Uncovering Factors Patients Use to Evaluate Meaningful Response to Migraine Treatment

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INTRODUCTION

The ever-changing landscape of headache and Migraine therapeutic options warrant a need to revise and improve methods of assessing treatment progression and disease modification. As the number of therapeutic options for those suffering from headache disorders continues to increase, the need for evaluation of patient's meaningful response to treatment also rises. Much of our initial understanding of the impact of migraine on patients' lives was focused on measuring response to acute treatment. While much research highlights the various areas in which Migraine patients are impacted, little research has been conducted to develop tools using the patients as the expert to find ways to efficiently assess meaningful response to treatment from a disease modification standpoint. This is the first phase of a larger project to create a new patient driven questionnaire aimed at measuring a patient's response to migraine medications.

OBJECTIVES

1. The objective of this project was to establish factors which are most important to patients when appraising the efficacy of Migraine treatment.
2. To develop a patient-reported outcome measure to evaluate meaningful response to headache treatment regimens, as defined by patients.

METHODS

Development of the semi-structured interview questions included a panel of experts including headache thought leaders, psychologists, and statisticians. As a way to increase patient involvement in identifying meaningful response factors (thematic domains), we also received guidance on topics to include during the data collection process from Migraine patients and an advocate.

A small, nationwide group of patients with Migraine participated in one-on-one semi-structured interviews collecting information regarding the patient's perspective on meaningful response to Migraine management. Patients were interviewed for approximately 60 to 90 minutes. A total of over 12 hours of interview data was collected, reviewed, and coded. Questions asked during the interview included a review of Migraine disease and treatment history, as well as typical Migraine symptoms. Patients were then asked to describe how they have evaluated their Migraine treatment response and improvement in the past. A list of Migraine domains expected to be identified as meaningful when measuring treatment response were covered with the patient, asking them to rate the level of importance of each domain. Upon inquiry, if any important domains for the patient were missing, a domain was added and rated on the level of importance as well. Data from these interviews was reviewed and analyzed by four staff members using thematic coding. This process helped to ensure responses were representative of the participants answers.

RESULTS

The patients participating in the semi-structured interviews ($N = 10$) were 80% female and 20% male, with a mean age of 47.6 years ($SD = 13.32$). Seven of the 10 were diagnosed with Chronic Migraine, while 3 were diagnosed with Episodic Migraine. Fifty percent of the subjects reported taking more that 5 prophylactic medications to help prevent their migraines. Sixty percent of the patients were gainfully employed while 40% were disabled due to their Migraine diagnosis.

