ata ACTION

Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

RE: ATA Action Comments in Response to CDRH Request for Information: Increasing Patient Access to At-Home Use Medical Technologies (FDA-2023-N-1956)

As the only organization completely focused on advancing telehealth, the American Telemedicine Association (ATA) and ATA Action, the ATA's advocacy arm, are committed to ensuring that everyone has access to safe, affordable and appropriate care when and where they need it, enabling the system to do more good for more people. The ATA and ATA Action appreciate the opportunity to comment on the Food and Drug Administration (FDA) Centers for Devices and Radiological Health (CDHR) request for information on these important topics such as digital health technologies, home-based models, and diagnostics. ATA Action is pleased to provide insights on the following questions below.

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?

Important factors to consider in instituting home-based care include a consumer-centric approach, driving value for health systems and payors, taking a needs-based approach, and targeting the populations most in need.

Best practice guidelines and resources to develop and support new technologies would facilitate the use of new technologies.[i] New technology evaluation should involve patient user feedback as well as the level of patient engagement to support the utilization of the technology.[ii]

What factors should be considered to effectively institute patient care that includes home-based care?

The technology needs to be integrated into the person's life, easy to use by patients and providers, and be inexpensive or covered by insurance, consumer centric, and needs driven. Education also is needed. Patients need to understand the technology and how the information will be used in their care, be confident in using the technology, know to troubleshoot problems and who to contact if problems persist, be able to track their progress for motivational reasons, and receive feedback and encouragement from their provider.

What are ways that digital health technologies can (a) foster the conduct of clinical trials remotely and (b) support local or home-based healthcare models?

To foster utilization in clinical trials and for home care, file share systems that meet 21 CFR Part 11 or HIPAA compliance requirements are needed. This can assist with documentation duplication, version control issues, and lack of standard filing structures or role-based security.[iii]

In addition, having the data be directly fed into an electronic medical record would be beneficial, and the data being incorporated into the clinical workflow is important. Machine learning and artificial intelligence can assist with improving data quality and analytics (specifically the accuracy and speed).

How can the FDA facilitate individuals accessing medical technologies in remote locations when they are unable or unwilling to access care in clinical settings?

Extensive research has shown that medical technologies can help overcome access to care problems in rural areas by reducing or eliminating barriers such as transportation, childcare, costs, time away from work, caregiving responsibilities to others (ill spouse), weather, disabilities, and more. For those seeking mental health care in rural areas remote care can eliminate the barrier of stigma and embarrassment by being seen entering the building as well as those who seek prescriptions for stigmatized issues.

Having trained champions at rural hospitals, community centers, elder service and home health agencies needs to occur. These well-trained champions should be available to work with providers and patients directly to engage them in using the technology through training and education. Nearly one-third of home healthcare providers do not incorporate technology into their services.[iv] Seventy-five percent of older adults use the internet while 93% of American adults use the internet.[v] "Teaching older users to accept and master the tools — and training employees and loved ones to work with them — will determine the success and direction of these critical applications".[vi]

Lack of access and awareness of access has been found to be a primary driver of disparities in rural telehealth use. Race/ethnicity was not associated with telehealth willingness in a 2023 study, suggesting that equal utilization is possible once granted access.[vii] Therefore, education about remote patient monitoring as well as building trust is needed. Community-based programs in libraries and other locations can assist with education about how to use the devices as well as digital literacy and data security information.

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?

There are different aging populations, and each has specific needs. For older people living alone, smart home apps and sensor-based systems are needed; for those living with family members the needs are home service robots and telemedicine apps; those in retirement communities can benefit from wearable and remote monitoring devices; and older adults in nursing homes and assisted living facilities would benefit from devices to assist with dementia.[viii] Therefore, the technologies need to be tailored to these four types of older adults.

In addition, first responders who arrive at a home for a medical emergency often do not have the needed information to assist the individual e.g., medical history, medications, emergency contact. A device that would allow first responders to have this needed information would be valuable.

What medical technologies could be ideal to transition to use in non-clinical settings? What aspects of those technologies could potentially benefit from modifications to optimize use in non-clinical settings?

The hospital at home (HAH) model could improve the intended results of monitoring vital signs. Two in-person checks is suitable for lower-acuity cases. HaH would be in better alignment with the standard clinical practice checking vital signs every 4-8 hours. The increased frequency would enable safe care for moderate-acuity medical and surgical floor-level patients not traditionally enrolled in HaH.[ix]

What design attributes and user needs would facilitate the use of medical technologies, including diagnostic and therapeutic devices, for use in a non-clinical setting, for example home use? 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)?
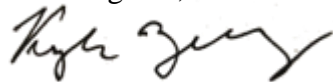
Design attributes that do not negatively affect mobility and lifestyle (e.g., the device being portable) are essential. Access by those with disabilities (arthritis, vision, hearing), button sizes, use of icons, ease of utilization, use of color (for those who are colorblind or visually impaired), use of raised buttons or braille, a talk back option, alerting mechanisms, use of alt texts, and on-screen magnifiers are recommended. Real-time language translation capabilities and an interface with different language options are needed. For those with low literacy, having a dictionary within the device may be valuable. In addition, images can be motivating for behavior change. When possible, incorporate images or other progress tracking capabilities to enhance behavior change motivation.

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?

Evidence to consider is patient feedback via surveys, focus groups, etc.; utilization levels; provider feedback on items such as ease of incorporation into the workflow; data from those who refused to utilize the device (reasons for not using, concerns, etc.).

Thank you again for soliciting feedback on these important topics. If you have any questions, please reach out to kzebley@ataaction.org, Executive Director, ATA Action.

Kind regards,

Kyle Zebley
Executive Director
ATA Action

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[i] Houlding E, Mate KKV, Engler K, Ortiz-Paredes D, Pomey M, Cox J, Hijal T, Lebouché B. (2021). Barriers to Use of Remote Monitoring Technologies Used to Support Patients With COVID-19: Rapid Review. *JMIR Mhealth Uhealth, 9*(4). https://mhealth.jmir.org/2021/4/e24743

[ii] ibid

[iii] Going Digital with Remote Monitoring: Key Considerations. (n.d.). Veeva SiteVault. https://sites.veeva.com/resources/going-digital-with-remote-monitoring-key-considerations/

[iv] Longly, J. (2020, Oct. 29). Why Home Healthcare Needs More Technology and Training. *HealthTech.* https://healthtechmagazine.net/article/2020/10/why-home-healthcare-needs-more-technology-and-training

[v] Pew Research Center. (2021, April 7). Internet/Broadband Fact Sheet. https://www.pewresearch.org/internet/fact-sheet/internet-broadband/?tabId=tab-9a15d0d3-3bff-4e9e-a329-6e328bc7bcce

[vi] ibid

[vii] Ko JS, El-Toukhy S, Quintero SM, Wilkerson MJ, Nápoles AM, Stewart AL, Strassle PD. (2023, June). Disparities in telehealth access, not willingness to use services, likely explain rural telehealth disparities. *J Rural Health, 39(*3):617-624.

[viii] Sapci AH, Sapci HA. (2019). Innovative Assisted Living Tools, Remote Monitoring Technologies, Artificial Intelligence-Driven Solutions, and Robotic Systems for Aging Societies: Systematic Review. *JMIR Aging, 2*(2).

[ix] Whitehead D, Conley J. (2023, Mar 16). The Next Frontier of Remote Patient Monitoring: Hospital at Home. *J Med Internet Res.* https://pubmed.ncbi.nlm.nih.gov/36928088/