

Barriers to self-administered therapy for hereditary angioedema

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ABSTRACT

Presently, the movement of care for hereditary angioedema (HAE) is out of the clinic, emergency department, and hospitals and into the home. Much of the transition relies on specialized nurses who teach patients self-administration skills. Our goal was to assess nurses to uncover barriers that they have encountered in an effort to improve self-therapy education and patient care. A survey of 21 questions was sent to 38 HAE home care nurses throughout the United States. Results were collected anonymously and data were analyzed. Nurses feel that there is an increased need for teaching patients self-therapy skills. The majority are very comfortable teaching self-administration and troubleshooting-associated problems. Perceived difficulties in providing adequate teaching include distance to patient's home and logistics of coordinating, scheduling, and obtaining supplies. Teaching is preferred when done at home by a visiting nurse with a care partner available and multiple training sessions are needed. Very few patients refused self-administration after initially being taught; reasons cited for refusal include fear of injection or infection, lack of skills, interference of daily activities, and financial restraints. As for nurses, they were most worried about safety, lack of skill retention, and inappropriate use of the drug. Self-administration of HAE treatment is increasingly more accessible and should be offered to patients as a safe and practical option. The barriers to self-administration revealed in this study include distance to the patient's home, coordinating care, obtaining medications/equipment, and scheduling training sessions. Moving to self- or home treatment through nursing instruction will improve patient's independence and quality of life, lead to earlier therapy, and reduce costs associated with care.

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Treatment of hereditary angioedema (HAE) has dramatically changed over the last several years. As we transition away from the traditional hospital setting, self-administration of therapies has gained popularity not only from the patient, but also from the clinician in various ways. The advantages of self-administration include rapid treatment of an attack, allowing patients to manage their own disease, decrease the need for emergency department care, decrease hospitalizations, allowing freedom to travel, and, most importantly, improving patient quality of life.¹ From a clinician's point of view, early treatment, optimized therapy, lower dose, and fewer visits to the emergency department are also some of the important benefits.² Therefore, there is an increasing effort to make self-administration of HAE treatment available, effective, and safe.

Currently, there are three drugs approved for self-administration. Two are intravenous (i.v.) drugs. The first is plasma-derived C1 inhibitor (C1-INH; Berinert; CSL Behring, King of Prussia, PA), which has been approved in the United States since 2012 for HAE treatment during attacks and short-term prophylaxis.³ The second is another plasma-derived C1-INH (Cinryze, ViroPharma Inc., Exton, PA) approved in the United States since 2009 for prophylaxis.³ The third drug approved for acute attacks is subcutaneous bradykinin receptor blocker icatibant (Firazyr; Shire Human Genetic Therapies Inc., Lexington, MA) approved in the United States since 2011.⁴ Ecallantide (Kalbitor, Dyax, Cambridge, MA) is subcutaneous but must be injected by a health care provider.⁵

In the United States, home care agencies staffed with specialized nurses are employed to teach i.v. and subcutaneous administration techniques and for supporting patients with HAE. As much of the transition relies on specially trained medical professionals, our goal is to assess the comfort of nurses with teaching self-administration and to identify barriers they anticipate or have noted in an effort to improve patient care. Information was sought regarding nurse experience relating to their training, logistics of providing care, and their interaction with HAE patients. These efforts will supplement the information already obtained from HAE experts.⁶

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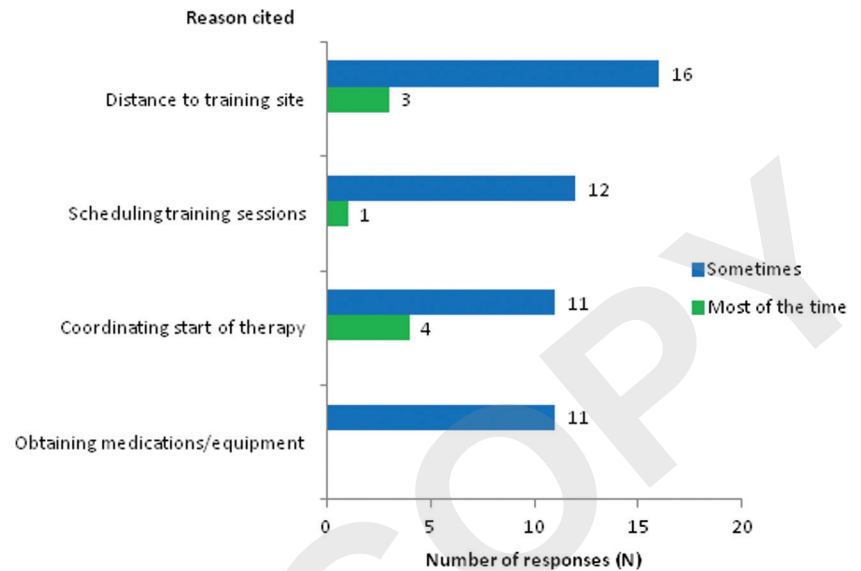


Figure 1. Perceived difficulties associated with teaching of self-administration as reported by nurses.

