

SUPPLEMENTARY MATERIAL

Usability and Acceptance of Autoinjector and Prefilled Syringe Devices by Patients With Generalized Myasthenia Gravis in a Human Factors Study

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Exhibit 1. User experience questionnaire

Participant ID: _____

Date: _____

Study Site: _____

Question 1

Based on your experience with the device today, how easy was the device to use? *(Select your answer using the 1-5 scale below)*

- | | | | | |
|----------------|-----------|-------------------------------|----------|-----------|
| 1 | 2 | 3 | 4 | 5 |
| Very Difficult | Difficult | Neither Easy nor
Difficult | Easy | Very Easy |

Why? *(Please select your top 3 from the list below)*

- | | |
|--|---|
| ☐ Device size or shape | ☐ Ability to control device |
| ☐ Packaging of device | ☐ Ease / difficulty to inject dose |
| ☐ Visibility of contents/liquid in device | ☐ Ease / difficulty to confirm dosing progress or completion |
| ☐ Ease / difficulty of cap removal | ☐ Needle shielding/protection |
| ☐ Ease / difficulty of needle insertion | ☐ Device disposal |
| ☐ Speed of injection | ☐ Instructions for Use provided |
| | ☐ Other (please explain):
_____ |

Question 2

Based on your experience with the device today, how intuitive was the device to use? *(Select your answer using the 1-5 scale below)*

- | | | | | |
|------------------|-------------|--------------------------------------|-----------|----------------|
| 1 | 2 | 3 | 4 | 5 |
| Very Unintuitive | Unintuitive | Neither Intuitive
nor Unintuitive | Intuitive | Very Intuitive |

Why? *(Please select your top 3 from the list below)*

- | | |
|--|---|
| ☐ Packaging of device | ☐ Ease / difficulty to confirm dosing progress or completion |
| ☐ Device colors | ☐ Visibility of contents/liquid in device |
| ☐ Device size or shape | ☐ Needle shielding/protection |
| ☐ Ease / difficulty of cap removal | ☐ Instructions for Use provided |
| ☐ Ease / difficulty of needle insertion | ☐ Other (please explain):
_____ |
| ☐ Ease / difficulty to inject dose | |

Question 3

Based on your experience with the device today, how would you describe your level of comfort with the device? *(Select your answer using the 1-5 scale below)*

1	2	3	4	5
Very Uncomfortable	Uncomfortable	Neither Comfortable nor Uncomfortable	Comfortable	Very Comfortable

Why? *(Please select your top 3 from the list below)*

- | | |
|--|---|
| ☐ Device size or shape | ☐ Ease / difficulty to confirm dosing progress or completion |
| ☐ Device colors | ☐ Ease / difficulty of device disposal |
| ☐ Needle visibility | ☐ Needle shielding/protection |
| ☐ Ease / difficulty of cap removal | ☐ Instructions for Use provided |
| ☐ Ease / difficulty of needle insertion | ☐ Other (please explain):
_____ |
| ☐ Ease / difficulty to inject dose | |

Question 4

Based on your experience with the device today, how confident do you feel about injecting this medication at home? *(Select your answer using the 1-5 scale below)*

1	2	3	4	5
Very Not Confident	Not Confident	Neither Confident nor Not Confident	Confident	Very Confident

Why? *(Please select your top 3 from the list below)*

- | | |
|--|---|
| ☐ Weekly dosing regimen | ☐ Ease / difficulty to inject dose |
| ☐ Storage of device | ☐ Ease / difficulty to confirm dosing progress or completion |
| ☐ Packaging of device | ☐ Ease / difficulty of device disposal |
| ☐ Device size or shape | ☐ Needle visibility |
| ☐ Device colors | ☐ Needle shielding/protection |
| ☐ Ease / difficulty of cap removal | ☐ Instructions for Use provided |
| ☐ Ease / difficulty of needle insertion | ☐ Other (please explain):
_____ |
| ☐ Speed of injection | |

Question 5

Based on your experience with the device today, how convenient would the device be to use weekly at home? *(Select your answer using the 1-5 scale below)*

1	2	3	4	5
Very Inconvenient	Inconvenient	Neither Convenient nor Inconvenient	Convenient	Very Convenient

Why? (Please select your top 3 from the list below)

- | | |
|--|--|
| ☐ Weekly dosing regimen | ☐ Dose delivery progression or confirmation of completion |
| ☐ Storage of device | ☐ Ease / difficulty of device disposal |
| ☐ Packaging of device | ☐ Speed of injection |
| ☐ Device size or shape | ☐ Needle shielding/protection |
| ☐ Ease / difficulty of cap removal | ☐ Instructions for Use provided |
| ☐ Ease / difficulty of needle insertion | ☐ Other (please explain):
_____ |

