Attachment—Additional Questions for the Record

Subcommittee on Health
Hearing on
"Enhancing Public Health: Legislation to Protect Children and Families"
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The Honorable Frank Pallone, Jr. (D-NJ)

1. Many Americans who suffer from mitral valve prolapse (MVP) or other valvular heart diseases do not know they are at serious risk. Public health outreach and data are needed to address the gaps in understanding about what makes valvular heart disease life threatening. As discussed in your testimony, valvular heart disease affects approximately two percent of the general U.S. population. Many who have MVP, a specific degenerative heart valve condition, are not aware of their condition. In most of these cases, the condition is mild and harmless with ongoing monitoring. Yet, mitral valve prolapse elevates the risk for sudden cardiac arrest by threefold in the affected population and valvular heart disease generally accounts for 25,000 annual deaths.

    a. What does currently available research indicate regarding the role of health disparities in heart valve disease diagnosis and/or treatment?

    Valvular heart disease (VHD) is a degenerative condition characterized by improper heart valve functioning, either due to stenosis (narrowing of the heart valve) or regurgitation (leaky heart valve). Despite the fact that new and emerging technologies like transcatheter aortic valve implantation (TAVI) for aortic stenosis and transcatheter edge-to-edge repair (TEER) for mitral regurgitation (a frequent consequence of mitral valve prolapse) are now widely available in most major hospitals, there still exists a major gap regarding access to these procedures by patients from underrepresented racial and ethnic groups (UREG). UREGs (primarily Black and Hispanic individuals) receive fewer treatments for VHD, and national valve registry data indicate a lower rate of TAVI utilization among Black patients compared to white patients. Furthermore, Black patients and other UREGs are not adequately represented in major randomized clinical trials of TAVI and other procedures for VHD. Valvular heart conditions, poor socioeconomic status, bias within the health care system, lack of awareness about the benefits of treatment, and mistrust of health care professionals are all barriers that can contribute to treatment disparities among those from underrepresented racial and ethnic groups. Other factors contributing to health disparities in heart valve disease diagnosis and/or treatment include patients' and health care professionals' lack of understanding and awareness about VHD and its prevalence; thus, the time to diagnosis and treatment may be

delayed and lead to worse outcomes.

One way in which the American Heart Association is working to overcome these barriers is through the ***Target: Aortic Stenosis*** *initiative, a program designed to better identify and treat patients with aortic stenosis, which includes multi-media educational resources for patients and clinicians, and self-management care plans for people living with structural heart disease. Overall, racial and ethnic disparities in health care access and care delivery are a public health concern given the changing demographics of the U.S. population and they highlight the need for additional research into contributing factors and appropriate interventions to address the lower rates of valve procedures as well as the higher morbidity and mortality among UREGs.*

2. Given the context of the pandemic in which the healthcare system has been overburdened and many who have been infected by COVID-19 may experience lasting harm to cardiovascular health.

    a. How has the impact of COVID-19 on individual health and the healthcare system impacted heart valve disease diagnosis and treatment?

    The majority of the published literature regarding the impact of COVID-19 on VHD diagnosis and treatment has been related to aortic stenosis. The pandemic imposed an unprecedented burden on the provision of cardiac surgical services that has necessitated a reallocation of workforce and resources. This has been especially challenging in the current environment as clinicians have had to weigh the risk of bringing susceptible patients into the hospital environment during the COVID-19 pandemic against the risk of delaying a needed procedure. This in turn has created a large backlog of cases and worsening of disease with subsequent increases in risk and cost of treatment, and the potential for worse long-term outcomes. Several small, single center case reports have been published that have shown an increase in cardiac events and worse outcomes for patients who had their procedures delayed. Several centers have published algorithms and decision pathways to help guide clinicians as they triage and prioritize VHD procedures in the current COVID-19 era. These and other tools can provide a framework for clinicians regarding when it may be appropriate to proceed with intervention despite the ongoing pandemic. As the pandemic continues, it will be important follow both short- and long-term outcomes for patients with significant VHD needing valve interventions.

3. H.R. 1193, The CAROL Act, includes an awareness campaign from the Centers for Disease Control and Prevention (CDC). How would the American Heart Association, for example, partner with the CDC on dissemination of awareness outreach to communities and what recommendations would you have to ensure success?

    Regarding the types of projects allowed under Section 3 of the bill, the American Heart Association and other patient groups could implement various outreach

and awareness campaigns. These could include social media messages using patients and providers as messengers, targeting at-risk communities, about the signs and symptoms of heart valve disease; or hosting a convening of patients and providers to share knowledge and to develop better training tools for clinicians so they understand how patients present with heart valve disease and to raise awareness about how to diagnose valve disease sooner and more accurately (something we know many providers struggle with); or patient groups could develop an awareness resource tool in partnership with an organization that reaches a target population and disseminate through that organization. In all cases, the patient group (or other type of grantee) would have to demonstrate an ability to reach target audiences, have the experience to be able to create impactful and accurate messages, and have the capacity to measure and evaluate the results. All of these efforts could be carried out in partnership with the CDC, as part of a coordinated campaign, or as independent projects funded by CDC grants.

