Predictors of Low Patient Activation When Initiating C1 Esterase Inhibitor Therapy for Hereditary Angioedema

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BACKGROUND

- Hereditary Angioedema (HAE) is a very rare and potentially life-threatening genetic condition. HAE occurs in about 1 in 10,000 to 1 in 50,000 people. Symptoms include episodes of edema (swelling) in various parts of the body including the hands, feet, face, and airway. Swelling can occur at any time and if located within the airway, the mortality rate was reportedly as high as 30% without proper, quick treatment.[1]
- Patients with this rare disease have a defect in the gene that controls a blood protein called C1 inhibitor. Because of the defect to this gene, a biochemical imbalance can occur and produce unwanted peptides that induce the capillaries to release fluids into the surrounding tissue; thus causing edema.
- The disease occurs in two main phenotypic variants: Type I (occurring in approximately 80-85 % of patients) is characterized by a decrease in the formation of C1-INH to about 10-30 % of normal. Type II (approximately 15-20 % of patients) is manifested by production of normal or increased levels of a non-functional C1-INH protein that is antigenically intact. The prevalence of HAE is estimated at 1:50,000.[3]
- Results of a study reported that the common burdens of living with HAE range from high rates of missed work, lost productivity and lost income. Payers typically account for 67% of direct medical costs when patients are not able to administer the therapy.[2]
- Though a rare disease, there are multiple products available to the consumer ranging from Sub-Q injections to self-IV administration. Given the severity of this rare, genetic condition, it is important to identify factors leading to low patient activation. Identifying factors could help optimize interventions to increase the quality of healthcare and assist in overall cost reduction within health centers.
- Following a patient-centered approach to providing individualized support and cadence, Lash Group leveraged the use of a validated PRO-tool called Patient Activation Measure (PAM). This PRO tool segments patients into four different levels of activation that measures their overall engagement of being active self-managers of their own care.
- The PAM segments patients into four levels of activation, 1 thru 4, with 1 being the lowest level of activation. This PRO and assessment were chosen as it puts focus on measuring a patients understanding and knowledge of their condition and treatment, the skills they have of administering the product and maneuvering through the health system, and measuring the patients overall confidence to be an active self-manager of their care.

Four levels of activation along 100=point continuum

Level 1	Level 2	Level 3	Level 4
Disengaged and overwhelmed	**Becoming aware, but still struggling**	**Taking action**	**Maintaining behaviors and pushing further**
• Individuals are passive and lack confidence. • Knowledge is low, goal-orientation is weak, and adherence is poor. • Their perspective: "My doctos is in charge of my health."	• Individuals have some knowledge, but large gaps remain. • They believe health is largely out of their control, but can set simple goals. • Their perspective: "I could be doing more."	• Individuals have the key facts and are building self-management skills. • They strive for best practice behaviors and are goal-oriented. • Their perspective: "I'm part of my health care team."	• Individuals have adopted new behaviors, but may struggle in times of stress or changes. • Maintaining a healthy lifestyle is a key focus. • Their perspective: "I'm my own advocate."
General Population			
15-20%	20-25%	25-30%	20-15%

INCREASING LEVELS OF ACTIVATION

OBJECTIVE

- To identify predictors of low patient activation measures (PAM) among patients initiating C1 esterase inhibitor (recombinant) (C1 – INH) for treatment of hereditary angioedema.

METHODS

PATIENT ACTIVATION MEASURE

- Patients who were prescribed C1 – INH were opted-in to a patient support services program that provided educational and individualized support to improve patient outcomes.
- During the initial Welcome Call with their assigned Telehealth nurse from the Lash Group call center, patients were assessed using the PAM to collect a baseline segmentation activation level and raw score. This PRO-tool segments patients into four levels of activation based on their skills, knowledge, and confidence of being effective self-managers of their own care. Activation levels are determined based on a raw score ranging from 0 to 100.
- Patients were grouped into 3 mutually exclusive cohorts: low patient activation ≤2 (levels 1 and 2), moderate patient activation =3 and high patient activation =4.
- Due to the rare nature of hereditary angioedema, standardized differences between available factors across PAM level cohorts were computed using PAM level 4 as the reference cohort.

RESULTS

- There were 94 patients included in the analysis, with the majority being female (74.5%), having a mean age of 40 years, and being from the southern region (40.4%) and privately insured (61.7%). Figure 1 shows that the majority of patients were in PAM level 4 (58.5%) followed by PAM level 3 (30.9%) and PAM level ≤2 (10.6 %). General data around the patient population and demographics can be found in Table 1.