METHODS

A survey was prepared with questions related to nurse's experience with training, comfort with teaching of self-administration, and concerns related to self-administration. The questions were assessed by multiple choice answers. The survey, consisting of 21 questions, was sent nationally to specially trained nurses at BioRx therapy centers across the United States. Thirty-six of the 38 questionnaires were completed and returned. Results were collected anonymously and data were analyzed. The statistics are descriptive only. The study met an Institutional Review Board exception because the survey did not contain patient data. The survey is available online as "supplemental materials" (see online supplement Table E1).

RESULTS

Prescribing Self-Administration

All of the responding nurses feel that there is a need for teaching patients how to self-administer (100%; $n = 36$). Fifty percent ($n = 18$) felt that physicians are hesitant to have patients self-administer HAE therapies, and 47.2% ($n = 17$) did not feel that physicians are hesitant. A large number of nurses frequently (38.9%; $n = 14$) or always (8.3%, $n = 3$) suggest to the prescribing doctor to order self-administration, and 11.1% ($n = 4$) rarely suggest and 27.8% ($n = 10$) do not suggest to the prescribing doctor to order self-administration.

Nurse Training Experience

The majority (77.8%; $n = 28$) feel very comfortable in teaching patients and troubleshooting problems as they arise and 25% ($n = 9$) report feeling somewhat comfortable and report they would benefit from further training. Surveyed nurses report feeling very comfortable in teaching self-administration of both subcu-

taneous (97.2%; $n = 35$) and i.v. medications (88.9%; $n = 32$). Perceived difficulties (reported as "sometimes" and "most of the time") in providing adequate teaching include distance to the patient's home (50%; $n = 19$), coordinating care (41.7%; $n = 15$), obtaining medications and equipment (30.6%; $n = 11$), and scheduling (36.1%; $n = 13$; Fig. 1).

Patient Demographics

Eleven percent ($n = 4$) of nurses report that education level affected learning "all of the time," 22.2% ($n = 8$) report it as "most of the time," and 55.6% ($n = 20$) report it as "sometimes." Patients aged 18–40 years most easily acquire self-administration skills (63.9%; $n = 23$), followed by those aged 12–18 years (22.2%; $n = 8$; Fig. 2).

Patient Teaching Experience

Most nurses prefer self-infusion teaching to be done at home by a visiting nurse at set sessions (94.4%; $n = 43$). Having a care partner in self-administration training was considered very helpful in teaching patients (83.3%; $n = 30$). After initial training, many patients are able to demonstrate the skills required for self-administration on that same day with only 13.9% ($n = 5$) reporting that none of their patients were able to demonstrate the ability. Nurses report many patients (47.2%; $n = 17$) required 1 or two training sessions, and 50% required 3–5 training sessions and the remaining 2.8% ($n = 1$) required 6–10 training sessions for skill retention. On follow-up visits, skill retention was reported as 8.3% ($n = 3$) for all patients, 77.8% ($n = 28$) for most patients, and 11.1% ($n = 4$) in some patients. As for calling with questions after initial training, 33.3% ($n = 12$) call after the first attack at home, 27.8% ($n = 10$) call within the 1st month, 22.2% ($n = 8$) call

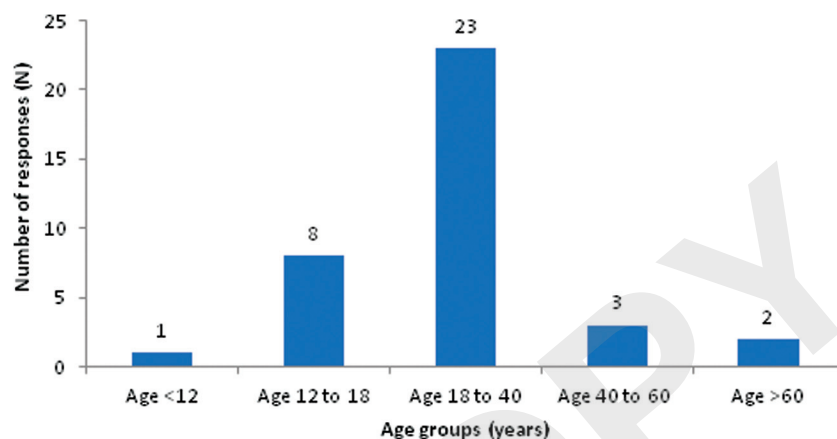


Figure 2. Ease of skill acquisition by age group.

