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Subject: Comments on the draft of the Tokyo Metropolitan Government Cardiovascular Disease Countermeasures Promotion Plan

To: Emergency and Disaster Medical Care Section, Tokyo Metropolitan Government Bureau of Social Welfare and Public Health

June 15, 2021

American Medical Device and IVD Manufacturers Association (AMDD)

The AMDD would like to thank you for your continued efforts to promote the health of the people of Tokyo. We would like to express our opinions on the draft of the Tokyo Metropolitan Government's Cardiovascular Disease Countermeasures Promotion Plan.

Organization Name: General Incorporated Association, AMDD

Address: 1-5-2 Higashi-Shinbashi, Minato-ku, Tokyo

Type of Business: Mainly U.S.-based medical devices and in vitro diagnostics business organization

Opinions and suggestions:

Chapter 1 What is the Tokyo Metropolitan Government Cardiovascular Disease Control Promotion Plan? (p.1)

"Stroke, heart disease, and other cardiovascular diseases (hereinafter referred to as "CVDs") (hereinafter referred to as "stroke, heart disease, and other circulatory organ diseases")

Opinion 1:

The national basic plan states that "Stroke, heart disease and other cardiovascular diseases (hereinafter referred to as "CVDs") are the leading cause of death in Japan. CVDs include many diseases such as ischemic stroke (cerebral infarction), hemorrhagic stroke (intracerebral hemorrhage, subarachnoid hemorrhage, etc.), transient ischemic attack, ischemic heart disease (angina pectoris, myocardial infarction, etc.), heart failure, arrhythmia, valvular disease (aortic stenosis, mitral regurgitation, etc.), aortic disease (aortic dissection, aortic aneurysm, etc.), peripheral vascular disease, pulmonary thromboembolism, pulmonary hypertension, congenital heart and cerebrovascular diseases, and genetic diseases.

We hope that the Tokyo Metropolitan Government's plan will include specific mention of



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"CVDs" in the same way as the national plan.

Reason for Opinion 1:

Diseases that cause stroke and heart failure include congenital and age-related diseases that are not solely caused by lifestyle, and countermeasures against them require not only lifestyle improvement, but also early detection, cooperation among medical institutions, intervention at the right time, and postoperative rehabilitation.

Chapter 3: Direction of Cardiovascular Disease Countermeasures Aimed at Realizing "Future Medical Care in Tokyo: A Grand Design" "Issue 1: Support for Patients and Families and Promotion of Medical Cooperation" (p. 26)

Opinion 2:

Regarding the statement "In addition to promoting collaboration and information sharing among medical institutions in Tokyo through the Tokyo Comprehensive Medical Network", we believe that it should be clearly stated that efforts should be made to develop a system and an environment for building evidence using real-world data so that data can be smoothly linked to the National Cardiovascular Center. In addition, we believe that a regional cohort should be built that can be tracked at least among various hospitals in the Tokyo metropolitan area to link treatment results to anonymous individuals.

Reason for Opinion 2:

Although there are several national databases such as NDB, DPC, NCD, etc., it has been pointed out in the discussion of the Council that utilization and research and development of medical data in the field of cardiovascular disease are difficult due to differences in data formats and management organizations, as well as limitations in use. The national basic plan proposes to establish a public framework to collect and utilize medical information on cardiovascular diseases in cooperation with medical institutions such as the National Cerebral and Cardiovascular Center and other related academic societies and to further discuss the operation and provision of the collected medical information, including secondary use and cost-sharing, in the field of cardiovascular diseases. As stated in the basic plan, to promote the collection and utilization of medical information, it is necessary to establish not only "collaboration" but also a system to ensure that data from all medical institutions are collected at the National Cerebral and Cardiovascular Center. It is also necessary to establish an environment for



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building evidence that is based on real-world data. These should be explicitly stated.

Chapter 3: Direction of Cardiovascular Disease Countermeasures Aimed at Realization of "Future Medical Care in Tokyo - Grand Design" "Issue 1) Dissemination of prevention and health checkups for cardiovascular diseases, and dissemination and enlightenment of knowledge" (p. 31)

Opinion 3:

In addition to "improving the implementation rate of the specified health checkups and specified health guidance," the current health checkup items should be reviewed (e.g., mandatory ECG testing, measurement of BNP or NT-proBNP for diagnosis of heart failure¹, heart auscultation for diagnosis of valvular disease). Moreover, the importance of early diagnosis and appropriately timed therapeutic intervention to stop heart failure from becoming serious should be mentioned. Prevention of severe disease through early diagnosis and therapeutic intervention will lead to improvement in the QOL of patients and their families, extension of healthy life expectancy, and optimization of medical costs and activities to verify them should be promoted in parallel.

On the other hand, there are some cardiovascular diseases, such as atrial fibrillation, which are not enough to detect through medical examinations and health checks, and in such cases, In such cases, monitoring during daily life is expected to improve the detection rate. The Tokyo Metropolitan Government should encourage the introduction and active use of digital technology to the people of Tokyo.

