%] were removed during data cleaning). Migraine case rate was 28.7% (16,789/58,418). ‡Because of the risk of potentially low response rates for the FBM, respondents who were considered to be over quota for CaMEO were resampled for the FBM only. Data from these over-quota respondents were not used for any other module.

living with a partner/spouse only (M-P; n = 3517), migraine probands living with child(ren) only (M-C; n = 1350), and migraine probands without a partner/spouse or child(ren) (M-O; n = 3557). Data on 4 theoretically related and validated measures collected in the migraine proband Core Module (see Adams et al[17] for details) were used to assess construct validity: (1) Migraine Disability Assessment Scale (MIDAS), a measure assessing headache-related disability[14]; (2) Migraine-Specific Quality of Life Questionnaire (MSQ), a questionnaire designed to measure how migraines affect health-related quality of life[24,25]; (3) the 9-item Patient Health Questionnaire (PHQ-9), a scale measuring symptoms of depression[26]; and (4) the 7-item Generalized Anxiety Disorder Assessment (GAD-7), a measure of generalized anxiety disorder.[27] We hypothesized that as a valid measure of family burden increased, MIDAS, PHQ-9, and GAD-7 scores should increase, and MSQ scores should decrease. SAS version 9.3[28] (SAS Institute, Inc., Cary, NC, USA) and Mplus version 7.2[29] (Muthén and Muthén, Los Angeles, CA, USA) were used for all data management and analyses. All authors had full access to all of the data.

Item Pool for the FBM.—The initial item pool from the FBM was derived based on our previous family burden study,[12] items from previous questionnaires, focus groups among migraine probands and their family members (MLR), and clinical experience (RBL, DCB). There were 53 candidate items that assessed the impact of migraine on general family activities, partner- and child-specific activities, and interactions with the partner and child(ren). The activity items inquired about missed and reduced participation over the past 30 days (range, 0-≥30 times) and past year (range, 0-≥52 times). "Does not apply to me" responses were coded as missing for the purpose of this analysis. The proportion of nonmissing responses differed across items, but all available data were used for this analysis. For scoring purposes, open-ended activity responses (ie, "how many times" questions) were reduced to 4 ordinal categories, determined by assessing the overall distribution of responses across all questions and identifying a split that approximated a quartile split (0 = 0 times; 1 = 1-3 times; 2 = 4-9 times; 3 = ≥10 times). This split was applied universally to all open-ended activity responses. Migraine probands responded to partner and child interaction items using a 4-point Likert-type scale (0 = disagree completely to 3 = agree completely).

Analytic Strategy.—To ensure inclusion of the most relevant items that would produce the most useful tool, the analytic strategy for developing the IMPAC scale consisted of 3 steps: (1) exploratory factor analysis (EFA) and item reduction, (2) bifactor analysis, confirmatory factor analysis (CFA), and scoring, and (3) construct validity analyses.

Step 1. Exploratory Factor Analysis and Item Reduction.—The first step of the analytic strategy was to assess the dimensionality of the initial 53 candidate items using an EFA model fitted to all available data from migraine probands. The EFA models were estimated using weighted least squares estimation with mean- and variance-adjusted chi-square (χ^2; for details, see Wirth and Edwards[30]). Oblique rotation was used. The optimal number of factors was selected using several criteria (eg, clarity of factor solutions, eigenvalues, model fit criteria). Model fit was assessed using χ^2, root mean square error of approximation (RMSEA), the comparative fit index (CFI), and the Tucker-Lewis index (TLI). The hypothesis was that correlated family impact factors (eg, activity factor, partner interaction factor, child[ren] interaction factor) would emerge from the data. From a theoretical perspective, these specific family impact factors were hypothesized to be correlated because they are indicators of a more general family impact construct.

The initial item set was reduced to a smaller set of items that could be used across the 4 types of family structures (ie, M-PC, M-P, M-C, M-O) using both quantitative results (eg, EFA results) and substantive information (eg, expert clinical input). The aim was to identify a parsimonious set of items applicable to everyone with migraine (general activity) and subsets of items that assess partner interactions and child(ren) interactions. We wanted strong indicators of the family impact of migraine, in line with the goal of developing a short and robust measure of general family impact.