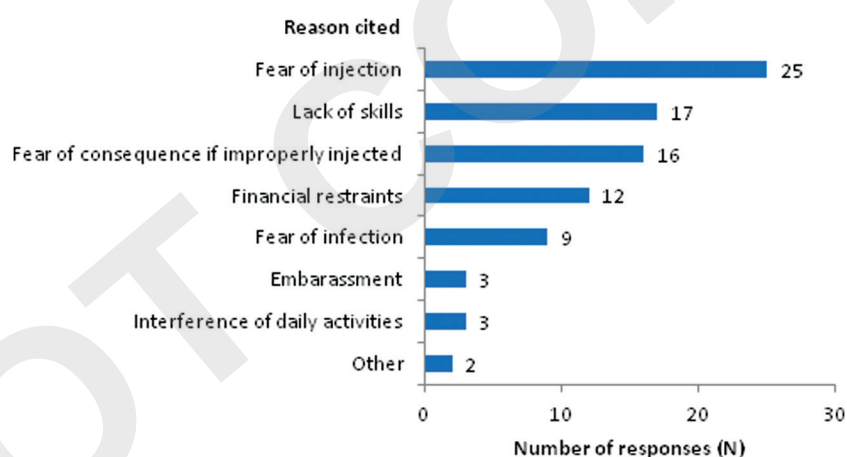


Figure 3. Reasons for refusing injection.

within the 1st week after training, 5.6% ($n = 2$) call within 2–6 months, and 5.6% ($n = 2$) rarely call.

Patients Who Refuse Self-Administration

The majority (61.1%; $n = 22$) felt that <10% of patients refused self-administration after initially being taught, and 13.9% ($n = 5$) reported that 25% of patients refused and 2.8% ($n = 1$) reported that 50% of patients refused. Eleven percent ($n = 4$) felt that none of their patients refused self-administration after initially being taught. The most commonly cited reasons for refusing self-administration include fear of injection (such as pain, anxiety, and bruising; 69.4%; $n = 25$), lack of skills (dexterity required for self-administration; 47.2%; $n = 17$), interference of daily activities (44.4% $n = 16$), financial restraints (medication cost/insurance coverage; 33.3%; $n = 12$), fear of consequence if improperly injected (25.0%; $n = 9$), fear of infection (8.3%; $n = 3$), and other reasons not listed (8.3%; $n = 3$; Fig. 3).

Nurses' Concerns Regarding Teaching and Approving Self-Administration

The major worries from a nurse's perspective include safety concerns (63.9%; $n = 23$), inability of patients to maintain their skills (55.6%; $n = 6$), fear that patients

may overdose on the drug (25% $n = 9$), and inappropriate use of the drug (22.2%; $n = 8$; Fig. 4).

DISCUSSION

The World Allergy Organization has recently published a guideline that states that physicians should prescribe self-administration of therapies to improve the quality of life of patients with HAE.⁷ As the treatment of HAE progresses away from the structured facilities to allow for convenience and efficiency, there is inherently less direct interaction between the physician and patient. As a result, specialized nurses are essential in helping with the transition of care.

Patient-driven therapy has shown to function well in other disease models such as in the management of patients with hemophilia.⁸ Similarly, as the treatment of HAE has moved in this direction, there is currently an increased need for proper teaching of self-administration skills; nevertheless, physicians and the office staff are often not prepared for this task. As suggested by the results of this study, home therapy nurses feel that a large number of physicians are hesitant with regard to prescribing self-therapy for patients. Furthermore, awareness of its applicability may encourage more widespread approval.

