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Trends in Reported Adverse Events for Automated External Defibrillators (AEDs)

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Abstract - Medical industry shifted focus on COVID-19, leading to many medical companies and professionals overlooking other more common medical ailments and equipment. Heart conditions are common in the United States and can be deadly, especially if individuals are in public and away from life saving equipment and doctors. An AED's purpose is to be able to restart the heart of an individual whose heart stopped beating by a medical professional or bystander. However, due to COVID, researchers became concerned if the rise in AED failures was significant or a coincidence. Using the t-test ($p<0.05$), the data showed that AED failures between 2013 and 2023 had a significant rise in occurrences.

***Keywords*:** COVID-19, AED devices, medical equipment, medical equipment failure analysis

1. Introduction

Since 2019, the medical industry has been struggling with the retention of medical personnel and providing sufficient medical care. Due to the Coronavirus Disease 2019 (COVID-19) pandemic, there was a decline in in-person cardiovascular care [1]. Cardiovascular procedures were postponed or cancelled in order to prioritise the care of patients who were diagnosed with COVID-19 and limit the risk of contamination at hospitals [2]. For example, in the Duke University Health System, in the first 15 weeks of the COVID-19 pandemic, there was a 33.1% decrease in the number of cardiovascular visits [3]. Along with that, 53% of cardiovascular visits were cancelled in 2020, compared with 35% cancelled visits in 2019 [3]. The purpose of this research is to investigate trends in reported adverse events for automated external defibrillators (AEDs) and determine whether the COVID-19 pandemic was associated with significant changes in reported adverse events for AEDs.

AEDs are devices that use external electrodes to detect any abnormal heartbeats a patient may have, and deliver an automatic shock to the patient. AEDs were developed as the result of the American Heart Association's Public Access Defibrillation initiative. The goal of this initiative was to place AEDs in common locations so that any person, regardless of training, could defibrillate victims of cardiac arrest [4]. As seen in Figure 1, an AED is being placed in a public area for community use, in case a person is suspected of developing cardiac arrest.

Figure 1: An AED is placed in a public park (Tomaszów Mazowiecki, Creative Commons CC0 1.0 Universal Public Domain)

AEDs play a critical role in providing emergency cardiac care; the speed at which a defibrillator shock is delivered is a key factor in its success, as the survival rate decreases by 10-12% per minute of delay in defibrillation [5]. These devices are located in multiple familiar places, such as schools, parks, and workplaces. Investigating adverse events in these devices involves researching the negative side effects of using AEDs, such as malfunctions, injuries, and deaths. If an AED malfunctions, this can lead to burns from the electrical shock, delayed heart treatment, unnecessary shocks, and skin irritation from the electrodes that attach to the patient's chest [6]. Understanding these malfunctions and why they happen can help improve production of these defibrillators so that adverse events do not happen again.

2. Methods

The Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database lists all reported adverse events, including malfunctions, injuries, and deaths, associated with all FDA-approved medical devices in the United States [7]. Device manufacturers, importers, and device user facilities such as hospitals are mandated to report adverse events to MAUDE. Healthcare professionals, patients, and consumers may also voluntarily report adverse events to MAUDE. Using data from the MAUDE database, we analysed monthly reported adverse events from 2013 to 2023 for two AED product classes: the NSA product class and the MKJ product class.

NSA and MKJ are three-letter product codes assigned by the FDA to distinguish between AED product categories [8]. There are multiple differences between NSA products and MKJ products. NSA products are over-the-counter AEDs, meaning that these products can be sold and used without a prescription [9]. These devices use external pad-type electrodes to sense, detect, classify and treat (with an electrical shock) ventricular fibrillation. They are intended to be used on suspected victims of sudden cardiac arrest, when a person is unresponsive and is not breathing normally. NSA products are intended to be used in public places. The device is to be used on adults and children who are either above eight years old or above 55 pounds. MKJ products, on the other hand, are non-wearable and require a prescription to use [10]. However, similar to NSA products, MKJ products have external pad-type electrodes and are meant to be used on suspected victims of cardiac arrest.

The analysed data includes monthly reported malfunctions for 2013-2023 attributed to AEDs through the FDA MAUDE database. Statistical significance was determined using a student t-test to determine the degree of overlap between two sets of data. A p-value of 0.05 was set as the cutoff for statistical significance. For each of the adverse event datasets attributed to the NSA and MKJ product codes, we used the t-test to compare the number of monthly reported malfunctions from year to year.

