EXECUTIVE SUMMARY FOR THE PATIENT ENGAGEMENT ADVISORY COMMITTEE MEETING

Advancing Health Equity in Medical Devices

September 6, 2023

PEAC Executive Summary– Advancing Health Equity in Medical Devices

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Introduction

Regardless of race, ethnicity, age, sex, gender, sexual orientation, income, community, or other physical or social characteristics, consumers can benefit from medical devices and health technologies that enable them to reach their full potential for health and well-being. But health and healthcare disparities exist across many dimensions. The FDA's Center for Devices and Radiological Health (CDRH) is committed to addressing these disparities by working toward assuring that all patients have access to safe, effective, and high-quality medical devices and safe radiation-emitting products. This commitment includes ensuring that devices are designed to be safe and effective, that evaluations of devices take into account the diverse populations for which they are intended, and that patients and consumers have the information they need to make decisions about their healthcare.

Strategic priorities

The FDA seeks to advance health equity by supporting the development of safe and effective technologies to meet the needs of all patients and consumers. No person should be excluded from healthcare and no patient left behind. As part of CDRH's 2022 to 2025 Strategic Priority to Advance Health Equity,[1] CDRH has set the following objectives:

- Facilitating availability of and access to medical technologies for all populations;
- Empowering people to make informed decisions regarding their healthcare;
- Supporting innovation of novel and existing technologies that address health inequities; and
- Reducing barriers to increase participation by diverse populations in evidence generation.

[1] https://www.fda.gov/media/155888/download

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Figure 1. Diagram of CDRH's Strategic Priority to Advance Health Equity.

Themes for discussion

CDRH has identified three broad themes to obtain expert advice from the Patient Engagement Advisory Committee (PEAC) that are relevant to medical devices and health equity:

Increasing patient access to home use medical technologies. Medical technologies[2], including digital health technologies, may help bridge the gaps by bringing healthcare directly to patients - at home, at work, at school, and in their communities, in urban, suburban, and rural settings.

Principles for when device evaluation in diverse populations may be needed. The benefits and risks of a medical device can vary across patient populations, which may need to be considered during clinical studies. As part of our strategic priority, CDRH is considering several key principles to guide consideration of when a device should be evaluated in diverse populations to support marketing authorization. CDRH's goal is to promote inclusivity in clinical research and high-quality evidence generation, and to advance equity in study participation, health outcomes, and timely access to safe and effective medical devices.

[2] For the purposes of this PEAC meeting, medical technologies encompasses a broader scope of products that includes medical devices and other technologies which may not be subject to regulation by CDRH.

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Communicating about devices to diverse audiences. To empower consumers to make informed decisions about their healthcare, it is important to provide clear, pertinent, accessible information about their medical technology options.

The recommendations provided by the committee will be used to address considerations for the FDA and industry on these topics.

Increasing patient access to home use medical technologies

Advances in healthcare technology and changes in how people access healthcare have helped to move the use of some medical devices from the clinical environment to the various places people spend much of their daily lives. Generally, a "home use" device is a medical device intended for use in any type of location outside of a professional healthcare facility, including but not limited to, a person's home, outdoors, workplaces, schools, vehicles, emergency shelters, and independent living retirement homes.[3]

Home use technologies may make many forms of healthcare more available and accessible, potentially providing significant benefits in both quality of life and cost of care. Home healthcare may offer more comfort and convenience to care recipients than hospital-based care and enable recipients to remain independent.

For these reasons, home use devices present an opportunity to advance health equity for underserved people, particularly those who face barriers in accessing care at healthcare-facilities. Home use devices can help diagnose, treat, and monitor many chronic and acute conditions, as well as support recuperative and long-term care. In addition, features of some home use devices can be tailored to the needs of diverse patients through intentional design. In particular, home use devices may be able to be designed with underserved communities in mind, such as diagnostic tests with features enabling use by visually-impaired individuals[4], digital stethoscopes for monitoring lung and heart disease[5], wrist-worn blood-pressure monitors[6] for hypertension monitoring, and wearable brain-oxygenation monitors[7] that can provide data important to several conditions.

[3] https://www.fda.gov/medical-devices/home-health-and-consumer-devices/home-use-devices
[4] https://www.nibib.nih.gov/covid-19/radx-tech-program/listening-session/agenda
[5] https://www.designdevelopmenttoday.com/industries/medical/news/22820626/medaica-announces-free-telehealth-stethoscope-for-rural-and-underserved-patients
[6] https://www.designdevelopmenttoday.com/industries/medical/news/22820626/medaica-announces-free-telehealth-stethoscope-for-rural-and-underserved-patients
[7] https://www.sciencedirect.com/science/article/pii/S1053811922003408

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The rapid, ongoing innovation in digital health technologies is amplifying the potential benefits of home use devices, including their ability to advance health equity. Smartphones and internet-connected technologies are already advancing the boundaries of what can be done outside of healthcare facilities. As new electronic devices and software continually provide more capabilities at lower cost, the opportunities for remote healthcare-related services grow, including monitoring patients in their daily lives for signs of problems, alerting caregivers and providers to the need for intervention, recording patient data in their healthcare records for better clinician analysis, communicating directly with clinicians, and informing patient decision-making.

At the same time, home use devices present unique challenges and potential safety risks[8], including the difficulties some may face in properly operating them, differences in performance of some devices compared to traditional care, and higher out-of-pocket costs for some devices. If not appropriately addressed and managed, these potential problems could limit the extent to which home use devices contribute to healthcare equity.

Design of Devices for Home Use

Home use medical devices have the potential to broaden and facilitate patients' access to healthcare. However, as their use becomes widespread, it will be important to also think about the design of devices for use outside the clinical environment. With varying environments, it's helpful to use a human-centered design approach: this method puts people at the center of the process and considers behaviors, ways of thinking, and peoples' needs and aspirations.[9]

Intuitive Interfaces

The reach and impact of a home use device may be limited if users of the device are highly reliant on instructions, manuals and training to use the device safely and effectively. Many users will prefer, and are more likely to safely and effectively use, products that do not require extensive training or lengthy reviews of written materials. That may be especially true for populations associated with lower levels of digital or health literacy, as well as for people with disabilities for whom documentation and training materials may present special challenges.

