

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

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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; **Figure 1**) systems include 2 vials and 2 needles and can be relatively time-consuming to prepare.
- A vial adapter (VA; **Figure 2**) has been developed that uses a 1-needle, 1-vial system to potentially speed up the reconstitution process.
- The adapter itself is a plastic assembly with a Luer opening on the syringe end and a hollow spike that points towards the vial-attachment end (see **Figure 2**, asterisk).

Figure 1. Traditional 2-Vial Reconstitution System.



Figure 2. The Simplified Vial Adapter System.



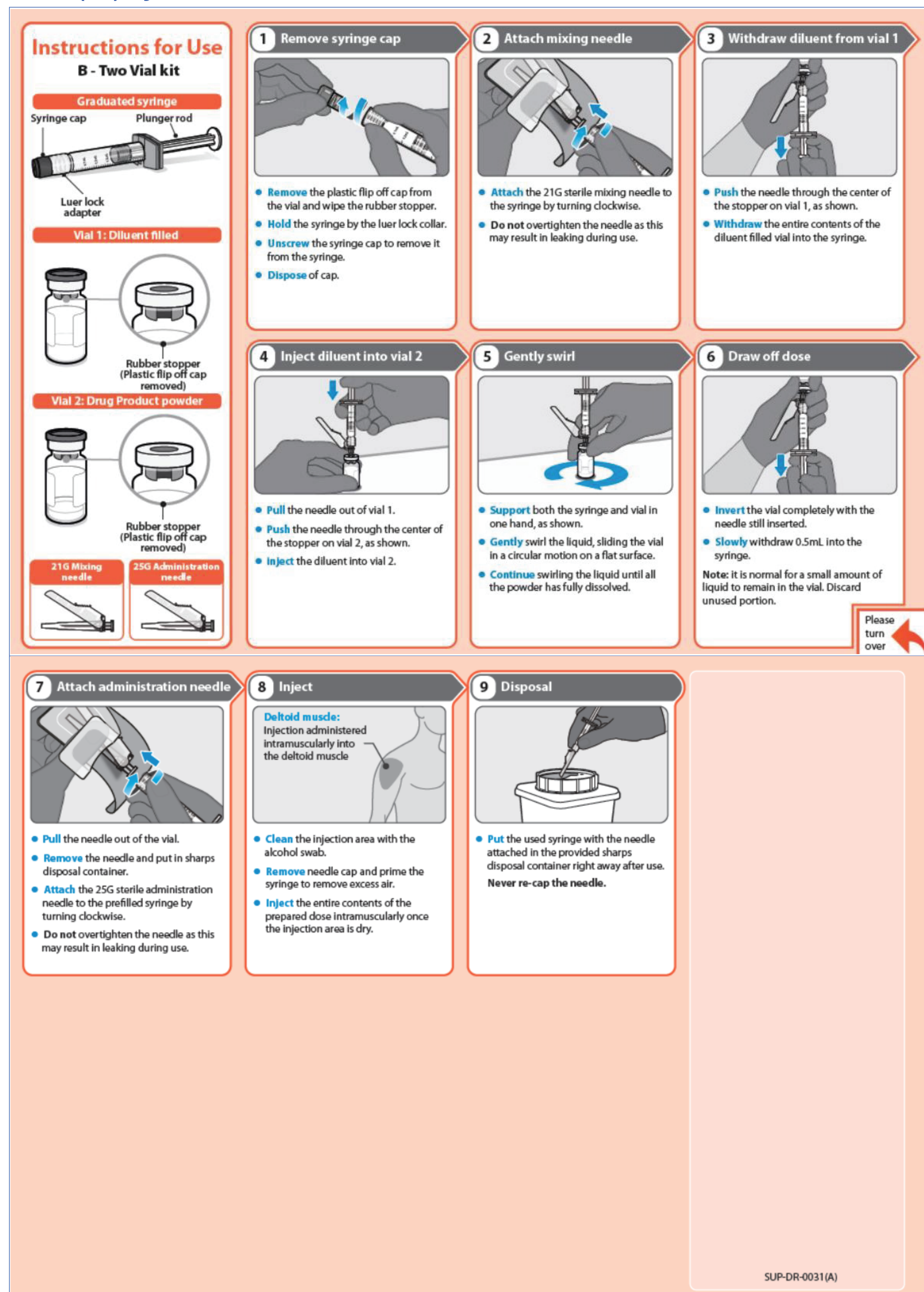
OBJECTIVE

- 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 RECONSTITUTION SYSTEMS

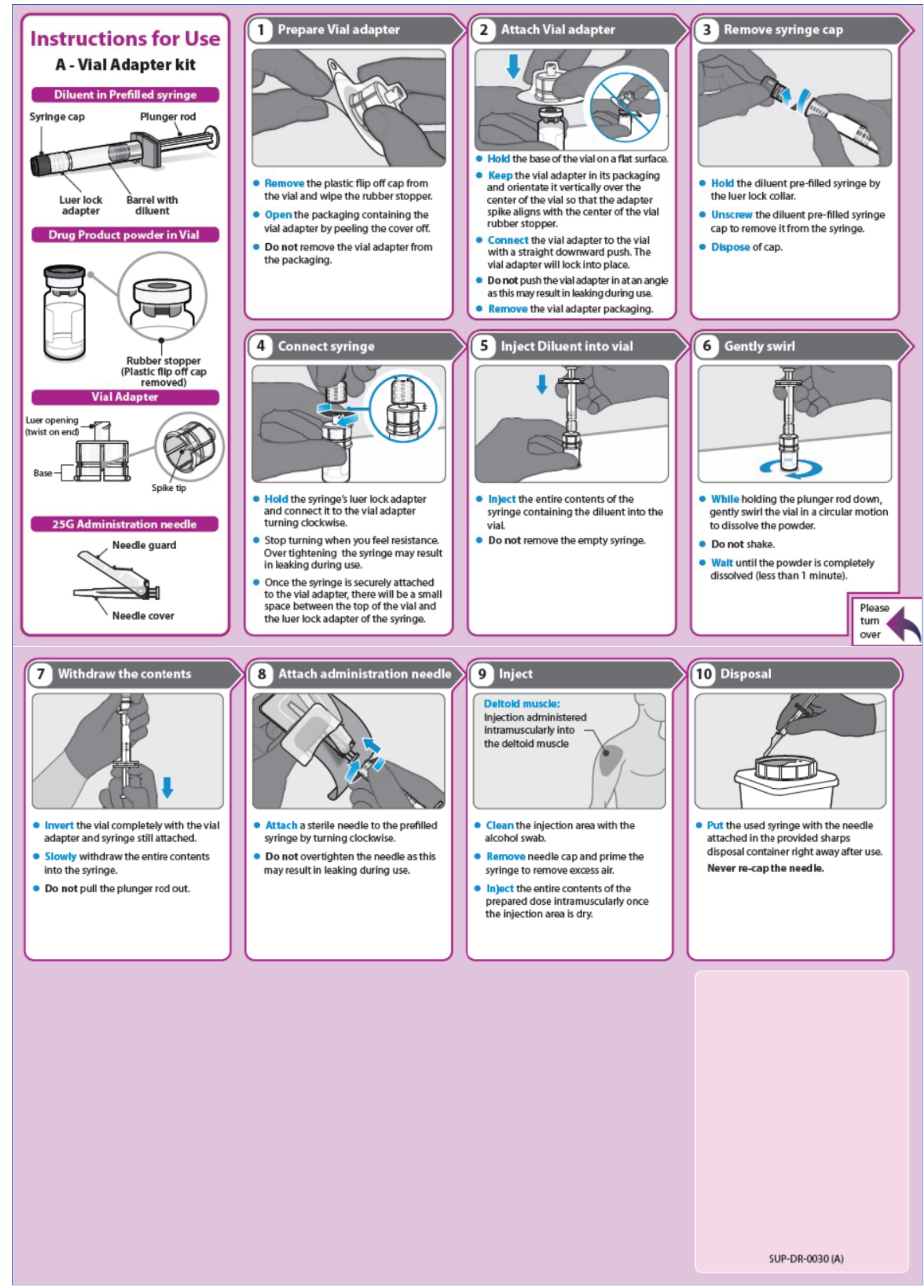
- Participants used quick reference guides (QRGs) to self-train on both systems.
- The 2V system (**Figure 3**) comprised a placebo powder vial, diluent vial, graduated syringe, 21-gauge mixing needle, and 25-gauge administration needle.
- The VA system (**Figure 4**) comprised a placebo powder vial, diluent in a pre-filled 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 pre-filled syringe via the Luer opening, allowing injection of the diluent into the vial.

