24- Hour Summary of the Patient Engagement Advisory Committee
September 6, 2023

Introduction:

The Patient Engagement Advisory Committee to the Food and Drug Administration (FDA) met on September 6, 2023, to discuss and provide advice on "Advancing Health Equity in Medical Devices." The FDA Center for Devices & Radiological Health (CDRH) is committed to working toward ensuring that all patients have access to high-quality, safe, and effective medical devices. This includes ensuring devices are designed to be safe and effective when used by various populations, are evaluated in the diverse populations for which they are intended, and that all patients and consumers have the information they need to make decisions about their healthcare and quality of life. Technology, including digital health technology, may help bridge gaps in health equity by extending access and bringing healthcare to patients at home, at work, and in their communities. The recommendations provided by the committee addressed considerations for the FDA and industry on these topics. The Committee considered ways to advance access to devices that allow for care outside a hospital or clinical care setting, for example, in the home setting. The Committee also discussed patient-focused considerations for when a device should be evaluated in diverse populations to support marketing authorization. Additionally, the Committee also discussed considerations for improving reach and comprehension of FDA's patient and caregiver communications across diverse demographic groups.

FDA Questions and Committee Discussion:

Question #1: Facilitating access to and use of medical devices outside of the clinical care setting, while reducing and mitigating problems that can occur in the home environment

a) Information important for patients to use a medical device in a non-clinical care setting

The Committee agreed information pertaining to data access and security, including who owns the patient's data should be clear. The Committee also agreed that customer service contact information (such as a 1-800 number) for whom the patient or caregiver can contact when a medical device is not working, and confirmation on whether the customer service number will provide a live-person, or an automated service should be clear. The Committee agreed that knowing what the medical device is composed of and whether the components pose a risk is important information for patients. The Committee discussed the importance of patients and caregivers knowing where to get the supplies for the medial device and accessibility of supplies, as well as how to dispose of the device. The Committee also agreed that medical device safety along with informed consent was important, including exploring the advantages and disadvantages of using the device outside of a clinical care setting. The clarity of instructions and thoroughness of the device training matters, including –appropriate interpretation and response to alarms. Finally, the Committee agreed that the clinical outcomes when using the device is important, including whether it

enhances the clinical care experience.

b) Diseases, conditions, or aspects of care for certain patient populations that may benefit from having medical technology that can be used outside a healthcare setting

The Committee agreed that over the counter or home use diagnostic devices for acute conditions, including common communicable diseases like influenza and strep throat, and conditions with social stigma such as sexually transmitted diseases may warrant considerations for outside healthcare setting use, especially for patients that live in rural or other medically underserved areas. In such areas, devices which facilitate remote specimen collection may be particularly beneficial to consider. The Committee also suggested that conditions such as chronic pain management and sensory issues might make it difficult to commute to care centers and would benefit from devices being available outside a healthcare setting. Committee members mentioned devices to help manage medications outside a healthcare setting may be of benefit, as would devices that help patients and caregivers dealing with chronic conditions manage acute exacerbations. The Committee agreed that diseases and conditions that require long-term and time-consuming management should be considered for having devices that can be used outside a healthcare setting.

c) Facilitating patient access to medical devices designed to be safe and effective outside the clinic setting

The Committee recommended the FDA facilitate access and payment issues by working with other federal agencies such as the Centers for Medicare & Medicaid Services (CMS), including appropriate coding to facilitate use by providers and patients. The Committee agreed that the use of real-world evidence and postmarket surveillance to evaluate benefit-risk once a device is on the market is important. The Committee suggested that patients be provided access to postmarket safety signals and data so they can keep making informed decisions about the use of their medical device at home. The Committee also recommended the FDA have a stronger role in ensuring the provider has access to postmarket information. The Committee recommended FDA consider issuing device-specific guidance that is risk based, with clear requirements for data needed to bridge care from clinic use to the home environment. The Committee recommended the FDA encourage industry to automate information flows regarding device use errors that occur outside the clinic setting, both in detecting issues and alerting patients about common use errors. The Committee also recommended the FDA ensure industry addresses issues regarding health literacy, how to trouble shoot, the timeliness and responsiveness informing patients about issues with a medical device, how to handoff care and reverse treatment settings, and access to replacement supplies.

d) Patient needs in the home environment to support the integration of medical technologies

The Committee recommended the FDA consider how care is practically given in the non-clinical care setting using the device, how accessible data from the device is, interoperability, risk to patients, the use of apps, issues of health literacy, and how telehealth ties into wellness for prevention and evidence.