Intuitive design is a way to reduce a reliance on training, instructions or manuals for safe, effective operation.[10] Training and user manuals may still be necessary to communicate

[8] https://www.ecri.org/top-10-health-technology-hazards-2023-executive-brief
[9] https://lab.opm.gov/our-services/
[10] https://www.interaction-design.org/literature/topics/intuitive-design

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important information, but intuitive design may enable making them simpler, and more focused on applications and benefits of the devices rather than on explaining technological details.

A user interface that is intuitive is one in which users recognize the device's controls, inputs and outputs as working in a familiar or obvious way.[11] Intuitive interfaces allow users to easily navigate the device's operations, so that they can focus on the task at hand rather than on figuring out how to operate the device. For example, many people in the U.S. are familiar with the image in Figure 2 representing "play" for audio or video files. The cultural familiarity associated with this symbol makes its use on other devices, platforms or contexts intuitive. Designing devices that are intuitive may increase user as well as clinician acceptance.

Figure 2. Example of Play button

Intuitive interfaces typically have the following characteristics[12]:

- It is easy to find and understand the different functions that a device performs, and the different types of information it provides.
- It is easy to determine how to perform a given function or access a given type of information.
- The results of performing a function are expected, and are immediately and clearly conveyed to the user.

[11] https://www.fda.gov/media/151482/download?attachment
[12] See Footnote 11.

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- There is a minimum of unnecessary or repetitive user interactions.
- The device does not malfunction or behave unexpectedly when a user makes a mistake, and allows the user to easily resume appropriate operation.

These design features can be incorporated through an iterative design process that involves direct interactions with or observations of the intended users, along with formative evaluations such as cognitive walk-throughs and simulated use testing. The process typically also involves the consideration of human factors principles in medical device design, which takes into account the physical, sensory, emotional, and intellectual capabilities of humans. The benefits of designs that are intuitive and that take human factors into account include making it easier for users to comply with recommended usage of the technology; making it easier for users to understand device output and functionality; reducing the demand for customer support; and quicker mastery of device operations and procedures.[13]

Mitigating Risks for Safe Use

The safety of end users is always of the utmost importance. Through the application of human factors principles, safety risks related to the home use of a medical device can often be determined and appropriately mitigated. Determining risks to safety involves identifying potential use errors. But predicting the types of errors that individuals will commit may require an in-depth and systematic analysis of ways a user might interact with a device, as well as errors a user might commit during each individual interaction.[14] Once these probable errors are identified, steps can be taken to modify the design to minimize the chances of users making these errors, and to ensure the device handles any errors in ways that reduce safety risks, and that allow the user to continue to operate the device correctly.

Special considerations for people with physical or cognitive disabilities

People with disabilities represent an enormous set of populations that are in many ways underserved by healthcare. Disabilities such as visual impairment, auditory impairments, reduced dexterity, motor and strength impairment, and cognitive impairments are extremely common in the U.S., as they are throughout the world. Devices that are intuitive and easy to use by others may be much more difficult to use for those with disabilities, if special attention is not considered for their needs. For example, basic but critical features of a device such as blinking

[13] IEC/ISO TR 62366-2 Medical devices – Part 2: Guidance on the application of usability engineering to medical devices
[14] Salvendy, Gavriel. (2012). Handbook of Human Factors and Ergonomics (4th Edition). John Wiley & Sons.

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lights, warning tones, and keypads may require alternatives for those with visual, auditory or dexterity challenges.

Automation Bias

Automation bias is the tendency for users to exhibit more trust than may be warranted in a device's actions or in the information it provides, simply because the device is equipped with technology. That potentially excessive trust can result in inappropriate decision-making based on the device's output,[15] or acceptance of a device's inappropriate actions.

There are two types of automation bias errors[16]: automation bias omission and automation bias commission errors. Automation bias omission error occurs when users rely on the device to inform them of or correct a problem, but the device fails to do so. Automation bias commission error occurs when users make choices based on incorrect suggestions or information provided by the device, or allow the device to perform an inappropriate action.

It is important to understand how to detect automation bias in medical device users, and how to enlist best practices for mitigating the risks related to such bias. Equipping the device with protective measures such as warning statements and alerts, and providing clear instructions for recognizing and avoiding safety risks, can help mitigate automation-bias-related risks. But the best way to mitigate use-related risk in medical devices is through safety by design—that is, designs that minimize the chances of a device performing an inappropriate action or providing inappropriate information in the first place.[17]

Home use Medical Device Examples

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. Following are some important applications, along with a few examples for each.[18]

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[15] D. Lyell, E. Coiera. Automation bias and verification complexity: a systematic review. J Am Med Informatics Assoc 2016;24:423-31.
[16] https://www2.deloitte.com/uk/en/pages/deloitte-analytics/articles/automation-bias.html
[17] ISO 14971 *Medical devices - Applications of risk management to medical devices*
[18] Except where otherwise explicitly stated, comments in this Executive Summary are not intended to be product-specific, nor to be used for product-specific regulatory decision-making. Also, please note that studies and other research cited in this Summary and not explicitly attributed to the FDA, are included strictly for reference purposes.

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Devices for pediatric seizures

Among children at high risk for seizures, monitoring for seizure onset can be critical to protecting the children from significant harm, and to better understanding and treating their conditions. Seizure monitoring is typically done through electroencephalography (EEG), which involves measuring electrical activity in the brain, usually through devices with electrodes that contact the scalp. There are numerous home use EEG devices, and some of these can connect by smartphone or other online device to alert caregivers or clinicians in case of abnormal brain electrical activity, and can track seizure activity over time to provide a clearer picture of the condition.[19] Additionally, some other types of wearable devices measure motion, heart rate, or muscle activity to monitor for seizures at home.