Figure 3. Quick Reference Guide Provided to Participants for Instruction in the 2-Vial (2V) System.



METHODS AND MATERIALS: STUDY RECONSTITUTION SYSTEMS (CONTINUED)

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



METHODS AND MATERIALS: STUDY DESIGN

- 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 2-3 minutes to study the QRG to familiarize themselves with each system before performing simulations.
- The participants could refer to the QRG at anytime 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 15 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 confusing.
- Participants also rated the VA system on 14 statements (**Table 1**) using a 5-point Likert scale (Strongly Disagree → Strongly Agree).

| Statement |
|---|
| Q5 I felt confident using the vaccine vial adapter system. |
| Q6 The vaccine vial adapter system was easy to use. |
| Q7 The vaccine vial adapter system was easy to understand. |
| Q8 The vaccine vial adapter system is reliable. |
| Q9 Vaccine preparation and administration using the vial adapter system would be faster than with a vial-and-needle system. |
| Q10 Vaccine preparation and administration using the vial adapter system would be safer than a vial-and-needle system. |
| Q11 Vaccine preparation and administration using the vial adapter system would be easier than a vial-and-needle system. |
| Q12 I felt that there was a lot for me to learn before I could get going with the vial adapter system. |
| Q13 I think that I would like to use the vial adapter system frequently in my own practice. |
| Q14 I would recommend the vial adapter system to other Healthcare Professionals. |
| Q15 I felt confident when delivering the dose using the vial adapter system. |
| Q16 It was easy to understand how the vial adapter system fitted together. |
| Q17 The vial adapter system requires a high degree of manual dexterity and coordination to be used effectively. |
| Q18 The Quick Reference Guide instructions were clear and easy for me to understand. |

Note: Participants rated each statement on a 5-point Likert scale (Strongly Disagree → Strongly Agree) after using both systems twice.

- Finally, participants' preferences and attitudes were assessed with the following questions:
 - Considering the 2 vaccine reconstitution systems that you used today, which would you prefer to use? Why?
 - Thinking about your current practice, what do you think would be the primary benefit(s) of this vial adapter system?

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%)
 - Pediatric (n=12; 21.4%)
 - OBGYN (n=13; 23.2%)
- 13/56 (23.2%) were retail pharmacists.
- 42/56 (75%) were female.
- 50/56 (89.3%) were right-hand dominant.
- 10/56 (17.9%) represented rural communities.