Table 1.—Demographic Characteristics of CaMEO Family Burden Module Respondents

	Migraine Probands With Partner and Child(ren) n = 4640	Migraine Probands With Partner n = 3517	Migraine Probands With Child(ren) n = 1350	Migraine Probands Only n = 3557	Pooled Sample N = 13,064
Age (years), mean (SD)	41.7 (10.1)	46.9 (16.4)	43.0 (10.7)	34.4 (15.0)	41.2 (14.3)
Caucasian, %	81.5	89.0	71.2	79.2	81.8
Women, %	71.4	73.8	88.1	73.3	74.3
Education, n (%)					
<College degree	2574 (55.5)	1383 (39.4)	786 (58.3)	1751 (49.3)	6494 (49.7)
College/technical school degree	1622 (35.0)	1457 (41.4)	475 (35.2)	1367 (38.4)	4921 (37.7)
Graduate degree	444 (9.6)	677 (19.2)	89 (6.6)	439 (12.4)	1649 (12.6)
Household income, n (%)					
<$30,000	728 (15.7)	539 (15.4)	547 (40.5)	1256 (35.3)	3070 (23.5)
$30,000-$74,999	1972 (42.4)	1311 (37.4)	589 (43.6)	1422 (39.8)	5294 (40.5)
≥$75,000	1918 (41.3)	1629 (46.4)	210 (15.7)	853 (24.0)	4610 (35.3)
Prefer not to answer	22 (0.5)	38 (1.1)	4 (0.3)	26 (0.7)	90 (0.7)
Chronic migraine, %	10.0	6.9	10.5	7.6	8.6
30-day headache frequency[†] (days), mean (SD)	5.3 (6.3)	4.3 (5.6)	5.6 (6.5)	4.5 (6.0)	4.9 (6.1)

[†]Headache frequency was defined as days-per-month average over the past 90 days. CaMEO = Chronic Migraine Epidemiology and Outcomes.

Step 2. Bifactor Analysis, CFA, and Scoring.—In step 2, bifactor analysis or CFA was conducted for each family type (ie, M-PC, M-P, M-C, M-O). All models were fitted using full information maximum likelihood and a logit link function. Because the M-O group had only 4 activity items and no uncorrelated constructs, a standard 1-factor CFA was fitted. Unique bifactor models were fitted to the applicable items for M-PC, M-P, and M-C groups. The bifactor model was ideal for measuring family impact in these family types because it allows each model to load on >1 uncorrelated construct (ie, the item pool contained general activity items as well as items more directly related to partner or child items)[31,32]; for example, the M-PC families had 3 specific factors (general activity, partner interactions, and children interactions) along with the general family burden factor. In these models, the general family impact factor and the specific factors were all assumed to be orthogonal (uncorrelated), and each item was allowed to load onto the general family impact factor and 1 specific activity/interaction factor. Standardized factor loadings were used to confirm the utility of each factor for each family group. Model fit was assessed using χ^2, RMSEA, the CFI, and TLI.

A user-friendly scoring strategy was created as part of the goal to produce a widely accessible family impact assessment tool for both research and clinical use. Using model results from step 2, scoring tables were derived to standardize IMPAC scale scores based on the general family burden factor, consistent with the item response theory and methodology described in Thissen et al.[33] As a result, item responses were summed and converted into standardized general family impact scores, corresponding to a 4-category family impact scoring technique: Grade I ("none/mild"), Grade II ("moderate"), Grade III ("severe"), and Grade IV ("very severe").

Step 3. Construct Validity Analyses.—In step 3, the construct validity of the IMPAC scale was assessed by examining the associations between IMPAC scale scores with episodic migraine (EM) and CM group classification and validated instruments (ie, MIDAS, MSQ, PHQ-9, GAD-7). We assumed that CM would have greater family impact than EM, and that higher levels of family impact

Table 2.—Summary Factor Structure of 21 Items Retained After Initial Exploratory Factor Analysis Model in Step 1

	Retained in Final Item Set	Item[†]	Factor		
			Activities[‡]	Partner Interaction	Child Interaction
All Migraine Probands	Yes	1. Did not participate in family activity at home	x	—	—
	Yes	2. Did not do anything "physical" with family	x	—	—
	Yes	3. Let your share of housework go undone	x	—	—
	Yes	4. Your involvement/enjoyment in family activities significantly reduced	x	—	—
	No	5. Participation in an important event significantly reduced (past year)	x	—	—
	No	6. How much of burden was headache	x	—	—
Migraine Probands With Partner	No	7. One-on-one time with partner disrupted	x	—	—
	No	8. Partner had to take over housework	x	—	—
	Yes	9. Enjoyment of time spent with partner significantly reduced	x	—	—
	No	10. Don't think partner really believes me about how bad my headaches are	—	x	—
	Yes	11. Partner gets upset/angry at me having headaches	—	x	—
	Yes	12. Partner avoids me at times because of headaches	—	x	—
	Yes	13. Partner resents having to do everything when I have headaches	—	x	—
Migraine Probands With Child(ren)	No	14. Unable to spend time with child(ren) when they needed help	x	—	—
	No	15. Partner had to take over parenting responsibilities[§]	x	—	—
	Yes	16. Involvement/enjoyment of child(ren)'s activities significantly reduced	x	—	—
	No	17. Ability to properly "parent" significantly reduced	x	—	—
	No	18. Child(ren) don't really understand my headaches			x
	Yes	19. Because of headaches, I get angry/annoyed more easily with child(ren)	—	—	x
	Yes	20. If I didn't have headaches, I would be a better parent	—	—	x
	Yes	21. The noise of my child(ren) can give me a headache or make it worse	—	—	x