Figure 1. PAM Level Distribution (N=94)

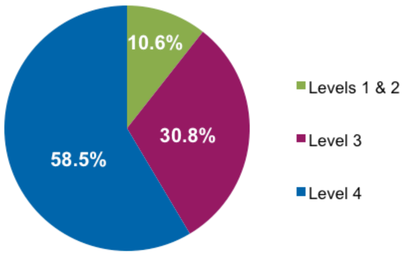


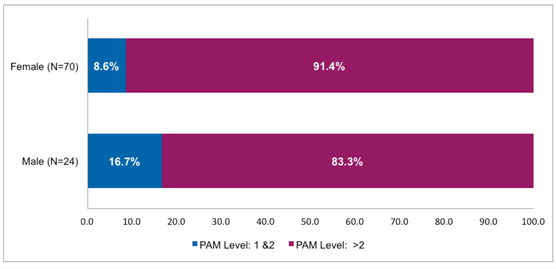
Table 1. Patient Demographics

Variables	Total Patients	
	N	%
Payer		
Private	58	61.7
Medicare	20	21.3
Medicaid	16	17
Total	94	100
MD specialty		
Others	20	21.3
Allergy	59	62.8
Immunology	9	9.5
Primary Care	6	6.4
Total	94	100
Sex		
Female	70	74.5
Male	24	25.5
Total	94	100
PAM Level		
1	2	2.1
2	8	8.5
3	29	30.9
4	55	58.8
Total	94	100
Region		
(Missing)	1	11
Northeast	15	16
Midwest	18	19.1
South	38	40.4
West	22	23.4
Total	94	100

PREDICTIVE FACTORS TO LOW PATIENT ACTIVATION

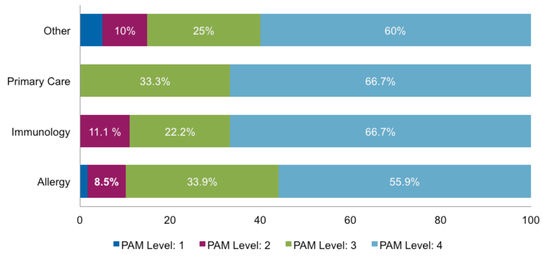
- Results indicated that low patient activation, ≤2, (as compared to highest activation level, 4) was associated with being in a younger age (35.7 vs 38.9; standardized difference [SD] =20.2), and being a male results in being 2 times as likely to having a low activation level indicated in Figure 2.

Figure 2. Male and Female Likelihood of Being at Low Patient Activation Level



- Patients who were segmented within the low patient activation level were likely to see a Specialist as compared to their Primary Care Physician. Patients in higher activation levels were likely to visit with their Primary Care Physician and Specialists as shown in Figure 3.
- There were no significant differences found within the insurance data to predict a patient being less activated ([SD]= Medicare, 0.6, Medicaid, 0.93, Private, 0.73)

Figure 3. MD Specialty Distribution by Activation Levels



LIMITATIONS

- Caution should be used in generalizing study results as multivariate analyses were not employed due to the small sample size.
- Distribution of PAM levels is limited due to the severity of this genetic condition.

CONCLUSIONS

- Results indicated that younger male adults were more likely to fall within the low action category when initiating a C1 Esterase Inhibitor Therapy.
- Given the severity of this genetic disorder, it is expected that patients are likely to be more activated and engaged in their care in order to prevent worsening of symptoms or even death.
- Interestingly, patients who were segmented into low activation levels did not visit with their Primary Care Physician and instead relied solely on Specialists. This could be due to patients needing a Specialist to educate them on their condition, provide guidance on how to manage symptom triggers, and understand when and how to administer the prescribed C1-INH.
- Patients who were more activated (higher PAM Levels) had a much better understanding of their disease and the triggers causing their symptoms; thus lowering their need to follow up with a specialist as often as they visit with their Primary Care Physician.
- The use of the Patient Activation Measure (PAM) provided a baseline value for a patient's level of activation. Patients enrolled in this patient support program will continue to receive support and will be reassessed every 90 days to measure the improvement or reduction of PAM Level.

REFERENCES

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Presented at International Society of Pharmacoeconomics & Health Outcomes Research Annual Meeting | Washington, DC | May 23rd, 2016

SPONSORSHIP: This research was sponsored by Lash Group.