





## Background

- The Migraine Clinical Outcome Assessment System (MiCOA project aims to establish a core set of outcomes for use migraine clinical trials
- In previous MiCOAS qualitative interviews, individuals with migraine identified the ability to function socially is important impact of migraine along with several oth domains (Mangrum, 2024)
- Consistent with MiCOAS findings, existing scientific researd consistently shows the social burden of migraine (e.g., Agos 2018; Solomon & Price, 1997)
  - Impacts various social areas including family and leisu activities (Buse et al., 2016; MacGregor et al., 2004)
- The current work presents findings from the psychometr evaluation of the MiCOAS 7- and 14-day recall-based measur for social functioning (SF)

## Methods

- The hypothesized IRT model showed good model fit after • After completing extensive MiCOAS qualitative work and accounting for local dependence between "Care for others" literature reviews, 7 candidate SF items were drafted and "Manage usual tasks" items (Figure 1; Table 3; TLI = • SF item response options ranged from either 1=Never to 0.92 - 0.95, RMSEA = 0.05)
- 5=Always or 1=Not difficult at all to 5=Unable to do
- A large, 3 cohort, observational study collected data on the draft MiCOAS measures and other relevant headache- and migraine-specific measures (Table 1)

• Participants met the study migraine case definition

Table 1. Diary lengths and recall periods for cohorts

		Retrospective
	Daily Diary	Recall MiCOAS
Cohort 1 (n = 169)	56 days	14-day
Cohort 2 (n = 375)	28 days	14-day
Cohort 3 (n = 611)	28 days	7-day

• Descriptive, polychoric correlation, categorical confirmatory factor analysis, item response theory (IRT), and reliability analyses were completed

References: Mangrum et al. (2024). The impacts of migraine on functioning: Results from two qualitative studies of people living with migraine burden of disease: From the patient's experience to a socio-economic view. Headache, 58, 17-32. Solomon & Price (1997). Burden of disease: From the patient's experience to a socio-economic view. Headache, 58, 17-32. of its socioeconomic impact. Pharmacoeconomics, 11 (Suppl 1), 1-10. Buse et al. (2016). Impact of migraine on patients and their spouse/domestic partner in the CaMEO study. Mayo Clinic Proceedings 91 (5), 596-611. MacGregor, et al. (2004). Impact of migraine on patients and their spouse/domestic partner in the CaMEO study. Migraine and Zolmitriptan Evaluation (MAZE) survey-Phase III. Current medical research and opinion, 20(7), 1143-1150.

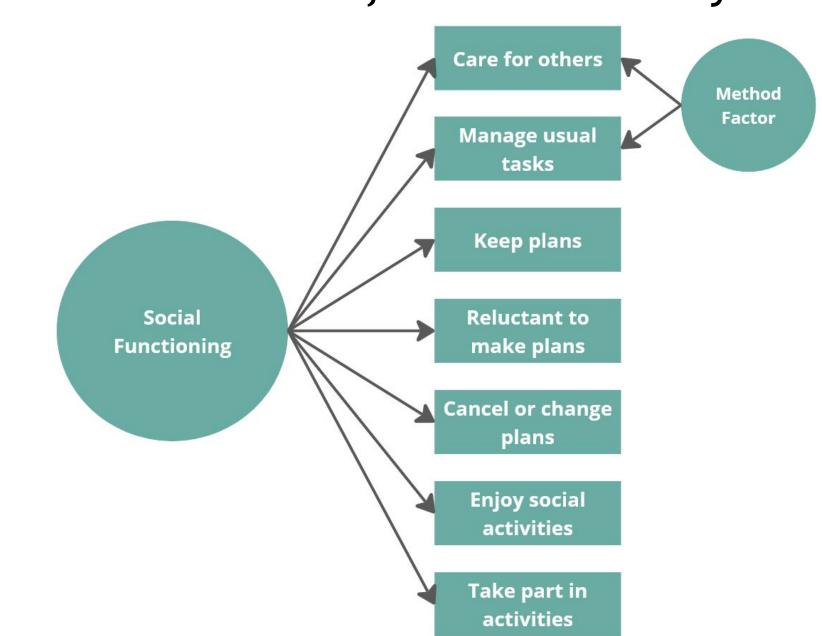
## The Migraine Clinical Outcome Assessment System (MiCOAS) measures: Social Functioning