[†]For parsimony, item labels are shortened. See the final developed instrument (Fig. 2) for precise wording. [‡]The activity items inquired about missed and reduced participation over the past 30 days (range, 0-≥30 times) and past year (range, 0-≥52 times). "Does not apply to me" responses were coded as missing for the purpose of this analysis. The proportion of non-missing responses differed across items, but all available data were used for this analysis. For parsimony and scoring purposes, open-ended activity responses were reduced to 4 ordinal categories (0 = 0 times; 1 = 1-3 times; 2 = 4-9 times; 3 = ≥10 times) for models. Migraine probands responded to partner and child interaction items using a 4-point Likert-type scale (0 = disagree completely to 3 = agree completely). [§]This item was administered only to migraine probands with child(ren) and a partner.

would be associated with higher symptomology/disability across the validated measures. Correlations and descriptive statistics were used to explore these relationships.

RESULTS

Study Population.—Of the 19,891 people with migraine invited to participate in the FBM, 13,064 (65.7%) returned completed surveys with valid data (EM, n = 11,938 [91.4%]; CM, n = 1126 [8.6%]; Fig. 1) and were included in this analysis. A demographic summary of the respondents in each of the 4 family types is included in Table 1. Some demographic differences were seen by family type. For example, the M-O group was younger than the other groups, while the M-P group was older; also, women were overrepresented in the M-C group. For parsimony, we focus on the M-PC group with

