

Successful Administration of *neffy*, Epinephrine Nasal Spray, When Provided with a Two-Dose Carrying Case— A Human Factor Study

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RATIONALE

- *neffy*, epinephrine nasal spray, has been approved as the first and only needle-free epinephrine device in the US and EU for the indication of severe allergic reactions including anaphylaxis.
- Severe allergic reactions primarily occur outside of a hospital setting and epinephrine is typically administered by patients or caregivers.
- Human factor (HF) studies are required to ensure that the products can be administered safely and effectively.
- Four HF studies (n=188) have been conducted which demonstrated that patients, caregivers, passers-by, and children can administer *neffy* during a simulated allergy emergency without prior training (Hernandez-Trujillo 2024).
- A fifth study was conducted using the optional carrying case designed to hold two *neffy* sprayers to validate that the intended population could administer *neffy* correctly in the event of a simulated severe allergic reaction.

METHODS

HUMAN FACTORS SUPPLEMENTAL VALIDATION STUDY

- Included 16 untrained subjects (eight adults and eight juveniles):
 - 4 adult type 1 allergy patients
 - 4 adult caregivers of type 1 allergy patients
 - 8 juvenile type 1 allergy patients (10 -17 years of age)
- Participants were asked to complete the following tasks:
 - Load the carrying case with two *neffy* sprayers
 - Correctly open the carrying case during a simulated allergy emergency
 - Remove the sprayers and administer the product both once and twice (10 minutes apart) in the same nostril.



RESULTS

- 100% of the adult and juvenile participants were able to successfully load the carrying case with two *neffy* sprayers.
- 100% of the adult and juvenile participants were able to successfully open the carrying case during a simulated allergy emergency.
- 100% of the adult and juvenile participants were able to successfully remove the sprayers and administer the product both once and twice (10 minutes apart) in the same nostril.



CONCLUSIONS

- The *neffy* carrying case enables patients and caregivers to always have two *neffy* sprayers available and easily accessible.
- The results of this study demonstrated that untrained patients can properly follow written instructions.
- Based on the final intended labeling, there were no use errors.
- This study confirms that the user-friendly *neffy* carrying case is suitable for use by both adults and children.

REFERENCES

Hernandez-Trujillo V, Tachdjian R, Brooks J, Dorsey BT, Tanimoto S, Lowenthal R. *neffy*, Nasal Epinephrine Spray, Demonstrated Successful Use by Patients and Caregivers: Human Factor Findings. Poster presented at: National Conference of the American Academy of Pediatrics; September 27-October 1, 2024; Orlando, FL.