Maternal health

Maternal health is subject to some of the most acute disparities in U.S. health, with studies showing that the risk of death from pregnancy-related causes is two to three times higher for American Indian/Alaskan Native and Black women, respectively, than for White women.[20] Many of these deaths may be preventable. Disparities also carry over into the much higher number of serious pregnancy-related complications, including clotting and bleeding disorders, hysterectomy, acute kidney failure, severe infection, stroke, cardiovascular events including arrest and heart failure, and adult respiratory distress syndrome.[21] Many of these deaths and complications may be preventable through home use devices, which can monitor and provide early warnings of compromised vital signs or other indications of medical distress. One major example is home monitoring of blood pressure,[22] which can be accomplished through a variety of devices, many of them easy to use, inexpensive, and capable of recording and even transmitting data. Importantly, clinicians are monitoring blood pressure and other health indicators during the postpartum period, which is when most maternal deaths occur, and which has historically been a time when women are less likely to be seen by clinicians.[23]

[19] https://www.sciencedirect.com/science/article/pii/S1538544220301565
[20] https://www.cdc.gov/healthequity/features/maternal-mortality/index.html
[21] https://pubmed.ncbi.nlm.nih.gov/30877505/
[22] https://www.preeclampsia.org/frontend/assets/img/advocacy_resource/Gestational_Hypertension_and_Preeclampsia_ACOG_Practice_Bulletin,_Number_222_1605448006.pdf
[23] https://pubmed.ncbi.nlm.nih.gov/31503166/

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Assistive technology

There are a vast number of technologies to assist those with a wide range of mobility, dexterity, hearing, visual, and communication challenges.[24] These include speech generating devices, scooters used for a medical purpose, hearing aids, and prosthetic devices, just to name a few. Many are inexpensive, simple to use, and readily accessed over-the-counter. However, access to and uptake of technologies that are more complex, expensive, or available only as medical technologies through prescription may be hindered in communities with lower levels of wealth,[25] access to healthcare,[26] and health literacy,[27]

In vitro diagnostics (IVDs)

The COVID-19 public health emergency highlighted the problem of healthcare disparities. Historically underserved populations experienced higher-than-average incidence rates of COVID-19, as well as higher rates of serious disease and mortality.[28,29] At the same time, the increase in home use in vitro diagnostics (IVDs), such as home COVID-19 diagnostic tests, demonstrated how home use devices can help mitigate certain test access issues. The availability of free or low-cost home tests, and in particular the federal government's program to distribute free home tests, appeared to largely close what otherwise would have been a gap in the ability of underserved populations to access home tests.[30] Making FDA authorized home tests for a variety of conditions more readily accessible to the public could help foster health equity. Rates of cancer screening, for example, vary across subgroups of the US population.[31] The availability and accessibility of authorized home use IVD tests, as well as laboratory-based IVD tests that use samples collected at home for additional types of cancer, beyond colorectal cancer where one test with home collection is available,[32] may help reduce disparities in screening rates.

FDA authorized home use IVD tests and IVD tests that use samples collected at home, may also offer the ability to provide earlier identification of potential health conditions that call for

[24] https://www.nichd.nih.gov/health/topics/rehabtech/conditioninfo/device
[25] https://www.federalreserve.gov/econres/notes/feds-notes/wealth-inequality-and-the-racial-wealth-gap-20211022.html
[26] https://www.ncbi.nlm.nih.gov/books/NBK425844/
[27] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6608915/
[28] for example, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7978471/
[29] for example,https://academic.oup.com/cid/article/72/4/703/5860249
[30] https://www.cdc.gov/mmwr/volumes/72/wr/mm7216a6.htm
[31] https://www.kff.org/racial-equity-and-health-policy/report/key-data-on-health-and-health-care-by-race-and-ethnicity/
[32] https://www.fda.gov/consumers/consumer-updates/colorectal-cancer-what-you-should-know-about-screening

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medical treatment, such as pregnancy, infectious diseases, or high cholesterol. When paired with resources to assist in finding and accessing treatment options, this early access to testing may similarly help reduce health disparities by reducing barriers to care for underserved populations who may postpone initial testing due to the challenges with finding time and resources to get to a clinic for an initial test.

It is important to note that, while home use and home collection IVD tests might well improve rates of screening and improve access to a variety of tests, use of IVDs in the home present unique risks as the person collecting the sample and in the case of home use tests, performing the test and interpreting the results, are lay-users rather than trained laboratory or healthcare personnel.

Chronic disease management

Some populations are more likely than others to be impacted by certain chronic diseases, and less likely to access the care required to effectively manage the disease, typically with significant adverse impact on health and quality of life. Here are some ways home use devices could help reduce the gap in chronic-disease management.

Diabetes

Diabetes offers a striking example of the impact home use devices may have on health-care inequities related to chronic disease management. The CDC estimates that more than one in ten adults and children in the US has diabetes. But incidence rates vary widely across the US population, from 7.4% among non-Hispanic whites to 14.5% among American Indians/Alaska Natives. Non-Hispanic blacks are twice as likely to die from diabetes as non-Hispanic whites.[33]

A range of home use devices may help manage diabetes. Some are as simple as blood glucose meters, while others are more sophisticated devices that can provide powerful monitoring and interventional functions. Many of these devices are aimed at monitoring and stabilizing glucose levels, which may otherwise spike or plunge to dangerous levels in people with diabetes and cause short-term crises and long-term harm. Closed loop control algorithms that integrate wearable insulin pumps and implantable glucose sensors can help maintain safe glucose levels while at most times requiring little attention from the user.[34] Many devices can gather and maintain data about glucose levels over time, helping patients and clinicians to make better-informed, more effective treatment decisions.