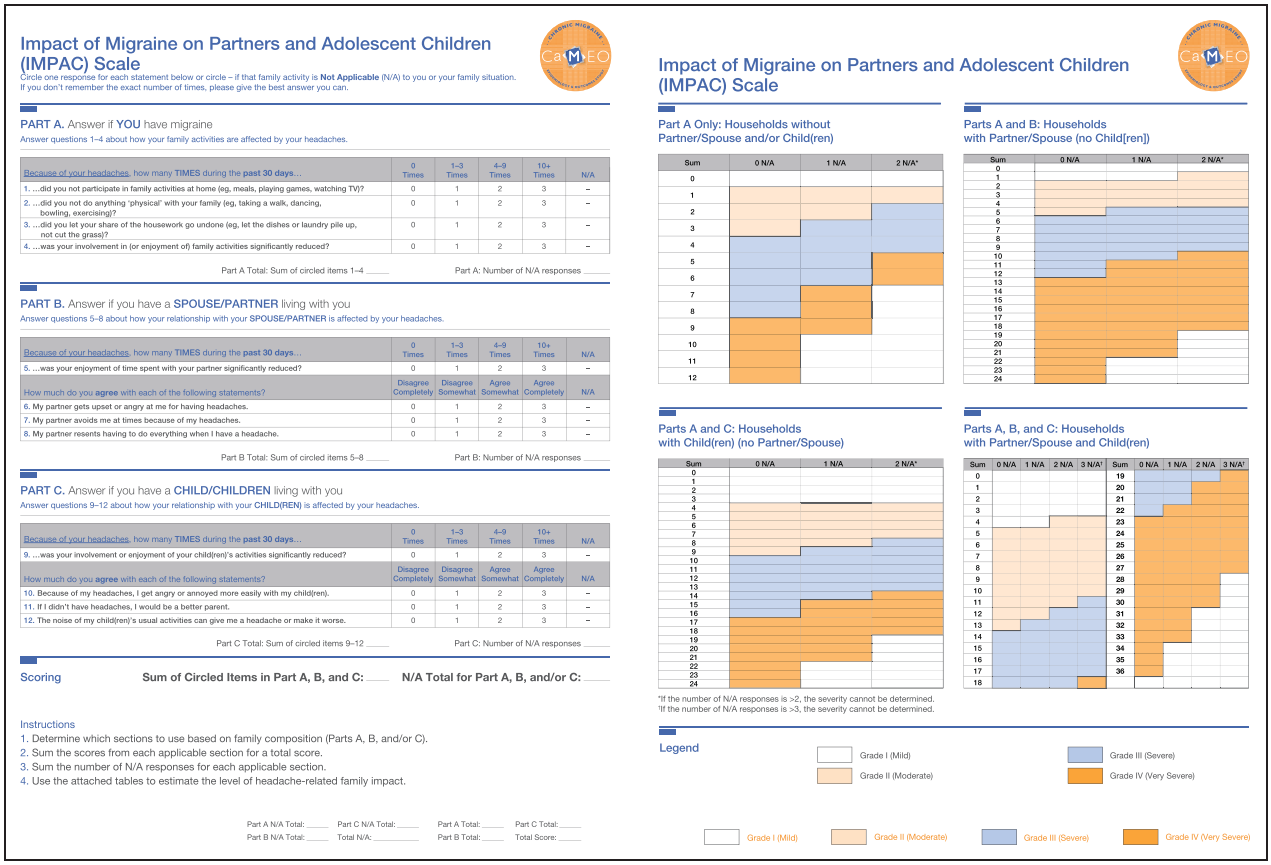

Fig. 2.—IMPAC scale tool. IMPAC = Impact of Migraine on Partners and Adolescent Children; N/A = not applicable.

both IMPAC scale scores and scores on the 4 measures being used to assess validity (n = 3300). Results for the other family types (M-P, M-C, and M-O) were substantively similar and are available in Appendix Tables 1-6 and Appendix Figures 1-3.

Step 1. Exploratory Factor Analysis and Item Reduction.—Results from the EFA model suggested that a 6-factor solution adequately characterized the full initial item set: χ^2 (1075) = 11,652.28 ($P < .001$, RMSEA = 0.03, CFI = 0.96, TLI = 0.94, each of the first 6 eigenvalues was >1). Based on the factor solution and clinical input, the analysis focused on 3 correlated factors defined by 21 items that characterized the following 3 domains: (1) activities, (2) partner interactions, and (3) child interactions (Table 2). The item set was further trimmed from 21 to 12 items using clinical judgment and statistical reasoning (eg, violation of model assumptions such as local independence, redundancy). The final set of 12 items are indicated "Yes" in Table 2 and displayed as the final tool in Figure 2. These 12 items adequately covered the unique familial backgrounds: 4 items apply to all migraine probands, 4 apply to migraine probands with a partner, and 4 apply to migraine probands with child(ren). The final instrument has 12 items for the M-PC family composition, 8 items for M-P and M-C families, and 4 items for the M-O group.

Step 2. Bifactor Analysis, CFA, and Scoring.—Table 3 provides the standardized factor loading results for the M-PC, M-P, and M-C bifactor models and the M-O CFA model fitted using full information maximum likelihood estimation. These standardized solutions were informative because the magnitudes of the factor loadings were directly comparable. We consider the relative effects of general family impact, specific activity impact, specific partner interactions, and specific child interactions.

Specifically, for the M-PC model, 12 items loaded on the general family impact factor with factor

Table 3.—Standardized Factor Loadings for M-PC, M-P, and M-C Bifactor Models, and M-O Confirmatory Factor Analysis Model[†]

	M-PC Model (12 Items) n = 4639				M-P Model (8 Items) n = 3517			M-C Model (8 Items) n = 1350			M-O Model (4 Items) n = 3125
		Specific				Specific			Specific		
	General FI	Act	PI	CI	General FI	Act	PI	General FI	Act	CI	Act
Items administered to all migraine probands[‡]											
1. Did not participate in family activity at home	0.59	0.63	—	—	0.88	−0.25	—	0.64	0.63	—	0.90
2. Did not do anything "physical" with family	0.61	0.63	—	—	0.87	−0.11	—	0.62	0.64	—	0.89
3. Let your share of housework go undone	0.58	0.64	—	—	0.84	0.02	—	0.64	0.58	—	0.85
4. Your involvement/enjoyment in family activities significantly reduced	0.64	0.66	—	—	0.92	0.12	—	0.71	0.57	—	0.90
Items administered to migraine probands with partners[‡]											
5. Enjoyment of time spent with partner significantly reduced	0.68	0.60	—	—	0.91	0.19	—	—	—	—	—
6. Partner gets upset/angry at me having headaches	0.64	—	0.66	—	0.42	—	0.82	—	—	—	—
7. Partner avoids me at times because of headaches	0.69	—	0.50	—	0.44	—	0.68	—	—	—	—
8. Partner resents having to do everything when I have headaches	0.69	—	0.53	—	0.43	—	0.74	—	—	—	—
Items administered to migraine probands with child(ren)[‡]											
9. Involvement/enjoyment of child(ren)'s activities significantly reduced	0.73	0.51	—	—	—	—	—	0.78	0.43	—	—
10. Because of headaches, I get angry/annoyed more easily with child(ren)	0.76	—	—	0.49	—	—	—	0.65	—	0.60	—
11. If I didn't have headaches, I would be a better parent	0.84	—	—	0.18	—	—	—	0.66	—	0.40	—
12. The noise of my child(ren) can give me a headache or make it worse	0.63	—	—	0.39	—	—	—	0.58	—	0.40	—

