U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Patient Engagement Advisory Committee (PEAC) Meeting
Virtual

FDA DISCUSSION QUESTIONS

September 6, 2023

1. With changes in technology and healthcare, medical technologies are increasingly being used outside of clinical care settings, such as in the home. Increasing patient access to healthcare, prevention and wellness through the use of such medical technologies, particularly those with digital capabilities, may benefit patients by bringing healthcare directly to patients, wherever they are – at home, at work, in cities, in rural communities, which has the potential to help bridge gaps in health equity. The FDA is committed to facilitating access to medical devices designed to be safe and effective when used outside of clinical settings, while reducing and mitigating problems that can occur in the home environment.
    a. Some technologies currently used in healthcare settings could be adapted for use in other settings, with design changes, additional training or instructions for a patient and/or caregiver, or other modifications. As a patient, what information would you want to know to feel comfortable using a medical device in a non-clinical care setting?
    b. Certain diseases or conditions may have diagnostic and/or treatment options or other aspects of care that are amenable to moving outside of a healthcare setting. This may include transitioning to "over the counter" access or involve monitoring or periodic visits with a healthcare professional to ensure appropriate use and treatment adherence. What diseases or conditions, or aspects of care for certain patient populations, may warrant consideration, due to the potential for a large benefit from having medical technology that can be used outside a healthcare setting (for example: at home, work, school)?
    c. What actions could be taken by industry or the FDA to facilitate patient access to medical devices designed to be safe and effective outside the clinic setting?
    d. The home setting could be an environment to support wellness and prevention as well as for clinical care and evidence generation for clinical investigations. What actions could be taken by the FDA and industry to establish such an environment that meets the needs and provides the experience expected of patients and consumers to support the integration of medical technologies in the home setting? Consider the following:
        i. Experiences patients and consumers would want in such an environment
        ii. Key features of such an environment for patients and consumers to have that experience

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2. In certain device areas, a subpopulation of users may respond to a medical device differently than another subpopulation. Intentional design of the device with the user in mind, appropriate human factors and usability testing, and clinical study evidence can play an important role in ensuring medical devices are developed and perform as intended to meet the needs of potential users.
    a. With the end users in mind, what aspects should the FDA and industry consider during medical device design and evaluation to confirm devices can be safely and effectively used by all potential users, particularly in the home use setting? Consider the following:
        i. Ability for individuals with reduced functional capabilities (physical, sensory, and cognitive) to safely and effectively use the device
        ii. Ability for individuals with limited health literacy to understand how to safely and effectively use the device
        iii. Technology aspects that may limit or impact safe and effective device use in certain populations or locations (for example, broadband internet requirements in rural settings)
        iv. Other aspects of the home environment that may limit or impact safe and effective device use (for example, presence of children or pets, access to caregiver assistance, ability to travel)
        v. Elements of the device-user interface that may limit or impact safe and effective device use (for example, controls, visual displays, alarms, labeling, training)
        vi. Conditions or diseases where current scientific knowledge suggests we might anticipate meaningful differences in overall benefit-risk profile among diverse groups of patients (for example: where treatment A is better in one group and treatment B is better in another group)
    b. Evidence from clinical studies that include diverse cohorts of patients may be necessary to determine whether or not that device is safe and effective in support of market authorization. In some cases, this may result in larger, longer studies, which could delay access to a new technology. The FDA is considering three main principles - inclusivity, data generalizability, and timely access - to guide its determination of when such studies may be necessary to support market authorization.
        i. Do these principles reflect what is most important to patients?
        ii. Are there additional principles the FDA should consider? Please explain your response.

3. As more diverse patient groups are included in clinical studies of medical devices, it is important to communicate potential differences in the level of benefits and risks various groups of patients may experience.
    a. What information do you think is most important to convey publicly about these differences in benefits and risks?
    b. What information do you think is most important to convey publicly about the study population included in the study?

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c. Is there additional information you think patients and caregivers should have available to aid their individualized discussion of benefits and risks of various treatment options with healthcare providers?

4. Digital media has allowed the FDA and industry to share information efficiently with audiences who are comfortable users of such technology; however, these communications are not able to reach all patients and consumers who use medical devices. Studies suggest certain groups are less likely to utilize or rely on digital forms of communication, whether due to age or generational differences, lack of access to reliable broadband service (commonly found in under-resourced urban and rural communities), cultural or other factors. What methods or approaches should the FDA and industry consider reaching individuals and communities who have limited digital literacy, engagement, or interest in digital media? Please consider both dissemination of information as well as hearing about needs and concerns of such individuals and communities.

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