

Patient Impressions of AI/ML- Enabled Medical Devices

Aubrey Shick

Jessica Weinberg

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Special thanks to Nikita Vozenilek and Eva Venema

Gathering Patient Perspectives



- Interviewed 8 Patient Engagement Advisory Committee (PEAC) Members
- Surveyed 1,827 Patient and Caregiver Connection Members



North American
Spinal Cord Injury
— Consortium —



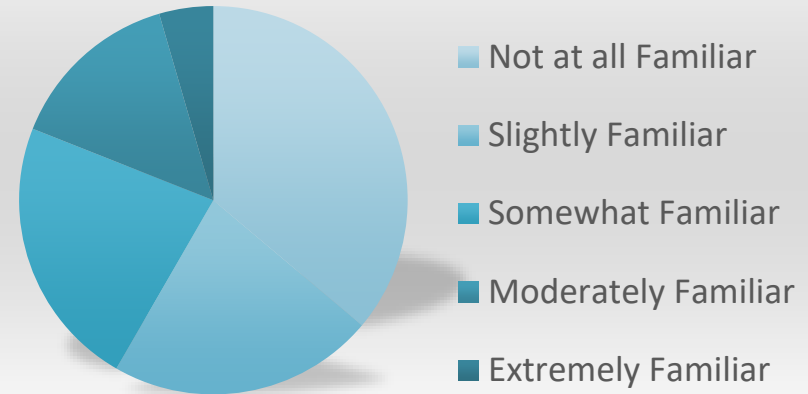
Gathering Patient Perspectives



We asked patients and caregivers about their experience and perspectives:

- Overall impression of AI/ML devices
- Familiarity with AI/ML-enabled devices
- What are the factors considered when deciding to use devices
- How do you prefer to learn
- Any additional information you want to share

Participants reported a range of familiarity with AI/ML in medical devices



Key Takeaways

1. Participants overall impression was favorable towards AI/ML-enabled medical devices
2. Participants want to know more about what AI/ML means to the patient experience
3. Participants would like specific information about AI/ML-enabled devices to decide if and how to use them
4. Participants want to understand how their HCP fits into the workflow of the AI/ML-enabled devices

1. Participants were overall favorable towards AI/ML-enabled medical devices



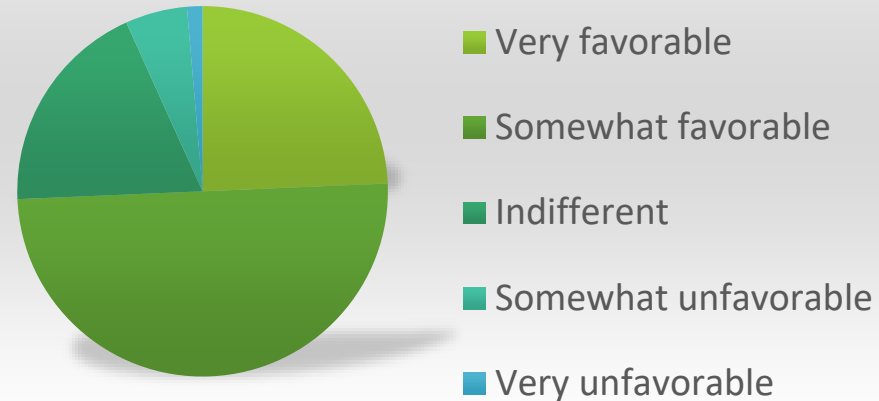
- Overall **favorable impressions**, expressing general enthusiasm and hope

“I think they are going to be critical to helping disabled people like me regain movement.”

- Potential to **improve condition** and enable them to **take control of their care**

“They might help us manage our conditions ourselves, and not always have to consult a doctor.”

Overall favorable impression of AI/ML-enabled medical devices



2. Participants want to know more about what AI/ML means to the patient experience



- What factors matter for **accuracy**?

“[Patients should be asking] is this [clinical trial data] representative of comorbidities, lifestyle, race/ethnicity, ability to work (functional status)?”

- How is **data privacy** handled?

“Who is selling/making money off [patient] data?”

- What are the technical requirements to **access** devices?

“What kind of infrastructure exists to support these devices? Does the device need the [broadband] internet?”

- Is it **reimbursable** and affordable?

“The costs associated with take home AI devices should be clear and covered by insurance.”



3. Participants would like more specific information about AI/ML-enabled devices to decide if and how to use them



- Want to know if **patients like them** can safely and effectively use the device without making mistakes

"Is there anything I do that would interfere with the [machine learning] algorithm?"

- Want **assurances of completeness and representation** in provided information

"I would like a technical disclosure about the evaluation of bias as part of training."

- Want the **right amount of information at the right time** to keep from being overwhelmed or confused

"I read the manual, I don't get it... you get setup, but then you don't know how to change things [and optimize over time]"



4. Participants want to understand how their HCP fits into the workflow of the AI/ML-enabled devices

- They **trust doctors to ensure safety and effectiveness** on their behalf.

“Patients are more likely to take data to their doctor to interpret versus feeling comfortable altering care independently, [They ask the doctor] what do you want me to do?”

- They **want to know where their HCP fits into the workflow** of the device and their HCPs’ knowledge of, and experience with, the device.

“[I’m concerned about] the ability of medical professionals to understand limitations of the device and properly interpret results.”



Considerations for Future

- Expand the **mediums for information sharing** with patients and providers
- Expand **education** for providers and **resources** for patients
- Enable patients to ask the right questions of HCPs



Further Questions or Feedback



www.fda.gov/digitalhealth



DigitalHealth@fda.hhs.gov

CDRH_PatientEngagement@fda.hhs.gov

**Center for Devices and Radiological Health, U.S.
Food and Drug Administration**