[†]Gray boxes represent items that were not administered. [‡]For parsimony, item labels are shortened. See the final developed instrument (Fig. 2) for precise wording.
Act = activity factor; CI = child-interaction factor; FI = general family impact; M-C = migraine probands with child(ren); M-O = migraine probands only (no partner/child[ren]); M-P = migraine probands with partner; M-PC = migraine probands with partner and child(ren); PI = partner-interaction factor.

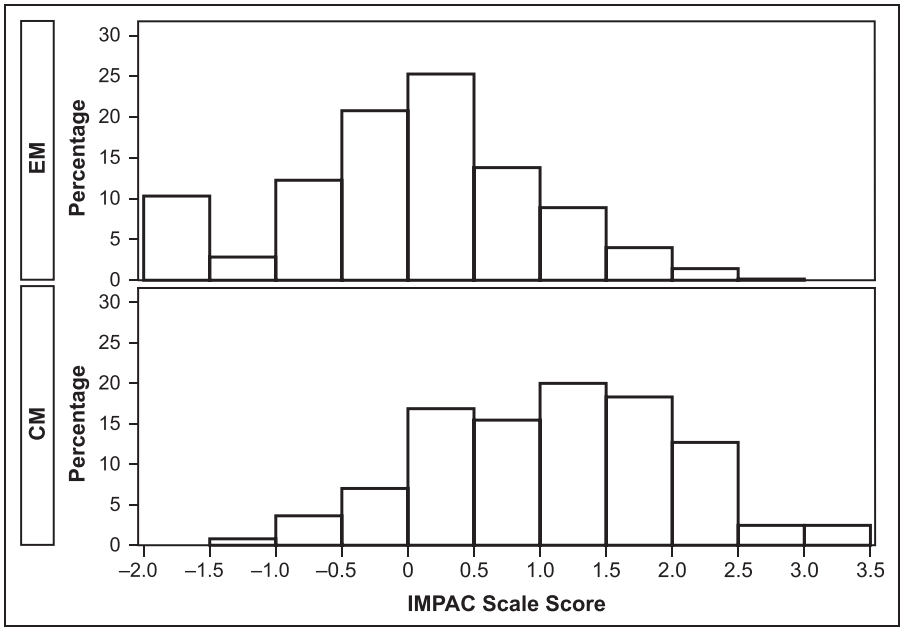

Fig. 3.—M-PC IMPAC scale score distributions for CM and EM. CM = chronic migraine; EM = episodic migraine; IMPAC = Impact of Migraine on Partners and Adolescent Children; M-PC = migraine probands with partner and child(ren).

loadings ranging from 0.58 to 0.84, 6 items loaded on the specific activity impact factor (loadings ranged from 0.51 to 0.66), 3 items loaded on the specific partner interactions factor (factor loadings ranged from 0.50 to 0.66), and 3 items loaded on the specific child interactions factor (factor loadings ranged from 0.18 to 0.49). For the M-P model, 8 items loaded on the general family impact factor (loadings ranged from 0.42 to 0.92), 5 items loaded on the specific activity impact factor (loadings ranged from −0.25 to 0.19), and 3 items loaded on the specific partner interactions factor (loadings ranged from 0.68 to 0.82). For the M-C model, 8 items loaded on the general family impact factor (loadings ranged from 0.58 to 0.78), 5 items loaded on the specific activity impact factor (loadings ranged from 0.43 to 0.64), and 3 items loaded on the specific child interactions factor (loadings ranged from 0.40 to 0.60). Finally, for the M-O model, 4 items loaded on a single activity impact

Table 4.—Correlations Among IMPAC Scale and Other Validated Measures for M-PC

	IMPAC	MIDAS	MSQ Restrictive†	MSQ Preventive†	MSQ Emotional†	PHQ-9	GAD-7
IMPAC	1.00						
MIDAS	0.41	1.00					
MSQ Restrictive†	−0.49	−0.44	1.00				
MSQ Preventive†	−0.48	−0.45	0.80	1.00			
MSQ Emotional†	−0.52	−0.45	0.76	0.76	1.00		
PHQ-9	0.44	0.35	−0.44	−0.42	−0.45	1.00	
GAD-7	0.38	0.28	−0.40	−0.35	−0.42	0.79	1.00

†Higher MSQ subscores correspond to better outcomes; thus, correlations between MSQ subscales and family impact are negative. GAD-7 = 7-item Generalized Anxiety Disorder Assessment; IMPAC = Impact of Migraine on Partners and Adolescent Children; MIDAS = Migraine Disability Assessment Scale; M-PC = migraine probands with partner and child(ren); MSQ = Migraine-Specific Quality of Life Questionnaire; PHQ-9 = 9-item Patient Health Questionnaire.