Question 6

Overall, how acceptable was the device you used today? (Select your answer using the 1-5 scale below)

- | | | | | |
|-------------------|--------------|-------------------------------------|------------|-----------------|
| 1 | 2 | 3 | 4 | 5 |
| Very Unacceptable | Unacceptable | Neither Acceptable nor Unacceptable | Acceptable | Very Acceptable |

Why? (Please select your top 3 from the list below)

- | | |
|--|---|
| ☐ Weekly dosing regimen | ☐ Comfort level with device |
| ☐ Speed of injection | ☐ Confidence with device use |
| ☐ Storage of device | ☐ Convenience of device |
| ☐ Packaging of device | ☐ Needle visibility |
| ☐ Device size or shape | ☐ Needle shielding/protection |
| ☐ Ease / difficulty of using device | ☐ Instructions for Use provided |
| ☐ Intuitiveness of device | ☐ Other (please explain):
_____ |

Table S1. Simulated use tasks for PFS-SD and AI

Task Number	Simulated Use Task Description
1	Store product in the refrigerator at 36 °F to 46 °F (2 to 8 °C)
2	Store product in the original carton to protect from light
3	Do not shake the product
4	Keep the syringe(s) out of the sight and reach of children
5	Check your prescription to confirm the dose your healthcare provider has prescribed
6	Gather supplies on a clean workspace (eg, alcohol swab, cotton balls, bandages, sharps disposal container)
7	Remove the carton from the refrigerator
8 ^a	Check the carton for damage
9^a	Check the expiration date on the carton
10	Open the carton
11	Grip the body of the device^b and remove from carton
12	Return extra devices^b back into the refrigerator in their carton
13^a	Check the expiration date on the device^b
14^a	Check the device^b for any damage
15^a	Check the medicine to make sure the liquid is clear or slightly yellow and has no particles
16	Let the device(s)^b sit at room temperature for 45 minutes before use
17	Wash your hands well with soap and warm water
18	Choose injection site
19	Clean injection site and let skin air dry
20	Remove needle cap
21 For PFS-SD For AI	Pinch skin and insert needle Position the purple needle end flat against the injection site
22 For PFS-SD For AI	Slowly press the plunger down until you cannot push any further Push down firmly
23 For PFS-SD For AI	Release plunger to activate safety device Confirm injection is complete and lift up
24	Confirm your dose
25	Check injection site
26	Put your used syringe(s) in a US FDA-cleared sharps container right away after injection

Bold type indicates a critical task.

^aThis task will be evaluated in knowledge tasks if the participant does not mention it out loud.

FDA, Food and Drug Administration.

^bQuestion referred to PFS-SD for participants in the PFS-SD group and to the AI for participants in the AI group.

Table S2. Knowledge tasks for PFS-SD and AI

Question Number	Question
1	How many times can you use the device ^a ?
2 ^b	After removing your device^a from the refrigerator, what should you do to bring it to room temperature?
3	How long can this product be left at room temperature?
4	Where should you store the device ^a if there are children at home?
5 ^c	Can you use this product if it has been frozen?
6 ^c	Can you tell me when this product expires? Based on that date, can you use this product today?
7	Let's say that your prescribed dose requires you to give yourself two injections. If you have already administered the first injection into [site participant selected] where should you administer the second injection?
8 ^c	How can you tell if the medicine in your device^a is good to use?
9	Where should you store the sharps container if there are children at home?
10	What should you do if this device^a or carton is damaged?
11	For participants assigned two injections For participants assigned one injection If your prescription changed to one injection, how many devices^a would you need to use to receive your full dose? If your prescription changed to two injections, how many devices^a would you need to use to receive your full dose?
12 ^d	From your understanding, has this device been used yet?

Bold type indicates a critical task.

^aQuestion referred to PFS-SD for participants in the PFS-SD group and to the AI for participants in the AI group.

^bAsked if not mentioned in simulated use.

^cIf cannot evaluate or not answered through simulated use (e.g., freezer not available).

^dUsed/unused device handed to participant.

AI, autoinjector; PFS-SD, prefilled syringe with needle safety device.