Patients ranked the importance of the expected thematic domains on a 7-point Likert Scale (with 7 indicating highest). As predicted, results indicated all expected thematic domains hold a high level of importance when assessing meaningful treatment response (see Figure 1). Pain severity was reported as the most important domain ($M = 6.80$), followed closely by Number of Migraine Days ($M = 6.30$) and Days Unable to Complete Tasks ($M = 6.15$). Mood Fluctuation ($M = 4.65$) was ranked as the least important domain; however, patients still identified this domain as moderately important on average.
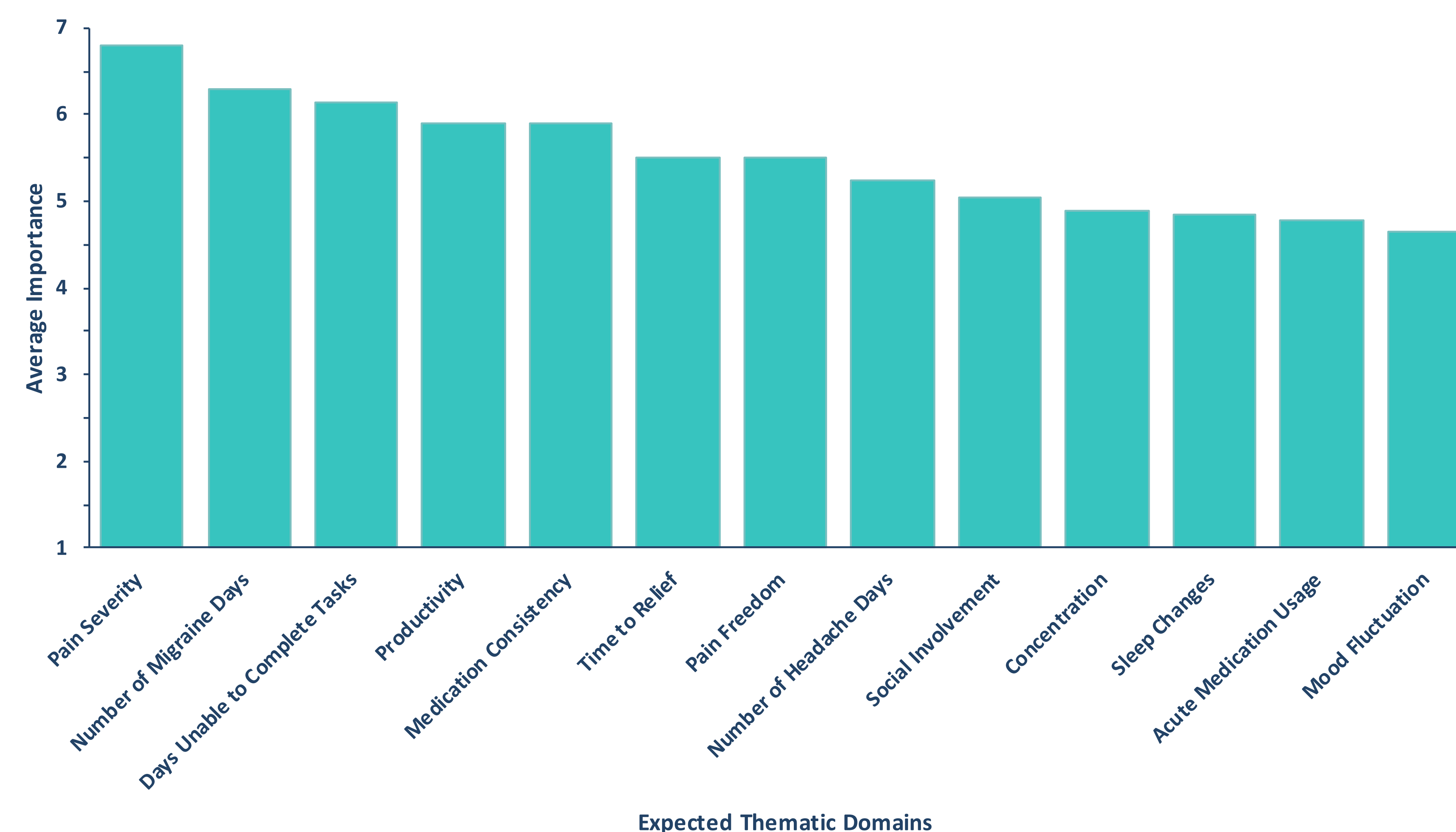

Figure 1.

Further review of additional survey responses yielded similar results. Patients frequently discussed topics such as being able to maintain schedules, friendships, less pain and fewer impacted days (see Table 1).

Table 1

Code Category	Example Responses
Normal Functioning	Emotional consistency; Exercise; Schedule events; Take a shower; Cannot interact; Activity level
Social	Not isolate friends; Ruin relationship; Go out to eat; Family; Do activities
Frequency	Fewer higher pain days; Less attacks; Headache free
Productivity	Do not have to miss job; Sick days; Daily accomplishments; Do housework
Medication	Knowing it will work; Less meds per day; More options on the market; Worries about safety
Pain	A cure; Less pain; Relief
Education	Be own biggest advocate; Articulate problems to provider; Help patients understand full symptoms; Other treatment options
Financial/Insurance	Monthly restrictions; What's covered on plan; Cost to treat migraine
Associated Symptoms	Decrease symptoms; How feel when having associated symptoms; Photobia
Self-Worth	Enjoy activities; Perception of competences; Satisfaction
Concentration	Clear head; Not thinking about head pain
Doctor	Actual access to the provider; Need for more options