Table 5.—Validated Scale Scores Within Ordinal IMPAC Scale Scores for M-PC

Ordinal IMPAC Scale Score	Validated Scale	Mean	SD
Grade I (2.1% CM‡)	MIDAS	5.9	11.8
	MSQ Restrictive†	73.1	21.0
	MSQ Preventive†	86.4	17.8
	MSQ Emotional†	85.0	20.3
	PHQ-9	4.5	5.0
	GAD-7	4.7	4.9
Grade II (5.9% CM‡)	MIDAS	13.0	18.7
	MSQ Restrictive†	59.7	20.7
	MSQ Preventive†	75.6	20.8
	MSQ Emotional†	70.1	25.2
	PHQ-9	6.8	5.4
	GAD-7	6.9	5.0
Grade III (15.8% CM‡)	MIDAS	26.6	31.2
	MSQ Restrictive†	47.8	20.9
	MSQ Preventive†	63.2	22.9
	MSQ Emotional†	53.7	27.2
	PHQ-9	10.1	6.3
	GAD-7	9.2	5.6
Grade IV (43.8% CM‡)	MIDAS	56.1	72.7
	MSQ Restrictive†	37.1	23.4
	MSQ Preventive†	49.1	25.9
	MSQ Emotional†	36.7	27.7
	PHQ-9	13.5	7.0
	GAD-7	11.5	6.0

†Higher MSQ subscores correspond to better outcomes.
‡% CM is the percentage of CM cases within the given impact severity category. The distribution of all respondents with migraine into the 4 grades is as follows: Grade I, n = 768 (23.3%); Grade II, n = 1442 (43.7%); Grade III, n = 798 (24.2%); Grade IV, n = 292 (8.8%). CM = chronic migraine; GAD-7 = 7-item Generalized Anxiety Disorder Assessment; IMPAC = Impact of Migraine on Partners and Adolescent Children; MIDAS = Migraine Disability Assessment Scale; M-PC = migraine probands with partner and child(ren); MSQ = Migraine-Specific Quality of Life Questionnaire; PHQ-9 = 9-item Patient Health Questionnaire.

factor (loadings ranged from 0.85 to 0.90; Table 3). Taken together, across all models, the general factor loadings were moderate to large in magnitude. These loadings support that the observed items were strong indicators of the general family burden latent construct of substantive interest.

Item responses were summed and converted into standardized general family impact scores corresponding to 4-category family impact grades: Grade I, "none/mild" (<0.5 SD below mean); Grade II, "moderate" (0.5 SD below mean to <0.5 SD above mean); Grade III, "severe" (0.5 SD above mean to <1.5 SD above mean); and Grade IV, "very severe" (≥1.5 SD above mean; Fig. 2, bottom panel; Scoring Appendix Tables 7-10). Each of the Scoring Appendix tables provides a range of sum scores (translated to standardized scores) corresponding to each IMPAC scale grade/severity level. Separate ranges are provided depending on the number of items answered as "not applicable"; the grade/severity level cannot be determined if the number of "not applicable" responses is >3 for M-PC or >2 for M-P, M-C, and M-O.

Step 3. Construct Validity Analyses.—Figure 3 shows the distribution of IMPAC scale scores stratified by migraine type in the proband (ie, CM or EM) for the M-PC group (migraine probands with partner and ≥1 child). The distribution of IMPAC scale scores was centered around higher family impact scores for CM than for EM. The mean IMPAC scale score for the CM group was roughly 1 SD higher than that of the EM group (CM, 1.10; EM, 0.04). Table 4 demonstrates that the IMPAC scale scores had moderate-to-large positive associations with MIDAS ($r = 0.41$), PHQ-9 ($r = 0.44$), and GAD-7 ($r = 0.38$). Strong negative correlations were found between the IMPAC scale scores and MSQ Restrictive, Preventive, and Emotional subscale scores ($r = -0.48$ to -0.52),