3. Results

According to the FDA MAUDE database, for the NSA product class, we found that there was wide fluctuation in the number of reported adverse events, as shown in Figures 2 and 3. We found that in 2013, there were 107 total malfunctions, and in 2014, the number of malfunctions increased by 70 to make a total of 177 total malfunctions. However, in 2015, the number of total malfunctions decreased substantially to 60 total malfunctions. In 2016, the number of total malfunctions once again declined to 42. In 2017, the number of total malfunctions increased to 56. Then, from 2018-2022, the number of total malfunctions declined from 71 to 22. In 2023, the number of total malfunctions increased from 22 to 53.

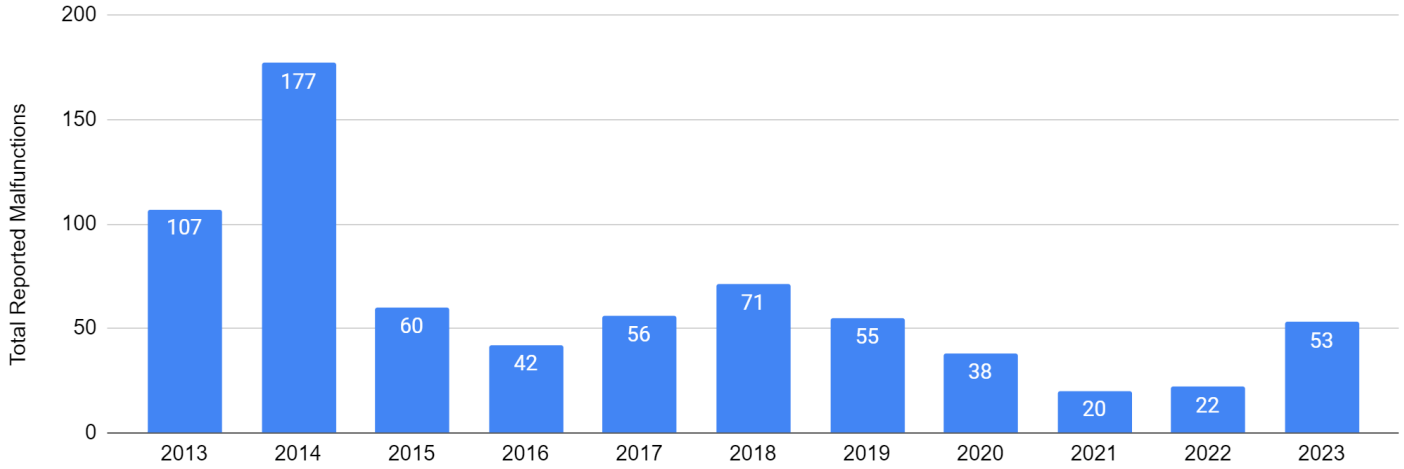

Figure 2: Data showing the number of malfunctions attributed to the NSA product class from 2013-2023.

