Collecting Better Quality Patient Reported Outcomes in Migraine: Baseline Patient Understanding of How to Record a Headache Day

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The Methodological Question Being Addressed: Baseline patient interpretation on headache duration

Introduction: Many clinical trials rely on the direct reports of subjects as a critical method to determine the treatment's efficacy and/or safety. Patient-reported outcomes (PROs) collected as endpoints in clinical trials often require patients to report symptom severity, frequency, or intensity, or the impact of symptoms on quality of life. It is generally accepted that variability in PROs should be reduced to ensure data quality. However, the assessment variability due to the subject's interpretation of measurement parameters may be overlooked.

Methods: We collected data from 78 migraine patients. Patients were given a scenario of overnight headache, "If you were participating in a clinical trial that asked you to report how many days you had a headache in a week and you had a headache from 8:00 pm Sunday night to 8:00 am Monday morning, does it count as 1 or 2 days with a headache", and were asked to select 1 answer from 4 choices. In addition, demographic data (age, gender, education and income), as well as whether patients have ever participated in clinical trials, was also collected.

Results: Among the total participants, 74 responded to the question. Only 25.7% (19 patients) answered the question correctly ("2 days. I had a headache on Sunday and Monday"). There were 56.8% of respondents (42 patients) who chose "1 day. The sum of hours that I had a headache is fewer than 24", and 17.6% of respondents either chose "It depends on how bad my headache was at each occurrence. I would need more information to answer this question" (2 patients), or "It depends on how bad my headache was at each occurrence. I would need more information to answer this question" (11 patients). In particular, among the majority of 55 patients (74.3%) who chose incorrect answers, 12 (21.8% of total wrong answers) reported they have participated in clinical trials at some point.

Conclusion: Our findings suggest that patients have diversified interpretations and would report differently on the number of headache days when encountering the same headache scenario in the absence of standardized training on how to use and report in their headache diary. This further suggests that without proper training, they would also record the same physical response differently during an actual clinical trial. The FDA migraine treatment guidance, as described in the 2014 draft, clearly stated that "The headache diary should be shown to be well defined and reliable for the target population based on the recommendations described in guidance for industry *Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims*. Our findings suggest that custom training for subjects in a migraine clinical trial to understand expectations and how to accurately complete a headache diary may be used to improve clinical trial data quality to comply with FDA regulation.

Disclosures: The authors are employees of ERT.