Reason for Opinion 3:

As shown in Chapter 2, "Total Number of Heart Failure Patients in Tokyo," the number of heart failure patients alone continues to increase. The definition of heart failure was established in March 2021 by the three societies of Japan, the U.S., and Europe²). Heart failure is classified into four stages ("A Heart Failure Risk," "B Pre-Heart Failure," "C Heart Failure," and "D Advanced Heart Failure")^{1), 2)} and appropriate measures must be taken according to each stage. It is important to note that heart failure is typically the culmination of all heart diseases (as once it becomes chronic, it cannot be reversed) and, therefore, it needs to be stopped at an earlier stage.

The AMDD can provide a variety of medical technologies and information to protect the health of Tokyo residents.

- Innovative remote monitoring using digital technology (e.g., smartphone-enabled implantable ECG recorders, pacemakers that detect heart failure one month before an



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exacerbation)

- Treatment support technology to promote lifestyle and behavior change (e.g., nicotine addiction treatment and hypertension treatment apps, atrial fibrillation research using wearable devices) => Contribution to stroke prevention
- Technology to treat diseases causing heart failure (e.g., myocardial ablation for arrhythmia, transcatheter aortic valve implantation for valvular disease, stenting for ischemic heart disease)

Chapter 3: Direction of Cardiovascular Disease Countermeasures Aimed at Realization of "Future Medical Care in Tokyo - Grand Design" "Issue 1) Dissemination of prevention and health checkups for cardiovascular diseases, and dissemination and enlightenment of knowledge" (p. 31)

Opinion 4:

We would like to see the following statement: "The Tokyo Metropolitan Government plans to educate and enlighten the public about medical technologies that are useful for disease prevention and treatment, and to realize this plan through initiatives based on partnerships between the public and private sectors.

Reason for Opinion 4:

For example, in the case of stroke, it is very difficult for the person himself/herself to notice the onset of the disease or to call an ambulance, and awareness and response by family members and others around the person to understand FAST play a major role in improving the survival rate. In addition, valvular disease, an age-related disorder of the heart valves, is often overlooked because the symptoms are similar to the changes in the body associated with aging. As in these cases, it is important for family members to be aware of the changes in the person's behavior and the behavioral restrictions that they unconsciously impose on themselves. In other words, in the case of stroke and cardiovascular diseases, it is important to share appropriate information on disease prevention and treatment techniques not only to patients but also to their families. Understanding treatment options will improve patient adherence and promote understanding of innovation.

We believe that improved adherence will lead to a virtuous cycle of treatment and, in turn, to the accumulation of appropriate data. In addition, in order to promote understanding of innovation, it may be possible for local governments to procure their own funds, such as social impact bonds, and for



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medical device and pharmaceutical industry organizations to undertake and implement these projects as public projects.

< Occurrence and Prevention of Cardiovascular Diseases > (p. 32)

Opinion 5:

As mentioned in Opinion 1, prevention of lifestyle-related diseases is very important; however, it is also necessary to address each of the other diseases that cause heart failure and stroke. Therefore, we believe that the following paragraphs of "(1) Prevention of cardiovascular diseases and dissemination and enlightenment of correct knowledge (p.12)" of the National Basic Plan should be cited here.

In addition, there are other CVDs that, if not properly treated, are likely to adversely affect their prognosis. For example, atrial fibrillation can affect the onset and progression of stroke and heart failure. Peripheral arterial disease of the lower extremities can also lead to amputation of the lower extremities if treatment is delayed, leading to a worse prognosis. Valvular diseases such as aortic stenosis and mitral regurgitation are often unnoticeable in their early stages, while delayed treatment tends to have a worse prognosis. Aortic aneurysms can lead to sudden death if they rupture and need to be treated before they rupture, but symptoms may not be recognized. Appropriate diagnosis, treatment, and prevention of serious illness are necessary for other cardiovascular diseases, including cardiomyopathy and genetic diseases.

Reason of Opinion 5:

Same as Opinion 1.

List of Indicators in the Tokyo Metropolitan Government's Cardiovascular Disease Control Promotion Plan" (p. 41)

Opinion 6:

We believe that target values should be stated as numerical targets. We also strongly request that the current status and target values (numerical values) for the "age-adjusted mortality rate due to



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heart failure (per 100,000 population)" be added.

Reason of Opinion 6:

Heart failure is the most important disease (condition) that needs to be addressed in Tokyo, and we believe that it can be reduced by stopping the disease in its early stages so that the people of Tokyo can enjoy a healthier life.

A large amount of money is invested in the admission and discharge of patients with heart failure, and we believe that dealing with this problem will reduce the financial burden on the people of Tokyo and the Tokyo Metropolitan Government.

Reference:

- 1) Guidebook on heart failure for local family physicians and multidisciplinary professionals" (Ministry of Health, Labor and Welfare, Grant-in-Aid for Scientific Research on Cardiovascular Diseases, Diabetes and Other Lifestyle-related Diseases)
- 2) Medical Tribune, "Three societies in Japan, U.S., Europe, and U.S. give new international definition to heart failure" (last visited June 10, 2021), <https://medical-tribune.co.jp/news/2021/0318535695/>

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