4. Despite the overwhelming evidence that patients benefit from cardiac rehab services—we know that there are significant inequities in who receives this care.

    a. Dr. Lloyd-Jones, could you speak to some of the disparities that exist with respect to access to cardiac rehab services and how this legislation would help?

    Despite the clear benefits of cardiac rehab, participation by a significant proportion of patients who suffer from cardiovascular diseases is severely lacking. Only one-third of patients eligible for cardiac rehab will ever receive it. Among Medicare beneficiaries, participation is even lower—only 1 out of every 4 Medicare patients eligible for cardiac rehab ever receivers these services, and an even lower proportion completes a full course of cardiac rehab, which is typically 32 sessions over approximately 10 weeks. There are also major geographic disparities in participation, with participation being 30 percent lower for individuals who live outside of metropolitan areas, and 42 percent lower for those who live in poor urban communities.

    One of the issues preventing increased participation in cardiac rehab is that many patients are simply not being referred by their clinicians. Sometimes when patients are discharged following an adverse cardiac event, they face long referral wait times, which have been shown to reduce enrollment in cardiac rehab programs. For every extra day a person must wait to begin cardiac rehab, that person is increasingly less likely to enroll.

    The elderly, women, people of color, those living in rural areas, and patients with lower socioeconomic position are all less likely to be referred to cardiac rehab. Unfortunately, they also are less likely to take that first critical step to enroll after referral. This is of great concern because women and people of color are far more likely to die within five years after a first heart attack than their white male patient counterparts. According to one analysis, 7 percent of the Black versus

white all-cause mortality gap could potentially be reduced by equitable cardiac rehab referral.

Medicare currently has a "direct supervision" requirement for cardiac rehab programs, which means a physician must be immediately available and accessible at all times when services are being furnished under these programs. Congress previously acknowledged that Medicare imposes a more stringent requirement for direct physician supervision than should be required. With the passage of the Bipartisan Budget Act in 2018, Congress authorized PAs, nurse practitioners, and clinical nurse specialists—referred to collectively as advanced practice providers (APPs)—to begin supervising patients' day-to-day cardiac and pulmonary rehabilitation care beginning in 2024. While we applaud this progress, patients cannot wait until 2024 for these changes to take place.

For too long, these requirements have made it a challenge for cardiac and pulmonary rehab programs to operate in areas where physicians are scarce, imposing unnecessary costs in both underserved rural and urban areas, while limiting patient access. This legislation would allow advanced practice providers to begin supervising patients' day-to-day cardiac and pulmonary rehab care beginning in 2022 instead of 2024. The bill also goes a step further and would authorize advanced practice providers to order cardiac rehab for patients—a change that would facilitate faster referral of patients and help close the referral gap and ultimately address disparities with participation.

5. As you've mentioned Medicare currently has a direct physician supervision requirement for cardiac rehab programs—meaning that other qualified providers like physician assistants, nurse practitioners, and clinical nurse specialists are limited in their ability to deliver these services to patients.

    a. Dr. Lloyd-Jones, as a practicing cardiologist why do you believe these non-physician providers are qualified to supervise and order these services? In your personal experience have you seen the current supervision requirements delay access to care?

    Advanced practice providers (APPs) are routinely on the front line in critical care environments, such as hospitals and hospital clinics, emergency rooms, and intensive care units, and they collaborate closely with physicians as part of a patient's care team. They are highly trained providers who are more than qualified to order and supervise cardiac rehabilitation services. APPs are fully trained in the skills needed to monitor patients during supervised exercise in cardiac rehab, and fully trained to call 911 and respond rapidly in cases of emergency, including administration of life support and CPR in the rare cases it is needed.

    I have had the distinct pleasure to supervise and collaborate with dozens of APPs throughout my career a a cardiologist at Massachusetts General Hospital and

Northwestern Memorial Hospital.. To a person, they have been extraordinarily knowledgeable, professional, and dedicated to their field, and to the patients for whom they care. They have all been extremely diligent in maintaining their clinical knowledge and their skills (including emergency resuscitation skills) in delivery of cardiovascular care in acute and chronic care settings.

In my personal experience, I have not seen current supervision requirements for cardiac rehabilitation directly delay access to care. However, I have had the good fortune to practice in highly-resourced academic medical centers; the situation in under-resourced rural and urban settings is clearly different.

