Conceptual Content Influences Patient Perspectives on Recall Time Frames and Response Options in Migraine Self-Report Measures

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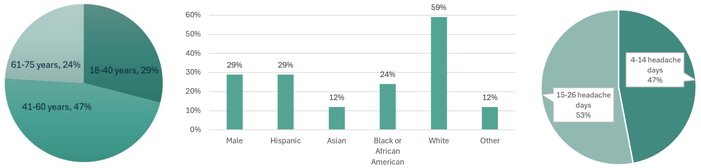
Background & Objectives

- The Migraine Clinical Outcome Assessment System (MiCOAS) is an FDA-funded project focused on integrating patient input into the development of clinical trial outcome assessments. To support decisions about optimal recall reference period and response options, input was gathered from people living with migraine through qualitative interviews
- Available migraine patient-reported outcome measures (PROMs) specify recall periods from 24 hours to 6 months and use different response options
- Research on optimal PROM recall periods[1-3] and response options[4-5] identifies factors that should inform selection, including:
  - characteristics of the recalled/rated phenomena
  - context in which recollection occurs
  - respondents' perceptions of feasibility of rating with provided options
- Variable, episodic phenomena like migraine create challenges for PROMs:
  - Short time frames may miss relevant episodes; long ones may result in recall bias
  - Respondents may have to blend highly varied episodes (e.g., one mild and one severe attack occurring in the same period) into a single rating or choose which episode to rate

Methods

- Semi-structured, 1-hour, virtual interviews conducted February-May 2023 with 17 individuals with self-reported migraine diagnosis. Interviewers presented potential PROM items, three possible timeframes (24 hours, 7 days, 14 days), and three possible response options (severity, frequency, and level of difficulty)
- Interview transcripts were analyzed using content analysis methods



Results

- All participants said 24 hours is easy to recall instantly and accurately (Table 1)
  - Participants thought daily assessment of migraine symptoms and proximal impacts is needed to achieve the "*best picture*" during a treatment trial
- Some said that they often went 7 days without symptoms/impacts and consequently thought 7 days was too short. All participants thought 14 days was sufficient to capture all relevant migraine experiences but varied regarding whether recalling 14 days was easy or required effort (i.e., taking time to think or checking a calendar).
- Confidence in recall and preferences for time frame were linked to overall prevalence, frequency, or duration of given experiences and the ease of anchoring one's memory
  - 14-day recall was easier for less frequent experiences (e.g., socializing) or distinctive (e.g., exercise); recall required greater effort for commonplace experiences (e.g., conversing, walking) because these tend to "*blur together*"

Table 2. Percent of participants reporting easy recall across time frames

Topic Area for Items	24 hours	7 days	14 days
Symptoms	All participants (n=17) found it **easy** to recall all experiences over 24 hours	100%	53%
Basic physical functions		94%	53%
Doing activities with symptoms present		100%	82%
Concentrate, complex tasks		94%	70%
Speak, remember words		100%	70%
Usual daily activities, errands		100%	59%
Usual responsibilities at home, work or school		94%	65%
Social activities		100%	100%
Irritable, depressed		94%	88%
Sense of control, worry, feel good		94%	94%

- Preferences for response options varied by question topic and time frame (Table 2). A minority of participants (6%-23% per question) reported challenges responding with non-preferred options; challenges were related to ability to recall or rate varied experiences over time
- For daily assessment, participants preferred severity for symptoms and level of difficulty for functioning. As the recall period increased to 7 or 14 days, preferences often changed and became more mixed across participants
- Frequency and level of severity/difficulty were highly interrelated: many participants referenced the frequency of an experience when rating its severity or level of difficulty

References: 1. Gries et al. J Patient Rep Outcomes. 2017; 2: 41. 2. Stull et al. Curr Med Res Opin. 2009; 25: 929-42. 3. Norquist et al. Qual Life Res. 2012; 21: 1013-20. 4. Sanghera et al. Patient. 2022; 15: 445-57. 5. Lu et al. AIDS Behav. 2008; 12: 86-94.

Table 2. Preferences for response scale by time frame

Topic Area for Items*	Preferred Response	24 hours	7 days	14 days
Symptoms	Severity	**70%**	**53%**	**59%**
	Frequency	12%	23%	23%
	Indifferent	18%	23%	18%
Basic physical functions	Difficulty	**59%**	**41%**	35%
	Frequency	12%	29%	**47%**
	Indifferent	18%	18%	6%
	N/A	12%	12%	12%
Doing activities w/ symptoms present	Difficulty	**59%**	41%	**53%**
	Frequency	12%	**47%**	47%
	Indifferent	29%	12%	0%
Concentrate, complex tasks	Difficulty	**76%**	**64%**	**53%**
	Frequency	12%	18%	23%
	Indifferent	6%	12%	18%
	N/A	6%	6%	6%
Speak, remember words	Difficulty	**47%**	18%	18%
	Frequency	12%	**41%**	**41%**
	Varied	6%	6%	6%
	N/A	35%	35%	35%
Usual daily activities	Difficulty	**65%**	29%	35%
	Frequency	0%	**47%**	**47%**
	Indifferent	35%	23%	18%
Usual responsibilities	Difficulty	**59%**	**41%**	**41%**
	Frequency	6%	12%	29%
	Indifferent	35%	41%	24%
	Varied	0%	6%	6%

**Difficulty response options were not offered for questions about social activities or mood states; N/A: indicates participants who said they did not experience the symptom or impact*

Conclusions

- Findings indicate that patient perspectives are important to evaluate directly when selecting a PROM recall period and response options, as question content may differentially affect ease of recall and the way ratings capture people's experiences
- When planning research assessments, use of measures with varied time frames and/or response scales may permit improved overall measurement of migraine experiences. Documenting contextual factors that may affect respondents' answers for specific symptoms or impacts could be important for interpreting scores

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