

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

Simon Moss,¹ Alex Pickersgill,¹ Brittany Conrad,¹ Lisa Gunther-LaVergne,² Parag Kolhe³

¹Devices Centre of Excellence, Pfizer R&D UK Ltd, Cambridge, UK; ²Farm Design, Inc., A Flex Company, Hollis, NH, USA; ³Pharmaceutical Research and Development, Pfizer Inc, Andover, MA, USA

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.



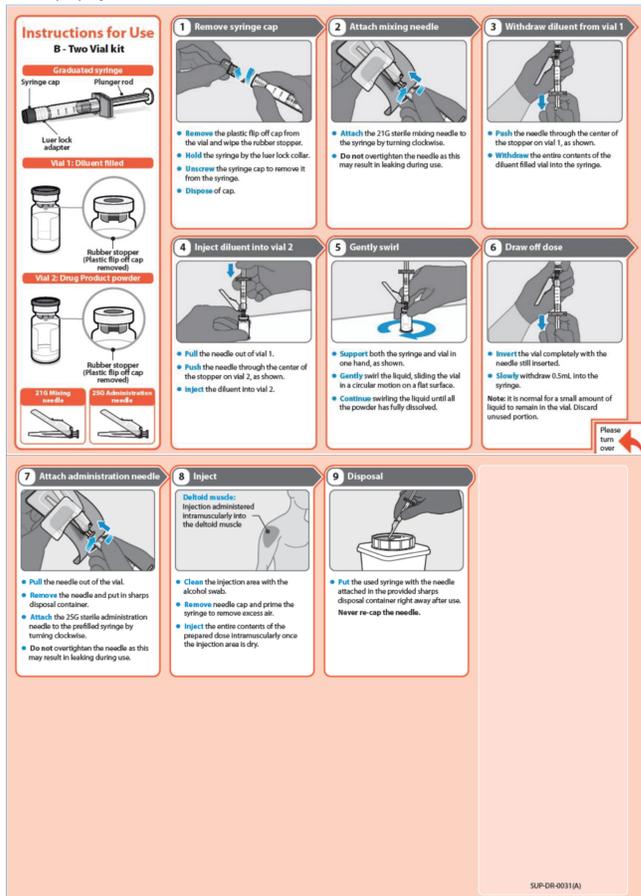
OBJECTIVE

- 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

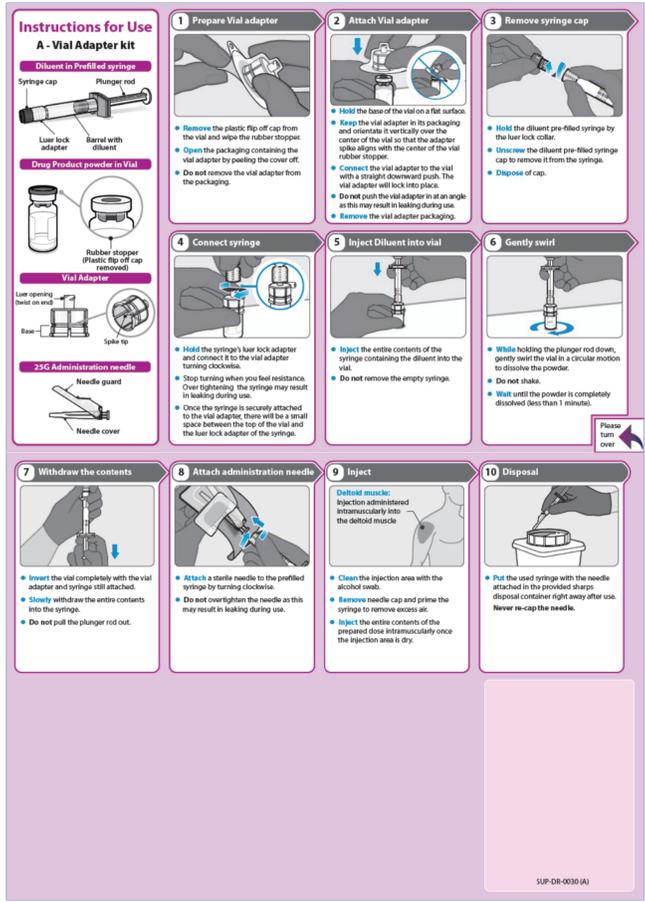
- Participants used quick reference guides (QRGs) to self-train on both systems.
- The 2V system (**Figure 3**) comprised a placebo powder vial, diluent vial, graduated syringe, 21-gauge mixing needle, and 25-gauge administration needle.
- The VA system (**Figure 4**) comprised a placebo powder vial, 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.

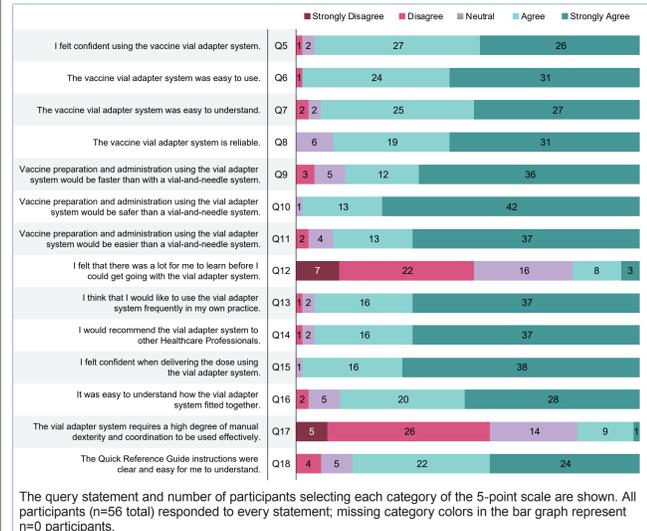
Usability

- 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.

Acknowledgments and Funding

Funding was provided by Pfizer Inc. Medical writing support was provided by Andrew Ray, PhD, at ICON (Blue Bell, PA) and funded by Pfizer.

Disclosures

SM, AP, BC, and PK are employees of Pfizer and may own stock or stock options. LGK has no potential conflicts of interest to disclose.

For more information please contact:
Simon Moss
Principal Human Factors Engineer
Pfizer R&D UK Ltd | Devices Centre of Excellence
Cambridge CB21 6GP
United Kingdom
Tel: +44 1304 616161
Email: simon.moss@pfizer.com