[33] https://minorityhealth.hhs.gov/omh/browse.aspx

[34] https://www.diabeteseducator.org/docs/default-source/default-document-library/continuous-subcutaneous-insulin-infusion-2018-v2.pdf

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While studies have shown that populations who are generally less likely to be active in self-management of diseases still tend to see health benefits when they enlist diabetes-management home use devices, research has also shown that some underserved groups are less likely to access these technologies.[35]

Kidney disease

Black people are three times more likely to develop end-stage kidney disease than White people.[36] Most people with end-stage kidney disease who do not have a kidney transplant undergo regular hemodialysis at a dedicated facility, using a machine that filters their blood. There are also devices designed for home use, including home hemodialysis devices, and peritoneal dialysis devices. The latter are far simpler and involve much lower out-of-pocket costs for most patients, and they are generally as effective and less likely to lead to adverse events.[37] However, access to peritoneal dialysis treatments varies significantly across diverse populations. Black and Hispanic patients, for example, were found in one study to be 34% and 31%, respectively, less likely to utilize peritoneal dialysis than White patients.[38]

Heart failure monitoring

More than 6 million adults and children in the U.S. have heart failure, in which the heart progressively loses its ability to pump enough blood to meet the body's needs.[39,40] Black adults are hospitalized for heart failure (HF) at a rate nearly 2.5 times higher than White adults, with higher death rates, particularly among young Black adults. Moreover, while other racial and ethnic minorities have seen an improvement in rate of HF hospitalization over the last decade, the same is not true for Black patients. These differences are not entirely explained by socioeconomic factors.[41]

Medications, lifestyle changes, and surgery or other procedures involving medical devices can help slow the progression of the disease and lessen its symptoms.[42] Devices that enable remote monitoring of heart failure patients have the potential to reduce or prevent HF

[35] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8442173/
[36] https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease
[37] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8957460/
[38] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7380419/
[39] https://hfsa.org/patient-hub/heart-failure-facts-information
[40] Heidenreich, Paul A., et al. "2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines." *Journal of the American College of Cardiology* 79.17 (2022): e263-e421.
[41] https://www.ahajournals.org/doi/10.1161/CIRCHEARTFAILURE.120.007264
[42] https://www.mayoclinic.org/diseases-conditions/heart-failure/diagnosis-treatment/drc-20373148

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hospitalizations by alerting patients and their healthcare team earlier that they may need adjustments to their care, although there are challenges integrating and using such data in a way that improves outcomes and patient care.[43,44]

Mental health

There are significant disparities across demographic groups in access to mental health services. The option of meeting with a mental health clinician through a telemedicine visit on a phone or computer from home or elsewhere has been discussed as a potential means for reducing some of these disparities.[45] While a surge in telemedicine visits related to mental health and substance use disorder at the height of the pandemic seemed to suggest some fulfillment of that promise, one study found that as COVID-19 restrictions started to wane, there were disproportionately steep drops in visits from patients in historically underserved populations—specifically, a 25% and 33% drop in visits from Hispanic and non-Hispanic Black individuals, respectively, compared to a 9% drop in visits from non-Hispanic White individuals.[46]

Use of smartphone applications or other digital therapy platforms are being explored for various mental health purposes. Some smartphone applications or digital platforms may be able to help people monitor, improve a general state of mental health, or self-manage their mental health without providing specific treatment or treatment suggestions. Others target treatment or improvement for specific disorders as an addition to other therapeutic programs, such as for substance use disorders[47] and attention deficit hyperactivity disorder. Research is ongoing to demonstrate the long-term effectiveness for such applications, and they are considered to be a promising approach.

Concerns and Challenges Related to Home Use Devices

Just as there are unique benefits provided by home use devices, there are also unique challenges to using devices in a home setting. Some devices are designed to be used with little training, but others involve more complex instructions. If the training and instructions patients and their caregivers need to safely and effectively use a device at home are not easily accessible and understandable, this may lead to adverse events. Home users may not be able to fully understand instructions or labeled warnings, precautions, and contraindications.[48]

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[43] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6545972/
[44] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8037296/
[45] https://www.sciencedirect.com/science/article/pii/S0165178119311175
[46] https://www.sciencedirect.com/science/article/pii/S0163834320301407
[47] https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-mobile-medical-application-substance-use-disorder
[48] https://www.fda.gov/media/78647/download

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Patients with disabilities may have trouble interacting with devices that are easy for others to use. If the patients' choice of a device is not guided by a clinician who is aware of their needs and limitations, they may end up with a device that is inappropriate for them.

The home environment is less controlled than the clinical environment and may for example have limited space, variable lighting, and be full of distractions from children, pets, phones and media devices. These conditions might make it difficult to consistently operate the medical device effectively and safely; for example, a patient or caregiver might not see or hear that the device is issuing an important alert or notice that a child has played with the controls. Home spaces may be subject to electrical interference, or to excessive heat, cold or humidity, any of which might impact the operation of the device. Power or device failures could suddenly take the device out of service, potentially creating a dangerous situation, particularly if the failure occurs at night when it may not be noticed. Home users may also fail to realize that a device needs maintenance or repair, or lack the resources to perform or obtain the needed servicing. FDA plays an important role in ensuring appropriate usability of devices.

In addition, differences across populations in digital, technical and general health literacy, in level of health insurance, in ability to afford out-of-pocket costs, in ability to see, hear and manipulate a device's controls, and in access to support and other resources, some home devices may actually exacerbate health inequities rather than mitigate them. Furthermore, it is also important to consider whether these risks may disproportionally affect certain patient populations over others. FDA weighs appropriate performance, usability, and user comprehension across the intended use population, as well whether the labeling is appropriate to support safe and effective use, in deciding whether to authorize a new device. The FDA considers whether risks of a device are adequately mitigated, such that the benefits outweigh the risks for the device. For example, the FDA looks at whether robust usability or user comprehension testing has demonstrated safe and effective use, whether there is appropriate lay-friendly labeling describing limitations of the test, whether there is information outlining performance discrepancies across the intended use population, and whether there are easy to use instructions.[49]

Many of these challenges could likely be addressed through device design and more readable instructions and labels, and CDRH is placing a strong emphasis on encouraging and supporting innovators and manufacturers in this regard.