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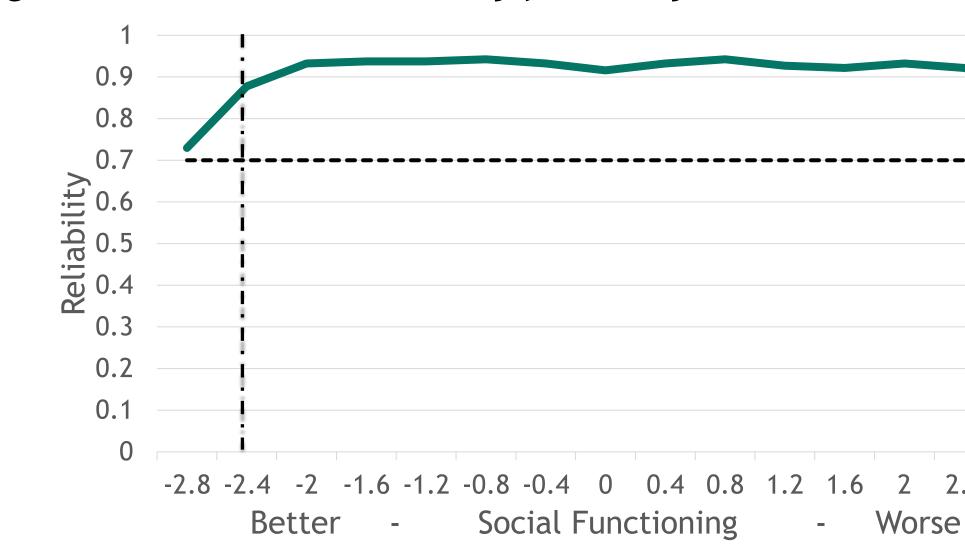
DAS) e in	<ul> <li>The N = 1155 partici predominantly fema</li> </ul>	pants Ile (81		the fu	<ul> <li>Both factor analyses showed similarly strong fact across 7- and 14-day recall measures (Table 3)</li> <li>Table 3. Standardized factor analysis loading estimates</li> </ul>						
with an ther	<ul> <li>age (mean = 38.9 ye</li> <li>Item-level descriptive</li> <li>floor/ceiling effects</li> <li>SF items were mode</li> </ul>	ves sh s and	polycł	noric d	correla	ations	U		Tuble 5. Standardized Jactor unatysis todain7-dayItem contentItem contentCare for others0.78Manage usual tasks0.79	14-day loading 0.74 0.73	
	Table 2. Polychoric correlations among SF items							Keep plans 0.88	0.85		
arch	Item content	1	2	- <u> </u>	Δ	5	6	7	Reluctant to make plans 0.79	0.76	
osti,	1. Care for others	1.00	0.73	0.60	0.44	0.64	0.63	0.62	Cancel or change plans 0.83	0.82	
050,	2. Manage usual tasks	0.77	1.00	0.59	0.57	0.55	0.62	0.59	Enjoy social activties 0.89	0.89	
	•							0.39	Take part in activities0.90	0.89	
sure	3. Keep plans	0.65	0.73	1.00	0.67	0.72	0.68		Model Fit TLI 0.92	0.95	
	4. Reluctant to make plans	0.58	0.56	0.68	1.00	0.57	0.62	0.64	RMSEA 0.05	0.05	
etric	5. Cancel or change plans	0.61	0.59	0.77	0.62	1.00	0.67	0.65	Note: A second nuisance factor accounting for	r local	
	6. Enjoy social activties	0.70	0.68	0.71	0.68	0.70	1.00	0.82	dependence between "Care for others" and "Manage usual		
ures	7. Take part in activities	0.68	0.68	0.75	0.68	0.68	0.81	1.00	tasks" is not presented here.		

Figure 1. Factor structure for SF 7- and 14-day recall measures



- (Figure 2; 7-day)
- No meaningful differential item functioning was across 7-vs. 14-day recalls and episodic vs. chronic

Figure 2. IRT-based reliability for 7-day SF measures



• Internal consistency was found to be high across and 14-day recall SF measures (coefficient alpha >



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tor loadings	<ul> <li>Summary</li> <li>D MiCOAS 7- and 14-day recall- based measures assessing SF in migraine were developed and showed strong psychometric properties</li> <li>Conclusions</li> <li>✓ The SF measures displayed adequate model fit and SF items exhibited moderate-to-strong interitem correlations and factor loadings</li> <li>✓ Internal consistency was excellent, and reliability was high across a broad range of SF</li> <li>✓ Measurement properties were similar for 7- vs. 14-day recall periods and EM vs. CM</li> <li>✓ Future work is underway to collect evidence of validity for the MiCOAS SF measures</li> </ul>					
range of SF as detected c migraine						
	<b>Sponsorship</b> This presentation was supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award (UH3FD006795) totaling \$3,986,552 with 100% funded by FDA/HHS. The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement by, FDA/HHS or the U.S. Government.					
4 2.8 both the 7- 0.9) f migraine: a review their families: the	Acknowledgements The authors would like to thank the FDA including Robyn Bent, MS; CHAMP; Elizabeth Nicki Bush, MHS, Roger K. Cady, MD, David W. Dodick, MD, Peter J. Goadsby, MD, PhD., Katie M. Golden, BA, Jason Sico, MD, and Walter F. Stewart, PhD, MPH for serving as advisors to the MiCOAS project.					