North American Spinal Cord Injury Consortium

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August 29, 2023

Center for Devices and Radiological Health
U.S. Food & Drug Administration
Silver Springs, MD 20993-0002

Submitted via: www.regulations.gov
Federal Register Docket: FDA-2023-N-1956
Title: Increasing Patient Access to At-Home Use Medical Technologies

Dear Administrator:

On behalf of the North American Spinal Cord Injury Consortium (NASCIC), we welcome the opportunity to provide comments to your request for public comment on "**Increasing Patient Access to At-Home Use Medical Technologies (FDA-2023-N-1956).**" This topic is critically important to our population for a variety of reasons but mainly the spinal cord injury community includes those living with long-term chronic conditions.

The mission of NASCIC is to bring about unified achievements in research, care, and policy by supporting collaborative efforts across the spinal cord injury (SCI) community. To do so, NASCIC has been designed to identify gaps, communicate resources, and be a conduit for collaboration between the community of people living with SCI and many stakeholders. These goals are achieved through 1) the formation of relationships and active engagement between the individuals and organizations representing SCI; 2) the exchange of valid, trustworthy, and useful information, experience, and knowledge; 3) promotion of and involvement with 'best practices of consumer engagement' in research, care, and policy; 4) the creation of a unified platform for SCI advocacy in North America; and 5) promotion of collaboration among experts in the fields of research, care, and policy of participating members.

To this end, we welcome the opportunity to provide comments on the questions posted in this notice. We did take the opportunity to gain direct feedback from our community members. In the attached document, you will find a summary of the feedback as noted. If you would like the individual responses, we are happy to share them with you upon request.

We would be happy to work with FDA and other federal agencies to connect with the spinal cord injury community regarding at-home use medical technologies. Again, thank you for your work on this important issue and for your consideration of these comments. If you have questions or require further information, feel free to contact me.

Sincerely,

Jennifer S. French, MBA
President, North American SCI Consortium

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Question: How can the FDA support the development of medical technologies, including digital health technologies and diagnostics, for use in non-clinical care settings, such as at home?
Comment: There were a variety of comments that align with the following themes:

- Build awareness and education among those living with the target condition
- Include those with lived experience in the review process and facilitate connections between submitters and those from the disability community
- Harmonize regulatory expectations with industry standards
- Provide consistency in policy and oversight
- Account for those with high levels of paralysis who use assistive technology and/or need help from care partners.
- Include patient reported outcomes measures, quality of life measures, and regulatory systems for safe use by a layperson with simple systems interfaces.
- Share in the new development of standards to allow the industry to grow

Question: What factors should be considered to effectively institute patient care that includes home-based care?
Comment: The responses we received from the community included factors such as: patient preferences, user training, support services (for the device), accessibility, safety limitations, accuracy and consistency of device output.

Question: What are ways that digital health technologies can foster the conduct of clinical trials remotely? Or support local or home-based healthcare models?
Comment: Digital Health Technologies (DHT) can help to improve recruitment, participant retention, participant monitoring & compliance, data collection and analytics. DHT can also help to shorten the timeline of data collection and analysis with real world outcomes. DHT can also help to interact with clinicians and gather patient/participant information without the barrier of the individual purchasing a smartphone. Health disparities are pervasive in our population and DHT can help to address those inequities and barriers to participation and access. DHT could also provide an alert system and communication to a clinician if improper use is detected. Ultimately, DHT can lead to better outcomes and more importantly address the holistic view of patient health and increased health data access for the end-user.

Question: How can the FDA facilitate individuals accessing medical technologies in remote locations when they are unable or unwilling to access care in clinical settings?
Comment: We did query members of our community about this topic and while we provide you with their collective comments, please keep in mind that many in our community use devices for mobility due to paralysis. On this topic, many medical facilities, clinical offices, care centers are not accessible and therefore many members of our community are “unable” to access care in a clinical setting. Guidance from the FDA on the use of at-home and mobile devices in communication with clinicians would be helpful along with standards of data and device compatibility. With this systems need to be

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flexible for individual comfort levels of data sharing and thoughtfully designed for those living with disabilities.

Question: What processes and medical procedures, including diagnostics, do you believe would be ideal for transitioning from a hospital and/or healthcare setting to non-clinical care settings, for example, home use or school/work use?
Comment: Telemedicine arrangements and health apps for better interactions and communications with clinicians for that transition home. The streamlining of multiple care clinicians and the monitoring for secondary complications is critical. To this point allow at-home users to monitor standard tests and diagnostics such as vitals, blood, urine, etc.

Question: What aspects of those technologies could potentially benefit from modifications to optimize use in non-clinical settings?
Comments: Aspects to consider include functionality, ergonomics, data compatibility, adaptive access for those with poor or no hand function, data privacy

Question: What design attributes and user needs would facilitate the use of medical technologies, including diagnostic and therapeutic devices, for use in a nonclinical setting, for example home use?
Comments: The following list of attributes are important to those with mobility disabilities and may be applicable to the broader community:

- Voice commands in different languages
- Push button operation instead of knobs, single touch interface
- Voice instructions and easy to understand instructions
- Manufacturer and Troubleshooting support that is 24/7
- Ease of installation
- Automatically generated health outcomes
- Ease to don and doff as well as clean.

Question: For digital health technologies, what design attributes could better facilitate their use by diverse patient populations outside of a clinical setting? What other factors are important to consider which may improve use and acceptance of different digital health technologies by diverse patient populations (for example, older adults, non-English speakers, lower literacy)?
Comments: Use plain language and assess the readability of all the materials. There should be standardization for ease of translation. Pre-training or videos for references on the use of the device with graphics. Use of pictorials or graphics in place of words on a device would be helpful.Universal design ideas, techniques, attributes, and methods are the only way to reasonably come about implementing this type of case-use. Starting from the "ground up", now would be the time to implement these types of design features. Getting all manufacturers on the same page so that utilization of specific designs would be as close to identical as possible between makes, models, and manufacturers. Consider that, for the most part, road signs, instructions, and warnings on public streets can generally be determined, even if outside a native country/language. Red octagon, yellow diamond/triangle, white background with black text, green background with white text,

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red/yellow/green/blue lights are just a few examples of what can be considered virtually universally understood. Ensuring that manufacturers incorporate similarities/likenesses in their designs from the start would increase the availability of comprehension and decrease the severity of a learning curve across diverse patient populations. Additionally, incorporation of "nonproprietary" attributes such as cables, ports, digital protocols, communication methods etc. would allow for quicker, simpler and easier replacement and/or repair by end users so that if something breaks or malfunctions, it is not a complete STOP to the device's use AND replacement/repair can be conducted without the extreme costs and time associated with insurance claims.

Question: What potential methods and strategies for evidence generation and data analysis could facilitate the regulatory review of medical technologies intended to be used in non-clinical settings, for example home use or school/work use?
Comments: Those who responded within our community suggest the use of patient-centric and intuitive evidence-generation. We would also like end-user feedback to include a level of diversity including but not limited to urban, rural, socioeconomics, race, ethnicity, and culture. Allow for an element of real-world testing or at-home use testing to gather better evidence. Offer the end-users options for monitoring and evaluation for continuous improvement of methods and interfaces.