6. Heart disease remains the number one killer of men and women in America. According to the CDC about 805,000 Americans experience a heart attack each year, and approximately 200,000 happen to people who've already had a heart attack. Dr. Lloyd-Jones you discuss in your testimony that cardiac rehab is highly recommended for patients who have experienced serious cardiac events like heart attacks. However, we know that only 1 in 4 Medicare beneficiaries eligible for cardiac rehab receives these services.

    a. Dr. Lloyd-Jones, what are some of the primary barriers to accessing cardiac rehab care for patients, particularly Medicare patients?

    Barriers to accessing cardiac rehab include inconsistency in referral patterns, including a lack of referral to participate from the patient's physician, and the absence of a system in hospitals that automatically refers eligible patients. Limited follow-up or facilitation of enrollment after referral is also a barrier. For every extra day a person must wait to begin cardiac rehab following referral, that person is increasingly less likely to enroll.

    Among patients who are referred to cardiac rehab, but do not enroll in a program, some do not understand the important benefits of cardiac rehab to their immediate and long-term health. Others may wish to enroll, but face practical or logistical challenges such as lack of transportation, work or home responsibility conflicts, or programs that have inconvenient hours of operation (potentially due to physician supervision requirements).

    The distance of a cardiac rehab facility from a patient's home is certainly a limiting factor, and participation is 30 percent lower for individuals who live outside of metropolitan areas. Overall scarcity of programs in rural areas and low-income communities are significant barriers to accessing cardiac rehab.

    Finally, the cost of cardiac rehab is also an enrollment deterrent for some patients. Although Medicare and most private insurers cover cardiac rehab for eligible individuals, patients typically face out-of-pocket costs, including deductibles or copayments. In Medicare, patients typically pay a 20% copayment

for each session, which on average would require $828 in copays for a full course of 36 sessions. Overall, individuals with lower incomes are significantly less likely to participate in cardiac rehab.

b. What does the evidence say about the outcomes of patients who receive cardiac rehabilitation services versus those who do not?

For patients who participate in cardiac rehabilitation services, cardiac rehab offers a multifaceted and highly tailored approach to optimize a patient's overall physical, mental, and social functioning. While cardiac rehabilitation does not change a patient's past, it can help improve their heart's future. Evidence shows that cardiac rehab programs can benefit numerous types of patients, including those who have had a heart attack, have stable angina, have received a stent or angioplasty, have heart failure with reduced ejection fraction, or have undergone coronary bypass surgery, heart valve surgery, or heart or heart-lung transplant surgery.

Beyond helping individuals recover from a cardiovascular event and make the necessary lifestyle changes to reduce the chances of further heart problems, compared to those who do not participate, participation in cardiac rehab has been shown to significantly reduce the risks of death from any cause, including cardiac causes and sudden cardiac death, as well as result in decreased hospital readmissions. As a clinician, I am an avid user of cardiac rehab services for all of my qualifying patients, and in addition to its proven benefits for health outcomes, I can also attest to its less tangible benefits. My patients who have participated in cardiac rehab routinely tell me that it teaches them what symptoms they need to pay attention to, and, crucially, it restores their sense of well-being and their ability to trust their body as they return to normal life and activities.

7. We know that the pandemic has disrupted access to essential health care services in many ways—and you mention in your testimony that 71 percent of in-center cardiac rehab programs closed temporarily during the pandemic.

    a. What has been the impact of the pandemic on access to cardiac rehab care and how have cardiac rehab providers adapted to continue providing these critical services?

    At the onset of the pandemic, patient access was severely reduced while many cardiac rehab programs temporarily closed. In many instances, cardiac rehab program staff were moved from programs to address increased hospital needs (e.g., COVID/other acute care needs). When programs across the country reopened, many patients faced multi-month-long waiting lists for cardiac rehab services due to reduced capacity and staffing levels. At some programs to this day, program capacity is still limited. In other places programs have closed altogether as result of financial difficulties.

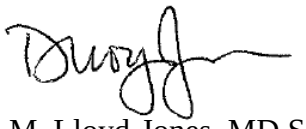
Other programs have successfully utilized virtual delivery options, allowing patients to continue to receive the benefits of cardiac rehab. However, a significant number of programs have not utilized virtual delivery options. According to recent survey by the American Association of Cardiovascular and Pulmonary Rehabilitation, 34% of surveyed programs are delivering care virtually, and up to 77% of programs who responded indicated their programs would continue or expand to include virtual delivery if it was a permanent option for Medicare beneficiaries.

The pandemic has further illuminated the benefit of virtual delivery options that integrate technology to improve and enable care delivery, including home based cardiac rehab and, and hybrid cardiac rehab models that utilize both home and center-based care. In instances where virtual delivery was an option, patients had the ability to realize the benefits of cardiac rehab where they otherwise wouldn't have been able to.

The American Heart Association supports alternative models to traditional center-based cardiac rehab programs, including home-based and "virtual" cardiac rehabilitation.

Thank you for the opportunity to clarify and expand on my testimony.

Respectfully submitted,



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