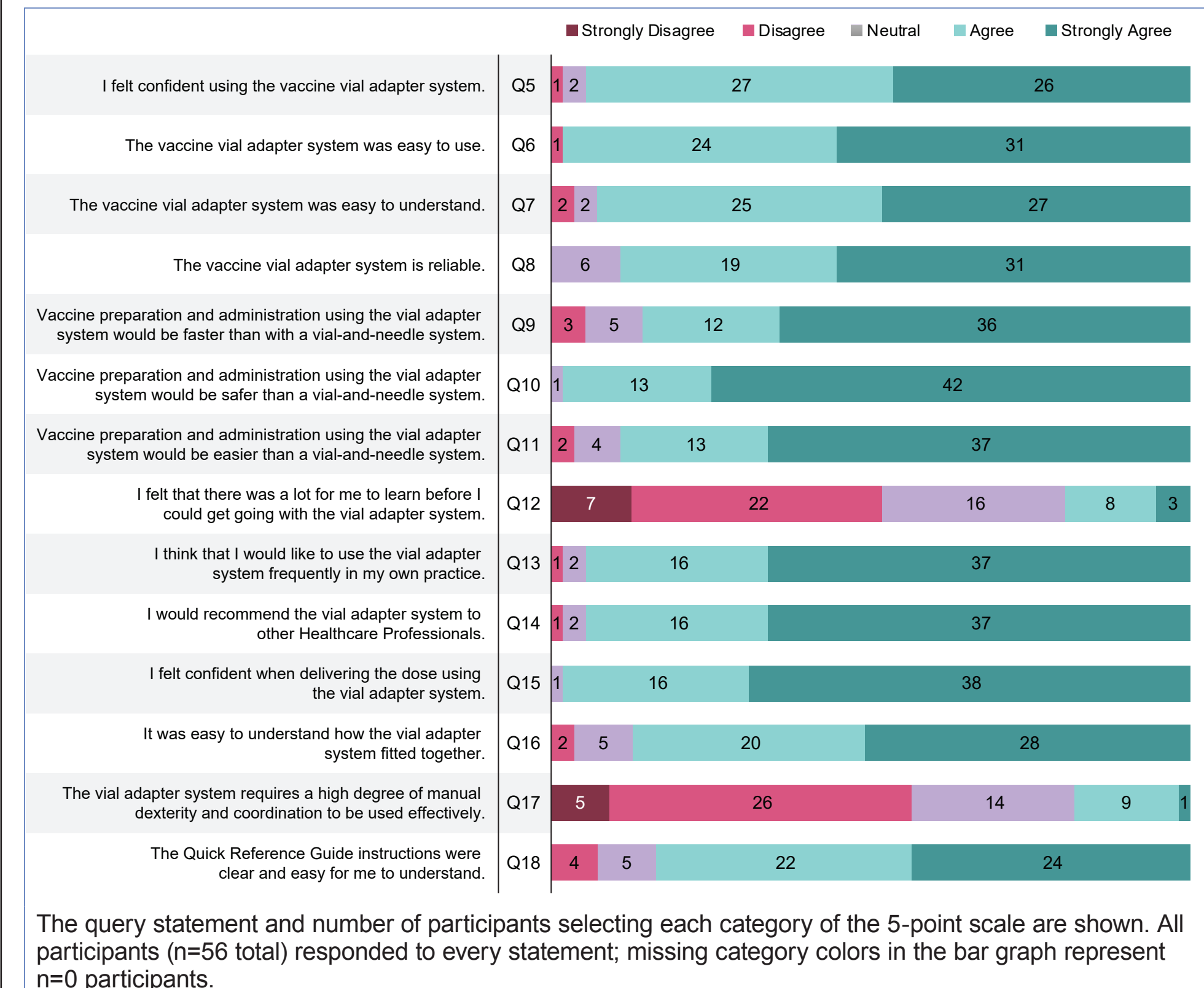
Usability

- Participants' overall success rates were comparable between systems.
- 2V: 76%
- 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 (see **Figure 4**, Q9–Q11, Q14).

Figure 4. Participant Feedback Regarding the Vial Adapter (VA) System.



The query statement and number of participants selecting each category of the 5-point scale are shown. All participants (n=56 total) responded to every statement; missing category colors in the bar graph represent n=0 participants.

Participant Feedback: Pros and Cons of the VA System

- **Pro – Ease of Use:** Easy to learn/use, much faster, fewer steps, less potential waste due to dosing mistakes or other user errors
- **Pro – Safer:** Fewer sharps for disposal, less likely to have needle sticks, less likely to use the incorrect needle (blunt tip/mixing needle) on a patient
- **Con – Applicability:** 2V system is more common/familiar, some vaccines are not provided to end-users with compatible packaging (ie, different vial types or pre-filled single-use syringes)
- **Pro or Con?** Some participants questioned whether the VA system would increase costs and waste (higher per-unit costs and more plastic waste) or reduce costs and waste (fewer sharps waste and error-related product losses)

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 that could benefit healthcare professionals who need to perform vaccinations frequently or in the field where procedures and vaccine accessibility can be more difficult.
- These findings indicate the use of VA for vaccines may increase convenience and save time relating to vaccine administration.

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