Question #2: Ensuring devices are developed and perform as intended to meet the needs of potential users, including subpopulations that may respond differently

a) Intentional design of the device with the user in mind

The Committee recommended the FDA consider coordination with international standards groups to establish home use safety and performance standards, including topics such as interoperability of multiple devices, cyber and data security, and data privacy. The Committee also recommended FDA consider revising the guidance on home use devices, in particular the definitions of what is considered a home use device. The Committee encouraged broad application of human factors testing for devices used in the home, with emphasis on environment and user interface, and recommended FDA consider ways to ensure consistent implementation of human factors recommendations to industry. The Committee agreed that linguistic inclusion and linguistic barriers, reading level, dexterity, age, dependency upon other medical devices, such as reading glasses, should be considered. The Committee agreed it's important to consider where people live and understand the challenges they may face. The Committee discussed the need to have special considerations for rural communities and suggested industry consider having signal boosters, on-device storage of data, and backup power supplies for people that live in areas that have limited broadband and intermittent power interruptions.

The Committee agreed that the issues of safety are important, including fail safes, and discussed what that means in a real-world setting. The use of alarm systems of medical devices, the safety to children and pets, how they are set up at home and in the workplace are important to patients. The Committee agreed that the term caregiver can be singular or plural and handoff or continuity of care can involve multiple care teams (short, mid, and long term) and turnover of people and devices is understandable. As a result, there is a need to ensure that devices are understandable across all care teams. The Committee highlighted that people with cognitive impairment and disabilities are often not accounted for during device design and that devices may be designed with one intention without accounting for other things patients deal with. The Committee recommended that medical devices be designed to accommodate the daily routines of patients with chronic conditions, including as their condition improves or worsens, as well as other comorbid conditions and their treatments.

b) Principles of inclusivity, data generalizability, and timely access

The Committee agreed that the FDA principles are good, but agreed that the pursuit of the ideal clinical trial can create substantial delays in in bringing important new

medical devices to patients. The Committee recommended balancing the sample size and study duration of conducting a clinical trial, with the need for patients to have timely access to devices. In addition to clinical trials, the Committee recommended utilizing real world data to further assess device performance in diverse populations. Other concepts mentioned for potential consideration as principles for a framework were data validity and affordability. Committee members also raised concerns about industry studies utilizing eligibility criteria that excludes complex patients who may benefit most from the device.

Regarding patient conditions or device characteristics where FDA may consider requiring adequate premarket data in diverse populations, Committee members recommended an approach involving prioritizing conditions and populations where the highest signal for healthcare disparities in outcomes and burden of disease are observed, to ensure premarket trials include populations most affected, while considering potential confounding related to access barriers in those populations. The Committee also suggested an adaptive approach where signals of meaningful differences in effect for a certain group be evaluated in further study. The Committee also mentioned that all trials should be intentionally inclusive whenever possible.

Question #3: Clinical study information to communicate regarding potential differences various groups of patients may experience

a) Information about differences in benefits and risks for different patients

The Committee recommended sharing comparative data on alternative treatments or diagnostics for a proposed home use device, as well as the magnitude of impact on morbidity and lifestyle. The Committee agreed that it is important to consider what is meaningful to patients, including quality of life, as well as limitations of the study; information to facilitate shared decision making, informed consent, and how the medical device is labeled; and quantifying risk and benefit longitudinally after being in the marketplace.

b) Information about the study population

The Committee agreed they wanted to see information on patients with whom they identify. They wanted to be made aware of who was included or excluded from the clinical study and if the study included participants from populations that matched the intended users. The Committee agreed that transparency in outcomes, specific quantitative ways of communicating benefits and risks, and whether data is generalizable (such as by age, gender, geographic location, comorbid conditions, and race) are important to patients.

c) Additional information patients and caregivers should have to inform their healthcare decisions

The Committee agreed that patients look to their providers to contextualize and

clarify the benefit-risk balance for that individual. Committee members also suggested the benefits and risks of patient use versus caregiver use is important information that patients and caregivers should have available to aid their individualized discussion of benefits and risks of various treatment options with healthcare providers. The Committee also recommended that Information about when the home use device may no longer be a viable option for the patient be made available.

Question #4: Communication approaches for reaching individuals and communities with limited digital engagement

The Committee recommended the FDA and Industry use community-specific communication methods. Digital communication methods (for example, social media, text, websites) and non-digital communication methods (for example, television, radio, print media like billboards, subway ads, leaflets for doctors' offices, and mailed recall notices) were suggested as possible ways to reach different communities. They also recommended the use of community-based methods such as mobile vans, incorporating local public health officials, and communicating within caregiver networks, to help disseminate information and engage with patient communities. The Committee also recommended leveraging organizations, such as, patient advocacy groups, patient organizations, support groups, professional organizations and communities, faith-based communities, community health centers, recreational teams/sport teams, researchers, to reach members of communities. Conducting qualitative research to determine the unique needs for effective communication of specific populations and communities was also recommended.

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Transcripts may be downloaded from:
https://www.fda.gov/advisory-committees/advisory-committee-calendar/september-6-2023-patient-engagement-advisory-committee-meeting-announcement-09062023

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