[49] See FDA's guidance "Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices)

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Principles for when device evaluations in diverse populations may be needed

Clinical studies play a critical role in understanding the safety and effectiveness of new medical technologies in the patients that will use them. In some clinical areas, clinical studies have also evolved as an important aspect of a participant's clinical care. The FDA has issued policy documents and other resources encouraging the medical device industry to collect, analyze, and report data in different groups of patients that may use a particular medical technology, to generate high quality evidence to inform regulatory decisions (See Figure 3). A lack of diversity, equity, and inclusion in clinical research undermines the principal goal of improving the health of all patients. As part of CDRH's 2022-2025 Strategic Priority[50] to Advance Health Equity, the Center has committed to developing a framework for when a device should be evaluated in diverse populations to support marketing authorization.

Central to this effort is the recognition that health equity should be foundational to not just how a device is used in clinical practice, but to how it is designed and evaluated in clinical studies. Ensuring device clinical studies include a diverse cohort increases the potential to understand how individuals with different backgrounds, lived experiences, and clinically important characteristics (such as comorbidities) are affected by medical devices. When data on diverse study cohorts is analyzed and clinically meaningful information is clearly communicated to the public, patients and healthcare providers can have greater trust in their diagnoses and treatment decisions. Diversity in clinical studies matters not only for supporting the generalizability of study results, but research suggests that a lack of representation may have an adverse economic impact on healthcare, may hinder innovation, may undermine public trust, may lead to lack of access to effective medical devices, and can compound health disparities in populations underrepresented in clinical studies.[51]

[50] See Footnote 1.

[51] National Academies of Sciences, Engineering, and Medicine; Policy and Global Affairs; Committee on Women in Science, Engineering, and Medicine; Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research; Bibbins-Domingo K, Helman A, editors. Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. Washington (DC): National Academies Press (US); 2022 May 17. Summary.

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Figure 3. Some of the FDA's resources[52] related to advancing health equity.

RACE AND ETHNICITY	WOMEN AND SEX-SPECIFIC CONSIDERATIONS	AGE GROUP CONSIDERATIONS
Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials (April 2022)[53]	Evaluation of Sex-Specific Data in Medical Device Clinical Studies - Guidance for Industry and Food and Drug Administration Staff (August 2014)	Ethical Considerations for Clinical Investigations of Medical Products Involving Children (September 2022)[54]
Collection of Race and Ethnicity Data in Clinical Trials (October 2016)		Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies (September 2017)
Evaluation and Reporting of Age-, Race-, and Ethnicity-Specific Data in Medical Device Clinical Studies (September 2017)		Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices (June 2016)

Proposed Regulatory Principles

CDRH is considering several key principles in determining when it would be beneficial for a device to be evaluated in diverse populations to support marketing authorization, including: **inclusivity**, **data generalizability**, and **timely access**. Evaluating the performance of a device in diverse patient populations may be necessary in certain cases to ensure that studies can meaningfully analyze how diverse participants respond to a particular medical-device intervention. The principles are intended to contribute to achieving three goals:

- equity in study participation,
- equity in health outcomes, and
- equity in access to safe and effective medical devices.

CDRH intends to gather feedback on these principles from the PEAC on their alignment with consumer preferences when considering the use of a medical device.

[52] For a complete listing of FDA guidance, please refer to the following website: https://www.fda.gov/regulatory-information/search-fda-guidance-documents
[53] FDA's draft guidance(s) are not for implementation. When final, those guidance(s) will represent FDA's current thinking on the topic thereof.
[54] See Footnote 53.

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Principle 1: Inclusivity

The importance of inclusion of diverse populations in clinical studies is rooted in both law and ethics. A major purpose of Section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations governing clinical studies is to protect the public by requiring safeguards for study participants and adherence to sound ethical standards. Ethical standards are outlined by the Belmont report[55], issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The report outlines three basic ethical principles of clinical research to guide researchers, regulators, and institutional review boards in protecting the rights, safety, and welfare of study participants: respect for persons, beneficence, and justice.

It is the principle of justice that calls for inclusivity. This speaks to fairness in distribution and whether the distribution of the benefits and burdens of the research or medical interventions are just.[56] Determining that a clinical study is fair and just requires scrutiny of many of its components with an eye to ensuring that populations of individuals are not systematically included because it is easy to include them or because of their vulnerability; and that populations of individuals are not excluded because of social or other factors unrelated to the study question.

Study components to consider when evaluating inclusivity include inclusion and exclusion criteria; recruitment, study design, and site selection practices; study retention techniques; participant incentives; and study closeout practices. The principle of inclusivity is relevant to all clinical studies, regardless of a researcher's intent to develop a device for commercialization, or whether or not the study is subject to prior FDA approval.

Principle 2: Data generalizability

The FDA's regulations establish that a finding of reasonable assurance of safety and effectiveness for marketing a device must be based on data that are relevant for the individuals who are intended to benefit from the device. When clinical data is necessary, the data needs to be generalizable to the intended user population. Data generalizability is a scientific question concerning the interpretability and applicability of study findings[57], whereas the general principle of inclusivity focuses on fairness and equitable access to the benefits of clinical research. Generalizing study data necessitates consideration of, and often inclusion of, individuals of

[55] https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
[56] See Footnote 55
[57] FDA's guidance "Evaluation and Reporting of Age, Race, and Ethnicity-specific Data in Medical Device Clinical Studies" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-and-reporting-age-race-and-ethnicity-specific-data-medical-device-clinical-studies)

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differing demographics, lived experiences, and clinically important characteristics (such as comorbidities) in clinical studies.