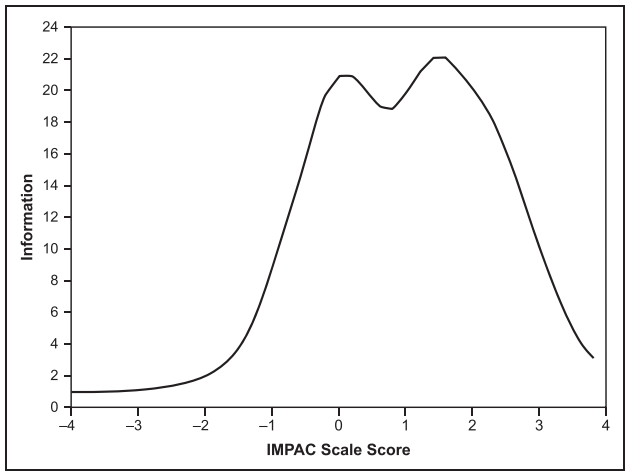

Fig. 4.—Test information curves for the M-PC model. Test information (y-axis) of 7 corresponds to a reliability of just over 0.85. IMPAC = Impact of Migraine on Partners and Adolescent Children; M-PC = migraine probands with partner and child(ren).

suggesting that greater family impact was associated with reductions in migraine-specific health-related quality of life. Furthermore, the 4-category ordinal IMPAC scale scores were also related to the validated measures; specifically, mean MIDAS, PHQ-9, and GAD-7 scores and proportion of CM cases increased with family impact severity, and mean MSQ quality-of-life scores decreased with greater family impact severity (Table 5).

Reliability.—To establish reliability or instrument precision for the IMPAC scale, test information curves for the general family burden factor were generated for the M-PC, M-P, M-C, and M-O samples. Figure 4 provides the model for the 12 M-PC items. Similar results were obtained for the M-P, M-C, and M-O versions (Appendix Fig. 4). The plots for each item set show that these items reliably measure family impact from about 1 SD below the mean through approximately 3 SDs above the mean.

DISCUSSION

This report describes the development of the IMPAC scale, a measure designed to quantify the impact of migraine on family members as perceived by the proband. Using data from a large sample of >13,000 people with migraine, the IMPAC scale was developed using a 3-step analytic process that included EFA with item reduction, bifactor analysis and CFA, and construct validity analysis. The EFA model and clinical input reduced the initial item set from 53 candidate items to the final set of 12 items (Fig. 2) covering 3 family social factors (ie, activity, partner interaction, child interaction). These measures cover the 4 types of families (ie, M-PC, M-P, M-C, M-O). Bifactor analysis and CFA produced moderate to high loadings on the general family impact factor, indicating that each of the final items was a strong indicator of the focal general family burden constructs.

Construct validity analyses showed that measures of family impact correlated well with other measures of migraine burden. In addition, the higher mean IMPAC scale score in those with CM compared with those with EM, and the distribution of people with CM by IMPAC scale grades, further support scale validity.

The information curves showed that the IMPAC scale items provided adequate reliability when measuring individuals with mild to severe levels of family impact. Family burden can be best managed only if it is identified, measured, and discussed. Quantifying family impact begins the process of understanding the effect of migraine on family members and provides an opportunity for clinicians to develop strategies to reduce migraine burden with patients and family members. This scale may also be useful in a research context for evaluating the impact of migraine on family members. With further study, it could be used in clinical trials to identify probands and families with high family impact for targeted interventions. Ultimately, it may prove useful as a measure of treatment/intervention targeting family burden.

We have not yet assessed the sensitivity of the IMPAC scale score to intervention. One approach to treating family burden focuses on reducing the impact of migraine on the proband through pharmacologic and nonpharmacologic interventions. Alternatively, viewed from a family system perspective, behavioral interventions with demonstrated efficacy[34] could reduce the impact of migraine on the proband and potentially reduce family distress.

Strengths and limitations of the CaMEO Study have been discussed previously (see Adams et al, 2015).[17] Although the CaMEO Study design used probability sampling from a nationally distributed online panel, response rates were low (16.5% of invitees), and only 11.9% of invitees provided usable data. Response rates to the FBM (65.7%) were much higher than the general response rates, though these results are confined to responders to the initial survey. Survey completion rates among partners and children were also reasonably high. Among the 13,604 respondents with migraine in this analysis sample, 8163 reported having a partner, and 4022 partners provided data (49.3% completion rate). Among respondents with migraine with at least 1 child (n = 3391), data were obtained from 2140 children (63.1% completion rate). Lack of participation could arise if the respondent failed

to invite the partner or child or if the partner or child did not respond to the invitation.

