EAI Nasal Spray Versus Crossover Healthcare Multicenter, PhD1, Patricia Anderson, MSE 1, Adam Shames, MBA1

Both patients and healthcare professionals (HCPs) show inadequate immediate administration of epinephrine, currently most commonly used in treatment protocols, which may in turn improve patient adherence and potentially reduce hospitalizations and anaphylactic deaths. Therefore, the objective of this study was to determine perceptions of patients and HCPs regarding an epinephrine nasal spray device (ENS) compared to an epinephrine autoinjector (EAI).

INTRODUCTION

Immediate administration of epinephrine, currently most commonly self-administered in patients via intramuscular or subcutaneous injection with a pre-filled autoinjector, has been the first-line therapy in the treatment of severe allergic reaction (anaphylaxis)1. Differing in administration method, at-home epinephrine nasal spray may improve compliance and ease of administration.

METHODS

Participants participated in the device in a randomized manner and then answered survey questions validated in advance of pivotal testing. The study involved ≥56 HCPs, including prescribing and clinical staff who train patients. The survey evaluated metrics including: portability, ease of learning, ease of use, overall preference, likelihood of recommending to others, and safety. Each question was analyzed with an excel binomial test (for statistical significance p <.05).

RESULTS

There was a statistically significant preference for ENS on all survey metrics evaluated. The EAI trainer devices, which do not contain the drug or a needle. The EAI includes a trainer device (which has no medication and training level) and an autoinjector device (which has medication and training level). The ENS device contains two equivalent doses; therefore, users only have to carry one device.

METHODS

This was a multicenter, randomized, crossover preference study of ENS versus EAI.

Study devices (Figure 1): The devices used in the study were:

- ENS device (left) and EAI (right) used in the study
- Empty but fully functional ENS devices. Each ENS device contains two equivalent doses; therefore, users only have to carry one device
- EAI trainer devices, which do not contain the drug or a needle. The EAI includes a trainer device (which has no medication and training level) and an autoinjector device (which has medication and training level).

CONCLUSIONS

- All participants provided written consent before their session and were compensated for participating in the study.
- Participants attended a one-on-one session with a Moderator during which they were trained on how to use both devices.
- Participants observed a demonstration of the first device and then simulated use of the device in a mock emergency. Participants observed a demonstration of the second device and then simulated use of the second device on their own. Presentation of the devices was counterbalanced between participants.
- After using both devices, participants completed the eight-item questionnaire.

Statistical analysis

This study was reviewed and approved by the Core Human Factors, Inc., an independent human factors testing and design firm, registered with the US Department of Health and Human Services.

RESULTS

For all metrics evaluated, the survey results indicated a statistically significant preference for the ENS device over the EAI (p <.001).

TABLE 1. Number of HCPs by participant type

<table>
<thead>
<tr>
<th>Participant Type</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary care physician</td>
<td>43</td>
</tr>
<tr>
<td>Allergy/immunology physician</td>
<td>16</td>
</tr>
<tr>
<td>Other</td>
<td>10</td>
</tr>
<tr>
<td>Total</td>
<td>70</td>
</tr>
</tbody>
</table>

TABLE 2. HCP preference for ENS Device

<table>
<thead>
<tr>
<th>Question</th>
<th>Preference for ENS Device</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which device do you think would be more effective for patients to use in an emergency?</td>
<td>69 (69.6)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Which device do you think would be easier for patients to learn how to use?</td>
<td>66 (66.1)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Which device do you think would be easier to use?</td>
<td>82 (82.1)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Which device do you think would be more portly?</td>
<td>50 (43)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Which device would you recommend to patients?</td>
<td>43 (43)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Which device do you think would be safer for patients to use in a real emergency?</td>
<td>94 (86)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Which device do you think would be more favorable to use in a real emergency?</td>
<td>73 (67)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

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ACKNOWLEDGMENTS AND DISCLOSURES

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REFERENCES