Scientific advances have highlighted the importance of understanding whether and to what extent individuals may respond differently to the benefits and risks of medical interventions.[58] Collecting and analyzing subgroup data in device studies is useful to achieving this understanding, and broader implementation of subgroup analyses in clinical studies is becoming increasingly critical for generating high-quality, high-impact evidence.

To assess the safety and effectiveness of some devices, it may be sufficient to ensure that a spectrum of the intended use population is represented in the study population and statistical analyses of the entire group overall. However, for other devices, it may be important to ensure that enough participants are enrolled in certain subgroups to provide scientifically sound evidence of the safety and effectiveness of the device in those subgroups, in addition to the study population overall. Many medical devices affect aspects of the human body known to be influenced by age, sex, race, ethnicity or other differences among patients.[59,60] Thus, these and other patient characteristics may significantly affect clinical outcomes.

Principle 3: Timely access

The FDA remains committed to providing timely access to beneficial medical devices and ensuring that marketed devices are reasonably safe and effective. Providing timely access to beneficial medical devices involves more than obtaining a marketing authorization from CDRH. It is also important to consider the impact of product labeling, and of the transparency of clinical results, particularly subgroup analyses. Access is also impacted by the extent to which the device was designed with inclusivity, and whether the device was evaluated in clinical studies with adequate representativeness and generalizability. Without transparency of clinical study enrollment and results, there may be uncertainty about the benefits of a device in certain populations, and thus to a reluctance to include a potentially beneficial device as a treatment option in those populations.

When intentional actions are taken to improve diversity in clinical studies, an evaluation can be made to determine how a diverse population of individuals responds to a medical technology intervention. By taking care to make sure individuals are not excluded because of social, environmental, or other factors unrelated to the study question, a determination can be made if

[58] See Footnote 51.
[59] See FDA's Guidance "Evaluation of Sex-Specific Data in Medical Device Clinical Studies" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-sex-specific-data-medical-device-clinical-studies-guidance-industry-and-food-and-drug)
[60] See Footnote 57.

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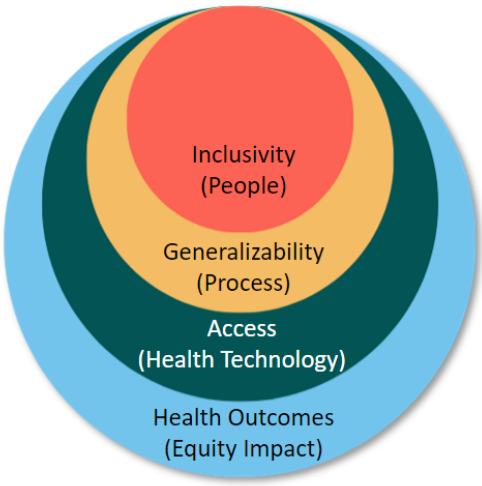
individuals with different lived experiences respond similarly or differently to the intervention. This not only expands medical knowledge but provides the opportunity to be aware of where unmet needs may exist to further drive innovation and reduce inequities. Furthermore, with greater knowledge of how a medical device intervention affects different populations, consumers can be better empowered to make decisions regarding their health and wellbeing, leading to improved health outcomes.

Figure 4. Illustration of the key principles, and how they support advancing health equity by increasing the exposure of beneficial devices to individuals that need them.



- Intentional actions that improve diversity in clinical research to meet the needs of individuals
- Expand medical knowledge of how individuals with different lived experiences respond to treatments and drive innovation for unmet needs
- Improve product acceptance and greater assurance in treatment decisions, expand availability of beneficial interventions
- Greater exposure to beneficial devices improves health outcomes

Challenges to Implementing Diverse, Inclusive Clinical Studies

Diversity, equity, and inclusion should be considered for any medical device clinical study. The FDA can and does provide guidance, support, and encouragement to industry to promote diversity and inclusion in clinical studies, but does not always require sponsors to take specific actions to enroll diverse populations. Medical devices must follow least burdensome principles[61] to eliminate unnecessary burdens that may delay the marketing of beneficial new products, while maintaining the requirements for authorization. In some cases, requiring a medical device study sponsor to enroll more diverse cohorts of patients may result in larger, longer studies, which could delay access to a new medical device.

For example, requiring that enough participants are enrolled to perform subgroup analysis as evidence of the safety and effectiveness of the device in those subgroups when it is not

[61] See FDA guidance "The Least Burdensome Provisions: Concept and Principles: Guidance for Industry and FDA Staff" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles)

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necessary to determine the safety and effectiveness for marketing a device would not follow least burdensome principles and may add additional time and cost to device development and lead to delay in a device coming to market.

Although FDA can encourage sponsors of IDEs to consider the principles of inclusivity, data generalizability, and timely access as part of clinical study design, there are limitations on disapproving an investigational device exemption (IDE) application if, among other reasons, "'[t]here is reason to believe that the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge gained.' In many cases, the Agency believes that effective risk management, including the application of risk controls, which includes risk mitigation measures, can result in a favorable IDE benefit-risk determination."[62] However, FDA can ensure that appropriate information is provided when considering a marketing application, such as intentional design, human factors and usability engineering design, and testing of the medical device. The important information to consider is to show that the medical device addresses the needs of the diverse populations for whom the device is intended.[63] For example, whether a software diagnostic device was developed using information from a diverse population or only a narrow subgroup.

The greatest opportunity for the FDA to engage with clinical study sponsors is through Pre-submissions and IDE applications.[64,65, 66] Pre-submissions offer companies an opportunity to receive input and recommendations from the FDA's review teams prior to a premarket submission, while IDEs allow an investigational device to be used in a clinical study to collect safety and effectiveness data. CDRH intends to maximize these engagement opportunities to broadly encourage inclusive trial cohorts.