We approached participation bias in the CaMEO Study in 2 ways. As mentioned above, we surveyed non-respondents to the initial CaMEO screening survey and showed that they were similar to initial respondents in demographic and headache features.[17] However, response rates in this survey of non-respondents were also low. In addition, we compared results of the CaMEO Study with the AMPP Study,[5] a large-scale epidemiologic study that used similar measures to CaMEO. Comparisons with AMPP data yielded similar demographic and clinical distributions within EM and CM samples, as well as similar headache-day frequency and headache-related disability between studies.[35,36] Results from the analysis of nonresponse bias and the comparison with AMPP Study data suggest that response bias is unlikely a major issue in the Family Burden analysis.

An additional weakness is that the study was based on self-reported data only. Social desirability may reduce reporting of family burden, which would lead to underestimation. Furthermore, in this report, we assess family burden exclusively from the perspective of the migraine proband. In future reports, we will use data gathered from partners and children to broaden this perspective.

Strengths of this analysis include the large sample size and the careful consideration of family types (ie, M-PC, M-P, M-C, M-O) where stratified data were used to create this scale. The items of the scale were developed based on literature review, focus group discussions with probands and proband family members, and clinical expertise followed by psychometric methods (ie, EFA, bifactor analysis, CFA) to optimize the clinical relevance, the discriminant and construct validity as well as precision of the final instrument. The use of clinical expertise to identify items for the scale is both a strength and possible weakness of our analysis. Because of the subjective nature of expert opinion, different clinical experts could have provided input that would have resulted in a different set of initial items and ultimately a different final scale. Nevertheless, using both quantitative (ie, EFA, bifactor analysis, CFA) and qualitative (ie, clinical expert opinion) approaches can optimize the clinical and psychometric properties of the final scale.[37]

The analytic approach also provided an evaluation of the instrument's ability to assess a range of burden severity levels. We created a psychometrically robust tool to capture a construct that did not have an instrument for measurement. In addition, the IMPAC scale is modularized to fit various household compositions.

We hope that this tool will be used to assess family burden in different populations and to facilitate dialogue on the broader impact of migraine. Future research will explore patterns of family burden among demographic subgroups of people with migraine (eg, men vs women, low vs high socioeconomic status), evaluate the utility of the scale in other clinic and nonclinic populations, and seek to identify the predictors of severe family burden among matched cohorts.

Acknowledgments/financial support: This study and analysis were sponsored by Allergan plc (Dublin, Ireland). The study sponsor was involved in the study design, data collection, data analysis, data interpretation, and writing of the article. RBL, DCB, AMA, SFV, and MLR were involved in development of the web-based questionnaire and statistical analysis plan. MLR provided oversight and direction for the statistical analyses in this manuscript. All authors had full access to all of the data. The corresponding author had final responsibility for submission of this paper. All authors met the International Committee of Medical Journal Editors authorship criteria. Neither honoraria nor payments were made for authorship. In addition, Valerie Marske of Vedanta Research (Chapel Hill, NC) was involved in questionnaire development. Statistical support was provided by James McGinley, PhD, of Vector Psychometric Group, LLC (Chapel Hill, NC). Writing and editorial assistance was provided to the authors by Amanda M. Kelly, MPhil, MSHN, of Complete Healthcare Communications, LLC (Chadds Ford, PA), and Dana Franznick, PharmD, and was funded by Allergan plc (Dublin, Ireland).

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article.

Appendix Fig 1. IMPAC scale score distributions for migraine probands with partner.

Appendix Fig 2. IMPAC scale score distributions for migraine probands with child(ren).

Appendix Fig 3. IMPAC scale score distributions for migraine probands only.

Appendix Fig 4. Test information curves for (A) migraine probands with partner, (B) migraine probands with child(ren), and (C) migraine probands only models.

Appendix Table 1. Correlations Among IMPAC Scale and Other Validated Measures for Migraine Probands With Partner

Appendix Table 2. Validated Scale Scores Within Ordinal IMPAC Scale Scores for Migraine Probands With Partner

Appendix Table 3. Correlations Among IMPAC Scale and Other Validated Measures for Migraine Probands With Child(ren)

Appendix Table 4. Validated Scale Scores Within Ordinal IMPAC Scale Scores for Migraine Probands With Child(ren)

Appendix Table 5. Correlations Among IMPAC Scale and Other Validated Measures for Migraine Probands Only

Appendix Table 6. Validated Scale Scores Within Ordinal IMPAC Scale Scores for Migraine Probands Only

Appendix Table 7. Migraine Probands With Partner and Child(ren) – 12 Items*

Appendix Table 8. Migraine Probands With Partner – 8 Items*

Appendix Table 9. Migraine Probands With Child(ren) – 8 Items*

Appendix Table 10. Migraine Probands Only – 4 Items*