Table S3. Use deviations terminologies and definitions

Terminology	Definitions
Use deviation	An observed use error, close call, or use difficulty during simulated use tasks
Use error	User action or lack of action that was different from that expected by the manufacturer and caused a result that (1) was different from the result expected by the user and (2) was not caused solely by system failure and (3) did or could result in harm or compromised medical care
Close call	A close call is an instance in which a user has difficulty or makes a use error that could result in harm, but the user takes an action to “recover” and prevents the harm from occurring
Use difficulty	Any observed difficulty on the part of the user while using the product, which does not result in a use error, but points to an underlying usability concern with the product’s design, accompanying documentation, labeling, packaging, or training

Table S4. Participant demographics

	Prefilled Syringe		Autoinjector		
	Patients (n=15)	Caregivers (n=15)	Patients (n=15)	Caregivers (n=15)	HCPs (n=15)
Age, mean (SD), years	60.1 (16.4)	49.1 (16.5)	52.9 (9.0)	54.7 (19.1)	39.7 (11.9)
Sex, n (%)					
Male	3 (20)	8 (53)	2 (13)	11 (73)	0
Female	12 (80)	7 (47)	13 (87)	4 (27)	15 (100)
Hand dominance, n (%)					
Right	15 (100)	14 (93)	13 (87)	13 (87)	13 (87)
Left	0	1 (7)	2 (13)	1 (7)	0
Ambidextrous	0	0	0	1 (7)	2 (13)
Injection experience, n (%)					
Naive	6 (40)	8 (53)	6 (40)	9 (60)	0
Experienced	9 (60) ^a	7 (47)	9 (60) ^b	6 (40)	15 (100)
Profession, n (%)					
Registered nurse	N/A	N/A	N/A	N/A	10 (67)
Medical assistant	N/A	N/A	N/A	N/A	4 (27)
Nurse practitioner	N/A	N/A	N/A	N/A	1 (7)

^aDrugs used for gMG included IVIG (infusion), ravulizumab (infusion), eculizumab (infusion), efgartigimod (infusion), prednisone (oral), mycophenolate mofetil (oral), azathioprine (oral), pyridostigmine (oral), immune globulin (subcutaneous infusion), and zilucoplan (prefilled syringe).

^bDrugs used for gMG included IVIG (infusion), rituximab (infusion), ravulizumab (infusion), eculizumab (infusion), efgartigimod (infusion and injection), plasma exchange, prednisone (oral), methotrexate (oral), mycophenolate mofetil (oral), azathioprine (oral), and pyridostigmine (oral).

gMG, generalized myasthenia gravis; HCPs, healthcare professionals; IVIG, intravenous immunoglobulin; N/A, not applicable.

Table S5. Simulated use performance for each task (PFS-SD)

Task Number	Simulated Use Task Description	Use Errors, n/N (%)		Close Calls, n/N (%)		Use Difficulties, n/N (%)	
		Patient	Caregiver	Patient	Caregiver	Patient	Caregiver
1	Store product in the refrigerator at 36 to 46 °F (2 to 8 °C)	1/15 (7)	1/15 (7)	0/15 (0)	0/15 (0)	0/15 (0)	0/15 (0)
2	Store product in the original carton to protect from light	0/15 (0)	0/15 (0)	0/15 (0)	0/15 (0)	0/15 (0)	0/15 (0)
3	Do not shake the product	0/15 (0)	0/15 (0)	0/15 (0)	0/15 (0)	0/15 (0)	0/15 (0)
4 ^a	Keep the syringe(s) out of the sight and reach of children						
5	Confirm your prescription to confirm the dose your healthcare provider has prescribed	0/8 (0)	0/8 (0)	0/8 (0)	0/8 (0)	0/8 (0)	0/8 (0)
6	Gather supplies on a clean workspace (eg, alcohol swab, cotton balls, bandages, sharps disposal container)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)
7	Remove the carton from the refrigerator	0/20 (0)	0/22 (0)	0/20 (0)	0/22 (0)	0/20 (0)	0/22 (0)
8 ^a	Check the carton for damage						
9 ^a	Check the expiration date on the carton						
10	Open the carton	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)
11	Grip the pre-filled syringe body and remove from carton	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)
12	Return extra syringes back into the refrigerator in their carton	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)
13 ^a	Check the expiration date on the prefilled syringe						
14 ^a	Check the syringe for any damage						
15 ^a	Check the medicine to make sure the liquid is clear or slightly yellow and has no particles						
16	Let the pre-filled syringe(s) sit at room temperature for 45 minutes before use	7/22 (32)	5/22 (23)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)
17	Wash your hands well with soap and warm water	2/22 (9)	1/22 (5)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)
18	Choose injection site	3/22 (14)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)
19	Clean injection site	3/22 (14)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)

20	Remove needle cap	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)	1/22 (5)	1/22 (5)
21	Pinch skin and insert needle	7/22 (32)	6/22 (27)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)
22	Slowly press the plunger down until you cannot push any further	2/22 (9)	0/22 (0)	0 (0)	0/22 (0)	1/22 (5)	0/22 (0)
23	Release plunger to activate safety device	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)
24	Confirm your dose	0/7 (0)	1/7 (14)	0/7 (0)	0/7 (0)	0/7 (0)	0/7 (0)
25	Check injection site	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)	0/22 (0)
26	Put your used syringe(s) in an FDA-cleared sharps container right away after injection	7/22 (32)	0/22 (0)	0/22 (0)	1/22 (5)	0/22 (0)	0/22 (0)

FDA, Food and Drug Administration; PFS-SD, prefilled syringe with needle safety device.