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[62] See FDA's guidance "Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions: Guidance for Investigational Device Exemption Sponsors, Sponsor-Investigators and Food and Drug Administration Staff" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-when-making-benefit-risk-determinations-medical-device-investigational-device)

[63] See FDA's guidance "Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/leveraging-existing-clinical-data-extrapolation-pediatric-uses-medical-devices).

[64] See FDA's guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program: Guidance for Industry and Food and Drug Administration Staff" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-programhttps://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program)

[65] https://www.fda.gov/medical-devices/investigational-device-exemption-ide/ide-approval-process

[66] https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide

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Communicating about devices to diverse audiences

It is important that patients, caregivers, and consumers, including those in diverse populations, be well-informed when they make healthcare choices. CDRH recognizes that transparency and effective communication about medical devices can help overcome barriers to health equity.

Instead of requiring diverse populations to proactively engage the healthcare ecosystem, CDRH is striving to meet patients and caregivers where they are, and to cultivate communication products that can support positive health impacts. Part of that effort involves working to provide clear, accessible information in plain language that better informs people's decisions about their healthcare, quality of life, and wellness. CDRH is committed to getting input from diverse groups of patients to inform the development of culturally tailored communication materials.

As part of its strategic priorities for advancing health equity, CDRH has set a goal of demonstrating year after year improvement in measures of consumer understanding of our patient/caregiver communications across diverse demographic groups. These improvements will be measured from a 2023 baseline through December 31, 2025.[67] To achieve that goal CDRH is developing a plan that includes tactics and approaches to increase the transparency, clarity, inclusivity, accessibility, and reach of CDRH communications.

Communicating benefits and risks

One of the most important roles of effective communications about medical technologies is to enable consumers to understand the d benefits and risks to them of a particular medical technology, so they are empowered to make decisions in collaboration with healthcare providers about whether or not a device is appropriate for them.

The first step for CDRH in improving communications about device benefits and risks is to develop a better understanding of patient information needs and barriers to accessing information, and in particular how those needs and barriers may vary across diverse populations. CDRH has, for example, worked with consumers, patient organizations, and healthcare professional societies to understand and address common questions and concerns related to device recalls,[68].

In addition, CDRH is collaborating with organizations with existing trust relationships with diverse communities to increase understanding of the best ways to message and reach diverse

[67] See Footnote 1.
[68] https://www.fda.gov/medical-devices/safety-communications/faqs-philips-respironics-ventilator-bipap-machine-and-cpap-machine-recalls#fda

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audiences. The goal, in part, is to gain insights and increase the body of knowledge and partnership needed to develop culturally responsive, accessible communication materials that effectively reach diverse populations.

In 2022, CDRH undertook an effort to integrate social science methods into its communications, with a focus on consumer message testing to improve the effectiveness of these messages, as appropriate. One of the efforts currently underway is a risk communication study in response to the PEAC's 2021 recommendation that the FDA consider changes to the communication approach used for medical device recalls.[69] The study, which includes patient and caregiver focus groups and interviews, seeks to identify best practices and evidence-based approaches for communicating product recalls and optimal strategies for communicating recalls across different types of medical devices. Study participants are diverse in terms of their demographics and educational attainment, to ensure the study recommendations consider how to effectively communicate with all consumers. Additionally, CDRH has engaged consumer, caregiver, and healthcare professional panels to recruit and obtain feedback on communications from small samples of target audience members. CDRH has made message testing a more routine part of its communication processes, helping to ensure the information it provides is understandable and useful to the public.

This sort of message testing can highlight the ways in which individuals in different populations may respond differently to information about device benefits and risks and enable more effective communications about potential outcome differences among participants, so that patients and caregivers can be informed when making device-related medical decisions.

In many cases it may be difficult to meet patient needs across diverse populations with the same information about benefits and risks. For example, health literacy—the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions—may vary widely among consumers. In those cases, separate content targeted to specific populations might be more useful such as generation-sensitive messaging.

Applying health literacy principles advances health equity by making information clear, accessible, and more inclusive.[70] For example, in addition to developing culturally tailored messaging and testing materials with intended audiences, CDRH aims to consistently use humanizing person-first[71] and meaningful language, ensure digital content is accessible to

[69] See Summary Minutes from 2021 PEAC Meeting on Medical Device Recalls: https://www.fda.gov/media/155222/download
[70] https://www.ahrq.gov/sites/default/files/wysiwyg/health-literacy/dhhs-2008-issue-brief.pdf
[71] https://www.ungeneva.org/sites/default/files/2021-01/Disability-Inclusive-Language-Guidelines.pdf

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people who use assistive technology, and ensure consumer and patient content is increasingly available in the languages and channels used by intended audiences.

The need for increasingly targeted information will likely grow as medical devices themselves become increasingly tailored to address the differing health needs and characteristics of consumers. In addition, healthcare is advancing toward an era of personalized medicine that may do much for patients and caregivers in underserved and underrepresented populations. But even as benefit and risk information becomes correspondingly more targeted, it will remain important to find a balance between that targeting and maintaining the information's inclusivity.

Other types of communication

How devices are studied. It is critical that patients, caregivers and healthcare providers trust the information used to develop and evaluate medical devices. Consumers are more likely to have that trust if they know that a device has been studied in groups that are especially relevant to them. As discussed above, CDRH is placing increasing emphasis on ensuring that devices are studied across diverse populations. But it can also be important to communicate information about the extent to which a device has or has not been studied in different populations in ways that are understandable and useful to patients and caregivers.

To that end, CDRH is evaluating ways to provide consumers with concise information about who participated in key clinical trials of devices they may use. This information could describe how benefits and risks of the device varied among different demographic groups.

Labeling and instructions. Device labeling[72] often includes warnings, precautions, and contraindications whose complexity and technical language may confuse readers. This information is often important for scientific accuracy and clinical guidance. But the increasing availability and promise of medical devices aimed at home use will amplify the need for clear and simple labeling information. Labeling could provide information on usages and warnings that might prove critical to whether and how a patient safely uses a device.