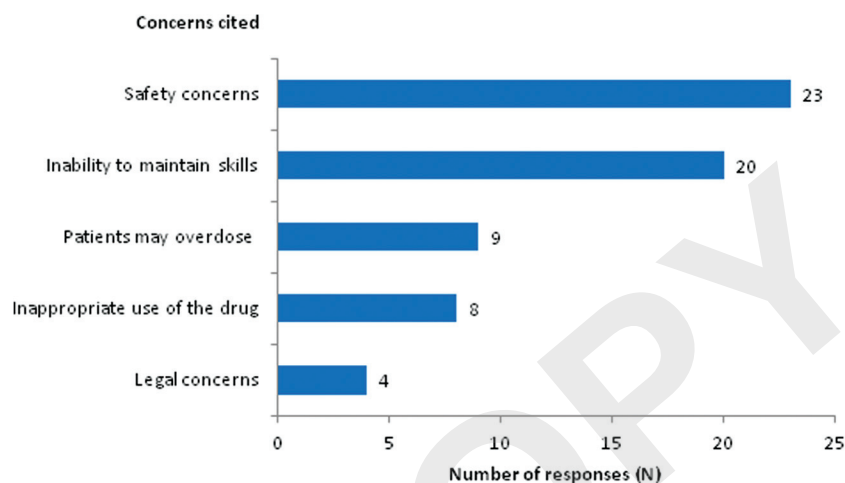


Figure 4. Nurse's concerns regarding patient self-administration.

The smooth transition toward independent patient-driven treatment relies in part on the specialized nurses trained to teach these patients the required skills at home therapy centers. These nurses have the most direct and frequent interaction with HAE patients as far as educating them, answering questions, and following-up with care. With this in mind, this study has uncovered barriers to self-administration as perceived by these nurses who serve to supplement the information gathered from current practice of HAE treatment across Europe.⁹

As far as nurse training, participants of the survey currently feel well prepared to help fill this need for teaching self-administration. However, barriers exist and our results will hopefully help physicians feel positive about the abilities of home care nurses to perform this function. Some areas of improvement should focus more on the logistics of providing adequate teaching. One of the measures should include having multiple training sessions at home with a care partner for learning assistance or to help out in therapy when the patient is not able to self-inject because of pain, hand swelling, stress, or panic. Providing appropriate training supplies, adequate time to train, and follow-up visits to ensure skill retention are all very important aspects for competent patient training. Also, nurses should return for follow-up visits even after the training is complete or at least they should be available by phone to answer questions as they arise. According to several nurses, patients have indicated the need for follow-up calls, especially after the self-treatment of the first attack at home. Our results again reinforce the work stating the importance of multiple training sessions and having a training partner.¹

Previous work has identified that physicians consider the main challenge of self-administration to be obtaining the necessary skill set.¹ Our work further describes other areas of improvement that go beyond the patient abilities. Better communication between physicians, nurses, and

patients would help to improve coordination of care. In addition, there is a need to have more interaction between insurance companies and specialty pharmacies to provide the necessary supplies and equipment to allow teaching of self-treatment.

As far as the patient demographics, it may be worthwhile focusing on the 18- to 40-year old age group because they most easily acquire the necessary skills for training and as such, they are the ideal patients for this type of therapy. Despite this age recommendation, training should be started in young patients to help overcome any fears of self-administration. Training the youth has been very successful in the hemophilia community.⁸

In regard to patient's perceptions, many are capable and willing to self-administer after being taught. Multiple studies have already shown that home-based therapy for HAE can be safely administered with minimal adverse reactions and has shown to be an effective option for treatment.¹⁰ Therefore, continued patient education and reassurance may be all that is necessary to overcome the perceived fears that were revealed in our study.

A limitation of this study is that it was restricted to home therapy centers using i.v. C1-inhibitor Berinert and icatibant through the BioRx company across the United States, entailing a selection bias. The nurses who responded also varied in terms of their years of experience with the drug; however, all had Berinert i.v. experience. Other limitations include recall bias and subjective qualifications of nurses who replied. Nevertheless, the detailed information supplied by these nurses is relevant to improve the quality and safety of self-administration.

This study has brought to our attention some additional areas of improvement needed to ameliorate the current state of practice. Moving away from in-office, infusion center, and emergency department treatment will reduce cost, decrease morbidity, and potentially reduce mortality. The reduction in morbidity and mortality are the result of early treatment; all available medications work best when given early during swelling or abdomi-

nal pain.⁵ Further efforts should be directed toward making the changes necessary to accommodate the switch toward patient independence in choice of therapy.

CONCLUSION

Self-administration of HAE treatment is increasingly more accessible and should be offered to patients as a safe and practical option. Specially trained nurses are essential for home-based teaching of the skills required for injection/infusion and for addressing patient's concerns regarding treatment. The barriers to self-administration revealed in this study include distance to the patient's home, coordinating care, obtaining medications/equipment, and scheduling training sessions. Moving to self or home treatment through nursing-provided education will improve a patient's quality of life, lead to more independence, provide earlier therapy, and significantly reduce the cost associated with care. Hopefully, our data will alleviate the concerns that doctors have regarding self-infusion and encourage physicians to prescribe self-therapy for their patients when they realize the expertise of home care nurses for training patients.

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