^aEvaluated as a knowledge task.

Table S6. Simulated use performance for each task (AI)^a

Task Number	Simulated Use Task Description	Use Errors Total, n/N (%)		
		Patient	Caregiver	HCPs
1	Store product in the refrigerator at 36 °F to 46 °F (2 to 8°C)	0/15 (0)	0/15 (0)	0/15 (0)
2	Store product in the original carton to protect from light	0/15 (0)	0/15 (0)	0/15 (0)
3	Do not shake the product	0/15 (0)	0/15 (0)	0/15 (0)
4	Keep the autoinjector(s) out of the sight and reach of children	Evaluated as a knowledge task		
5	Confirm your prescription to confirm the dose your healthcare provider has prescribed	0/7 (0)	0/7 (0)	0/8 (0)
6	Gather supplies on a clean workspace (e.g., alcohol swab, cotton balls, bandages, sharps disposal container)	0/23 (0)	0/22 (0)	0/22 (0)
7	Remove autoinjector carton(s) from the refrigerator	0/23 (0)	0/22 (0)	0/22 (0)
8	Inspect the carton(s) for any damage	Evaluated as a knowledge task		
9	Check the expiration date on the carton	Evaluated as a knowledge task		
10	Open the carton	0/23 (0)	0/22 (0)	0/22 (0)
11	Grip the autoinjector body and remove autoinjector from the carton	0/23 (0)	0/22 (0)	0/22 (0)
12	Return extra autoinjectors back into the refrigerator in their carton	0/23 (0)	0/22 (0)	0/22 (0)
13	Check the autoinjector for damage	Evaluated as a knowledge task		
14	Check the expiration date	Evaluated as a knowledge task		
15	Check the medicine to make sure the liquid is clear or slightly yellow and has no particles	Evaluated as a knowledge task		
16	Let autoinjector(s) sit at room temperature for 45 minutes before use	5/23 (22)	6/22 (27)	12/22 (55)
17	Wash your hands	0/23 (0)	2/22 (9)	0/22 (0)
18	Choose injection site	3/23 (13)	3/22 (14)	2/22 (9)
19	Clean injection site and let skin air dry	1/22 (5)	0/20 (0)	1/21 (5)
20	Remove needle cap	0/23 (0)	4/22 (18)	0/22 (0)
21	Position the purple needle end flat against the injection site	0/23 (0)	0/22 (0)	0/22 (0)
22	Push down firmly	0/23 (0)	0/22 (0)	0/22 (0)

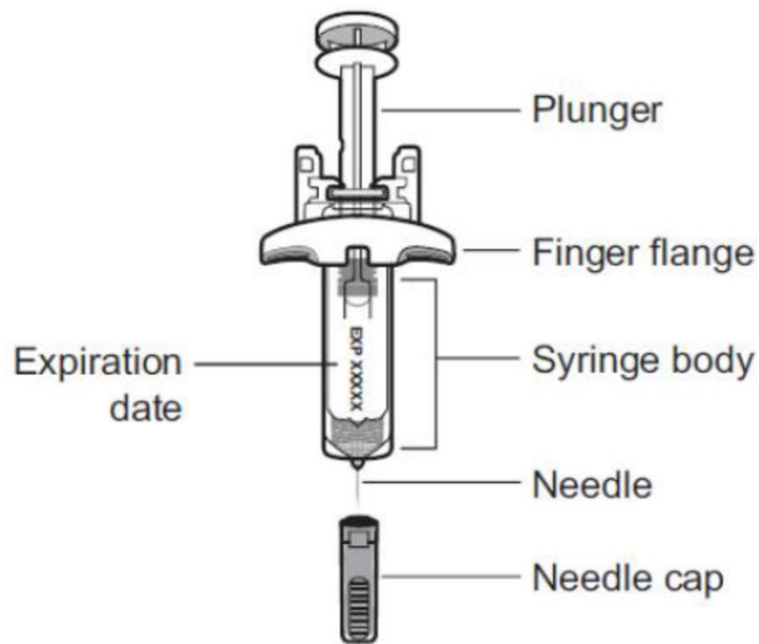
23	Confirm injection is complete and lift up	0/23 (0)	1/22 (5)	1/22 (5)
24	Confirm your prescription to confirm the dose your healthcare provider has prescribed	0/8 (0)	1/8 (13)	3/7 (43)
25	Check injection site	0/23 (0)	0/22 (0)	0/22 (0)
26	Put your used autoinjector(s) in an FDA-cleared sharps container right away after injection	0/23 (0)	0/22 (0)	0/22 (0)

^aNo close calls or user difficulties were observed during simulated use.