The need to make labeling information clear to patients and caregivers across diverse populations adds to the challenge. Different groups may find different uses and warnings on labels more relevant and helpful, presenting a challenge in how to meet those differing needs without providing an overwhelming amount of information on the label.

[72] https://www.fda.gov/medical-devices/overview-device-regulation/device-labeling

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The same is true for device usage instructions and education. Use of a device outside of a healthcare setting may require additional training or instructions for a patient or caregiver.[73] Without clear instructions and educational materials written for a lay audience and useful across diverse populations, patients and lay caregivers may not be able to use the device safely and effectively. The FDA has already been actively engaged in outreach and education related to home use, and the agency will continue to expand this work.[74]

Safety concerns. Concerns about a home use device's safety may arise after the device has been placed into use. Providing home-care patients and caregivers with prompt, clear, understandable and highly accessible information about potential safety concerns with a device they are using, and steps to address those concerns, is critical. This information, too, must be appropriately tailored to diverse populations.

Language

In each of these cases, the language used to communicate information is critical to making the information understandable and useful to patients and caregivers. To help ensure that no person is excluded from healthcare, CDRH is committed to providing clear, accessible information in plain language that better informs people's decisions about healthcare, quality of life, and wellness.

As part of that commitment, CDRH is engaged in an ongoing effort to make content available in languages other than English. In 2022, CDRH audited its website to ensure consistent use of inclusive images and to identify additional high demand content for translation. CDRH began consistently posting both English and Spanish medical device safety communications and promoting other CDRH and agency content available in Spanish and plans to continue this practice.[75]

More is not always better when it comes to communicating clearly and effectively to a lay audience. An important element of providing patients and caregivers with the information they need to make important decisions about health and healthcare is to avoid overwhelming them with more information than they can comfortably and usefully digest. Offering too much information can obscure that subset of the information that is critical and relevant, and may

[73] See FDA's Guidance "Guidance on Medical Device Patient Labeling: Final Guidance for Industry and FDA Staff" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-medical-device-patient-labeling)
[74] https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/cdrh-seeks-public-comment-increasing-patient-access-home-use-medical-technologies
[75] For an example: https://www.fda.gov/medical-devices/safety-communications/2023-safety-communications

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discourage some individuals from taking on the task of reading through it, and perhaps from even using the device.

The form of media is another important consideration. In particular, people with disabilities may require the availability of various types of communications in specific types of media, such as braille, large print, or audio.

The need to provide information that is tailored to different populations may require longer, or multiple versions of, documents that address these populations' different concerns. In those cases it would be helpful to ensure that patients and caregivers are able to easily determine which sections or documents best apply to them, so they can omit other material without missing out on essential information.

Disseminating information

Improving the public availability of relevant and helpful information is one of the CDRH's overarching priorities. CDRH's efforts to employ communications in ways that advance health equity include disseminating information through the technologies and information sources people already use. Examples of such efforts include posting FAQs to FDA.gov, use of a dedicated and easily joined email distribution list targeting patients and caregivers, and the extensive use of social media.

Despite the overall widespread use of digital communications, the access to or use of online resources varies considerably among different audiences. Ensuring that diverse and especially underserved populations are reached requires taking into account the fact that many people lack digital literacy or internet access. The agency uses available metrics to determine the reach of many of its FDA.gov communications pages, as well as email and social media reach, but the metrics do not currently provide demographic data on users.

In the meantime, CDRH is exploring ways to bring needed, appropriately tailored information to patients and caregivers who may lack online access or digital literacy, or who otherwise are not engaging with CDRH online.

In Summary

The FDA's CDRH is committed to pursuing the elimination of health and healthcare disparities that currently exist across many dimensions. Those efforts must be active on multiple fronts, including supporting the development of devices that can improve healthcare access, ensuring devices are evaluated for safety and effectiveness in the diverse populations that will use them,

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and providing patients and consumers with the information they need to make decisions about their healthcare.

Home use devices present one important opportunity to advance health equity for underserved people who face difficulties in accessing healthcare-facility-based care. These devices are already helping many patients better monitor and manage both acute and chronic conditions, including diabetes and complications during and after pregnancy, outside of healthcare facilities. What's more, digital health technologies are broadening the reach of healthcare and wellness, for example through smartphone applications or other digital therapy platforms that help people monitor or improve a general state of mental health. The promise of home use devices needs to be balanced with awareness of the difficulties many people may have in operating them, their potential differences in performance compared to facility-based care, and potential disparities in the accessibility and affordability of these medical devices.

It is also critical to address a lack of diversity, equity, and inclusion in clinical research relating to medical devices. CDRH is developing a framework to guide researchers and manufacturers in determining when a device should be evaluated in diverse populations, with the goals of improving the generalizability of study data and ensuring that patients have timely access to beneficial medical devices and health technology. Although FDA can encourage sponsors of IDEs to consider the principles of inclusivity, data generalizability, and timely access as part of clinical study design, there are statutory limitations on disapproving an investigational device exemption (IDE) application. The growing availability of home use devices and monitoring tools may help enable more diverse trials, by making it easier and more convenient for patients to participate in trials.

Finally, CDRH is working to ensure that patients have access to clear, concise and accessible information in plain language to support their healthcare decisions, such as, whether a device is right for them, and their ability to effectively and safely use a device. To that end, the Center is committed to incorporating diverse patient input in support of developing culturally tailored and linguistically appropriate communication materials and improving the ability of consumers to find and access materials, online and elsewhere, about medical devices, taking into account disparities in both health and digital literacy.

These efforts to advance health equity present challenges and require ongoing research, investment, and collaboration among CDRH, industry, payors, providers, and patients. CDRH is committed to the efforts, so that all people in the United States can access the medical devices they need to protect and improve their health and well-being.

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