RESULTS CONTINUED

From these patient responses, 12 common themes emerged as important in evaluating efficacy in Migraine treatment (see Figure 2). As expected, pain ($f = 21$) and associated symptoms ($f = 14$) were frequently discussed. However, these interviews also elucidated other concerns not commonly covered on current Migraine assessment tools. Specifically, normal functioning was found to be discussed most often ($f = 48$), indicating this domain is highly important in the assessment of meaningful treatment response. Other commonly discussed topics included social connections with family/friends ($f = 33$), productivity at work and home ($f = 26$), emotions such as self-worth ($f = 14$), and cognitive concerns such as concentration/brain fog ($f = 6$). Finally, a set of provider-specific options were coded, medication concerns ($f = 23$), cost and insurance ($f = 16$), and education ($f = 19$) of self and doctor as peripheral barriers to access of treatment.
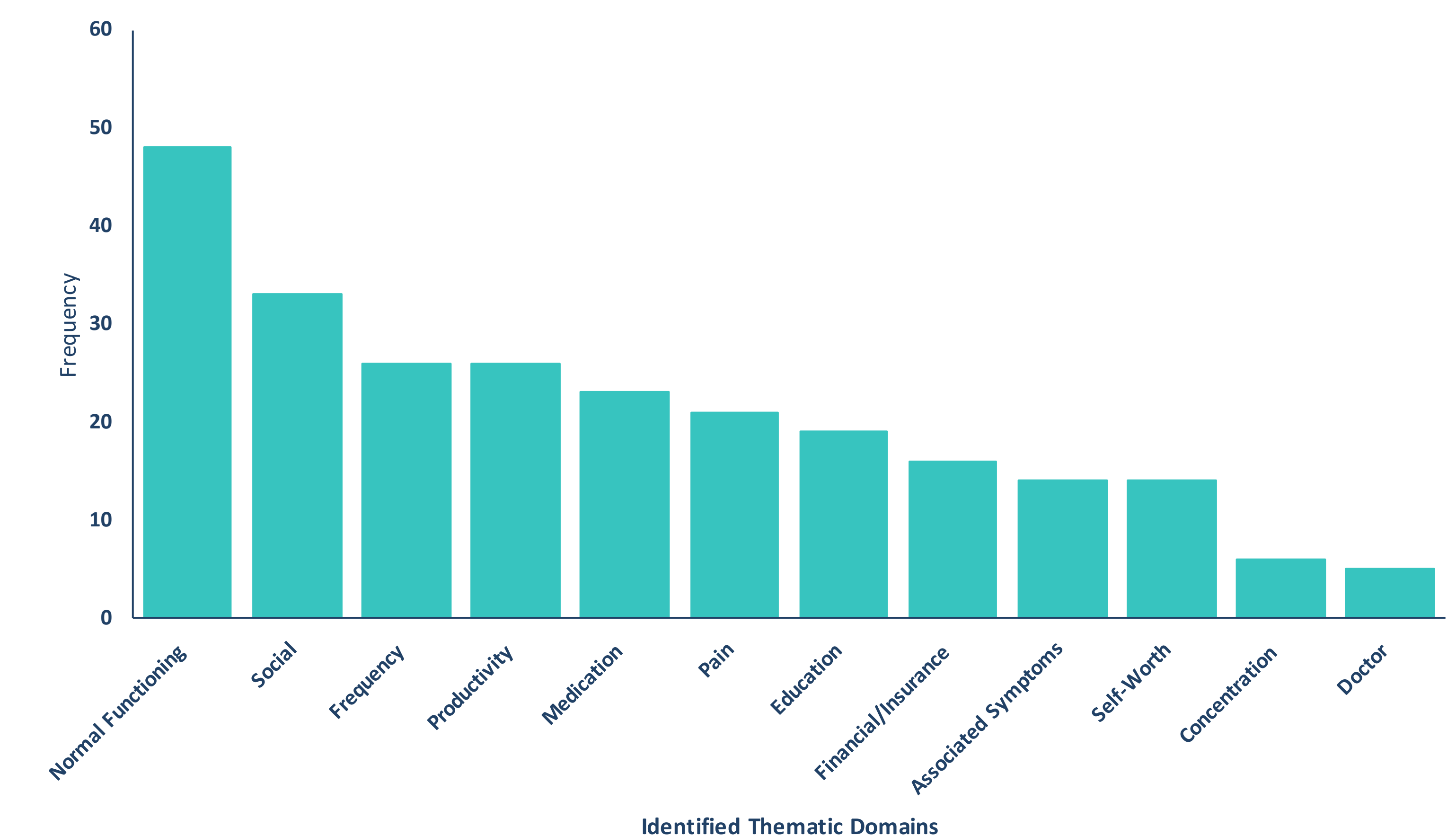

Figure 2.

CONCLUSIONS

Surprisingly, Normal Functioning and Social topics were the most commonly discussed domains; more than the common endpoints, Frequency and Pain, used in clinical trials. This research indicates a gap between the factors patients with Migraine find important when appraising the efficacy of headache treatment and current assessment tools. Further research into developing patient-centric assessments would help to improve patient communication with their provider and give a quantitative way to assess treatment response, all while focusing on important factors patient's use to gauge their response to treatment. Next steps in our scale development include drafting questions targeting the 12 identified thematic domains and electronically administering to 100 patients to identify the highest performing questions. Our final phase of this grant funded project will conclude with a draft questionnaire exhibiting psychometrically valid properties.