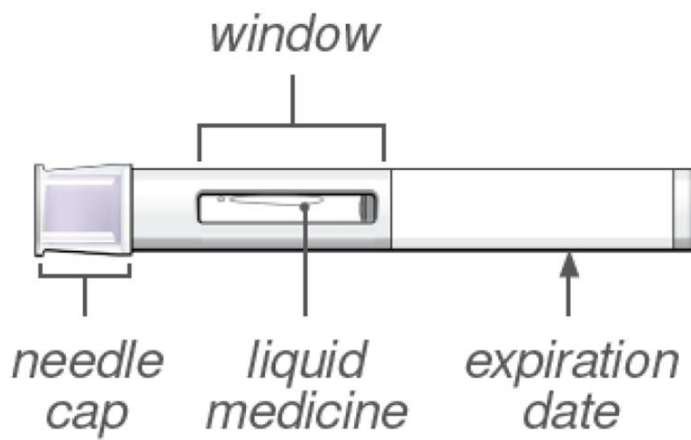
AI, autoinjector; FDA, Food and Drug Administration; HCPs, health care professionals.

Fig. S1. (i) PFS-SD and (ii) AI devices.

i.

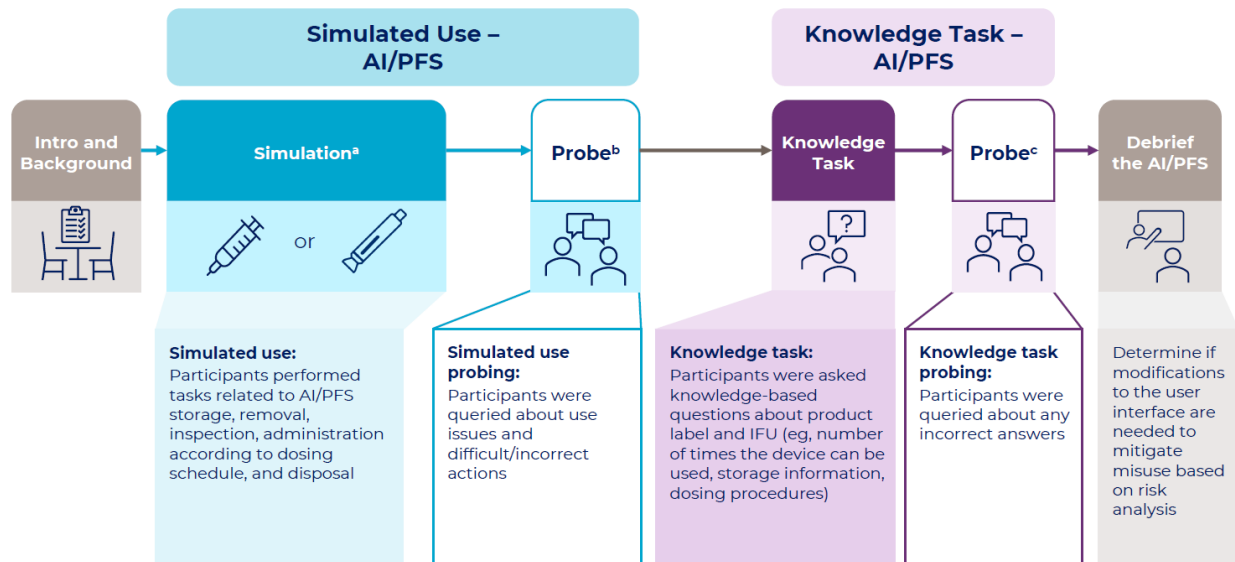


ii.



AI, autoinjector; PFS-SD, prefilled syringe with needle safety device.

Fig. S2. Study design.



^aBoth PFS-SD and AI were filled with a surrogate solution that did not contain active drug product. Participants simulated injections into an injection pad as if they were administering the dose in a real-life setting.

^bFirst probe avoided tasks that influenced the knowledge task.

^cProbe on knowledge task and any remaining simulation use tasks.

AI, autoinjector; IFU, instructions for use; PFS-SD, prefilled syringe