An Evaluation of Human Factors Surrounding the Usability of a Novel Vial Adapter System Versus a Traditional 2-Vial Vaccine Reconstitution System

INTRODUCTION

• Many vaccines are supplied as lyophilized powders in vials that require reconstitution by a healthcare professional just before administration.
• Traditional 2-vial reconstitution (2V) systems include 2 vials and 2 needles and can be relatively time-consuming to prepare.
• A vial adapter (VA) system (Figure 2) has been developed that uses 1 needle, 1-vial system to potentially speed up the reconstitution process.

OBJECTIVE

• To evaluate the relative usability of the 2V and VA systems in the hands of healthcare professionals who frequently provide vaccinations to the public.
• To identify and understand the preferences of the users regarding their experiences with the 2 systems.

METHODS AND MATERIALS: STUDY DESIGN

Participants used quick reference guides (QRGs) to self-train on both systems.
• The 2V system (Figure 3) comprised a placebo powder vial, diluent vial, graduated syringe, 27-gauge mixing needle, and 25-gauge administration needle.
• The VA system (Figure 4) comprised a placebo powder vial, diluent vial in a prefilled syringe with the vial adapter and 25-gauge administration needle. The vial flip cap is removed, and the adapter locked onto the vial base-down, wherein the spike pierces the vial's rubber stopper. The adapter-vial assembly is then twisted onto the prefilled syringe via the Luer opening, allowing injection of the diluent into the vial.

METHODS AND MATERIALS: STUDY RECONSTITUTION SYSTEMS

• Healthcare professionals who provide vaccinations to the public were recruited in Atlanta and Boston, US in March 2022.
  ▪ Each participant attempted 2 simulations of the vaccine reconstitution and administration process for each system.
  ▪ Participants were not given study-specific training in advance of the simulations, although they were given 2.5 minutes to study the QRGs to familiarize themselves with each system before performing simulations.
  ▪ The participants could refer to the QRGs at any time throughout the simulations for a given system; however, the study moderator was prohibited from offering guidance or providing any other indications of the participant's performance at any time.
  ▪ The reconstitution systems were presented to participants in a counterbalanced order to mitigate against possible order effects.
  ▪ Usability was based on participants' successful and independent completion of each step of each system's workflow.
  ▪ After all simulations were completed, participants were interviewed by the study moderator for approximately 10 minutes to solicit subjective feedback regarding each system.
  ▪ Participants answered several open-ended questions to describe their experiences during the simulations, such as problems they faced or aspects they found frustrating.
  ▪ Participants also rated the VA system on 14 statements (Table 1) using a 5-point Likert scale (Strongly Disagree → Strongly Agree).

RESULTS

Population Characteristics
  ▪ A total of 56 participants were recruited: 43/56 (76.8%) were nurses/vaccine coordinators representing the following practices:
    ▪ Family/General (n=18; 32.1%)
    ▪ Pediatrics (n=12; 21.4%)
    ▪ OB/GYN (n=13; 23.2%)
    ▪ 13/56 (23.2%) were retail pharmacists.
    ▪ 42/56 (75%) were females.
    ▪ 50/56 (89.3%) were right-hand dominant.
  ▪ 10/56 (17.9%) represented rural communities.

Usability
  ▪ Participants' overall success rates were comparable between systems.
  ▪ 2V: 77% VA: 81%
  ▪ Generally, participants showed comparable, albeit small, improvements from the first to the second simulation in both systems.

Subjective Outcomes
  ▪ 50/56 participants (89.3%) expressed a preference for the VA system; 3/56 participants (5.4%) expressed a preference for the 2V system.
  ▪ A large majority of the participants considered the VA system easier (89%) and faster (85%) than the 2V system, and would recommend the system to other healthcare professionals (Pearson’s chi-square test, p<0.05).

CONCLUSIONS

• Healthcare professionals who administer vaccinations regularly performed simulated vaccinations with the VA system, as well as they did with the 2V system.
• Nearly all participants preferred using the VA system, citing its ease and speed of use as their main reasons.
• The vast majority of participants stated they would be open to recommending the VA system to their colleagues, primarily for efficiency, speed, and safety reasons.
• The VA system may provide a simpler, cost-effective option to mitigate against possible order effects.
  ▪ Usability was based on participants' successful and independent completion of each step of each system's workflow.

METHODS AND MATERIALS: STUDY RECONSTITUTION SYSTEMS (CONTINUED)

Figure 4: Quick Reference Guide Provided to Participants for Instruction in the Vial Adapter (VA) System.

Table 1. List of Statements Given to Participants for Rating the Vial Adapter System

<table>
<thead>
<tr>
<th>Statement</th>
<th>Q5</th>
<th>Q7</th>
<th>Q9</th>
<th>Q10</th>
<th>Q12</th>
<th>Q13</th>
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</thead>
<tbody>
<tr>
<td>I felt confident using the vial adapter system.</td>
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<td>The vaccine vial adapter system was easy to use.</td>
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<td>The vaccine vial adapter system was easy to understand.</td>
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<td>The vaccine vial adapter system is reliable.</td>
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<td>Vaccine preparation and administration using the vial adapter system would be faster than with a vial-and-needle system.</td>
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<tr>
<td>Vaccine preparation and administration using the vial adapter system would be easier than a vial-and-needle system.</td>
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<tr>
<td>I feel that there was a lot to learn before I could get going with the vial adapter system.</td>
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<td>I think that I would like to use the vial adapter system frequently in my own practice.</td>
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<td>I would recommend the vial adapter system to other Healthcare Professionals.</td>
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<td>I felt confident when delivering the dose using the vial adapter system.</td>
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<td>It was easy to understand how the vial adapter system fitted together.</td>
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<td>The vial adapter system requires a high degree of manual dexterity and coordination to be used effectively.</td>
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<td>The Quick Reference Guide instructions were clear and easy for me to understand.</td>
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</table>

Note: Participants chose 1 or 2 statements (Strongly Disagree → Strongly Agree) after each simulation.