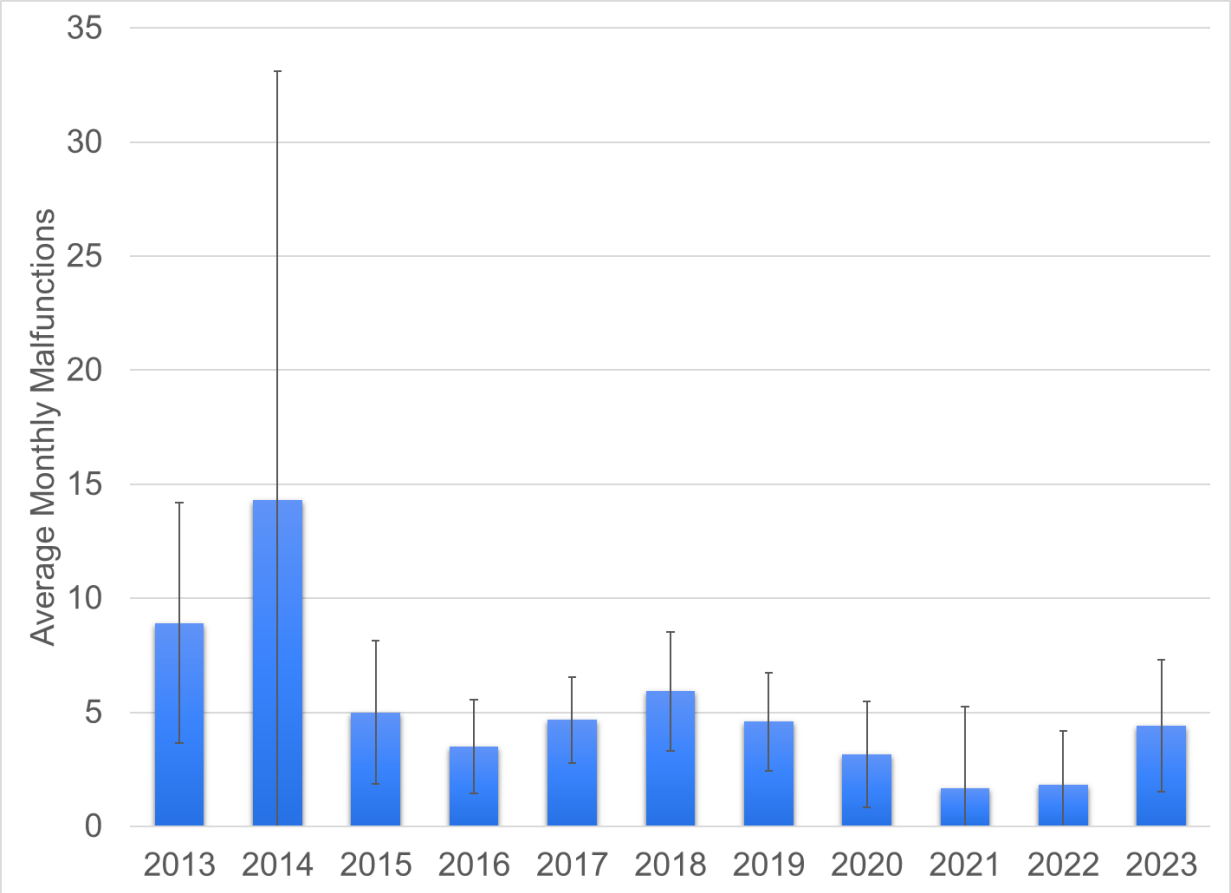

Figure 3: Data showing the average monthly malfunctions attributed to the NSA product class from 2013-2023. Error bars represent standard deviation.

The results for the MKJ products were largely different from the NSA products, as shown in Figures 4 and 5. According to the FDA MAUDE database, for each month, with a few outliers, there were over 1000 reported malfunctions. In 2013, there were a total of 13393 malfunctions. In 2014, the number of malfunctions increased to 15086. The number of malfunctions then continuously increased to reach a peak of 16861 in 2016. After that, the number of malfunctions decreased to 16326 in 2018, before increasing to 16350 in 2019. From 2020-2023, the number of malfunctions decreased sharply from 15602 malfunctions to 10337 malfunctions.

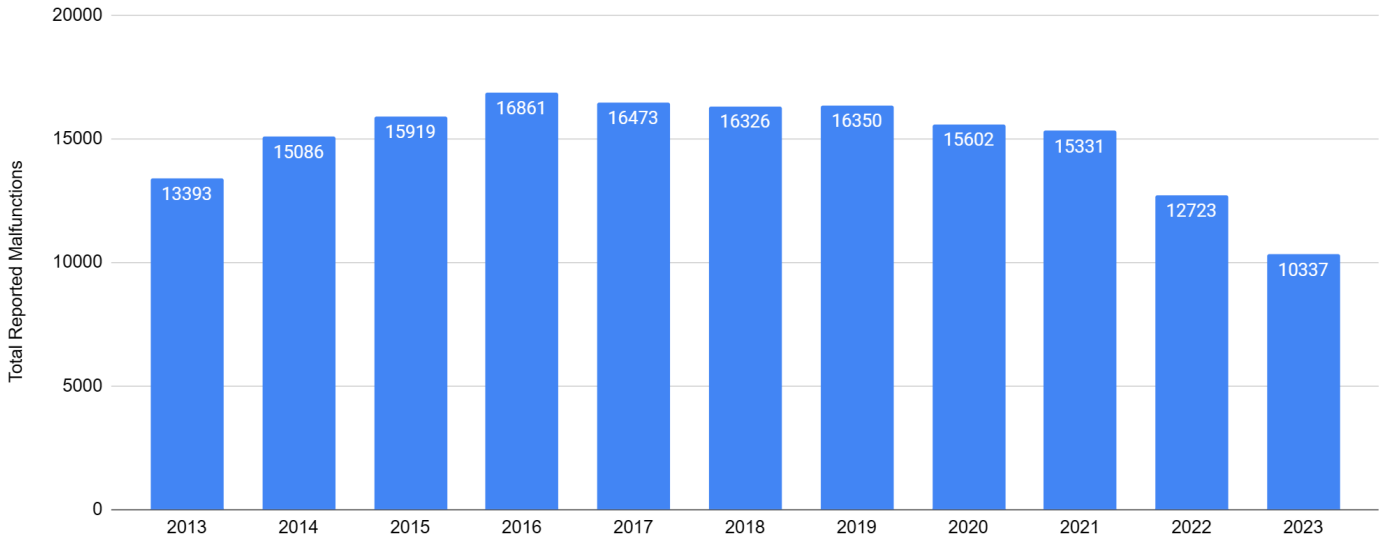

Figure 4: Data showing the annual number of malfunctions attributed to the MKJ product class from 2013-2023

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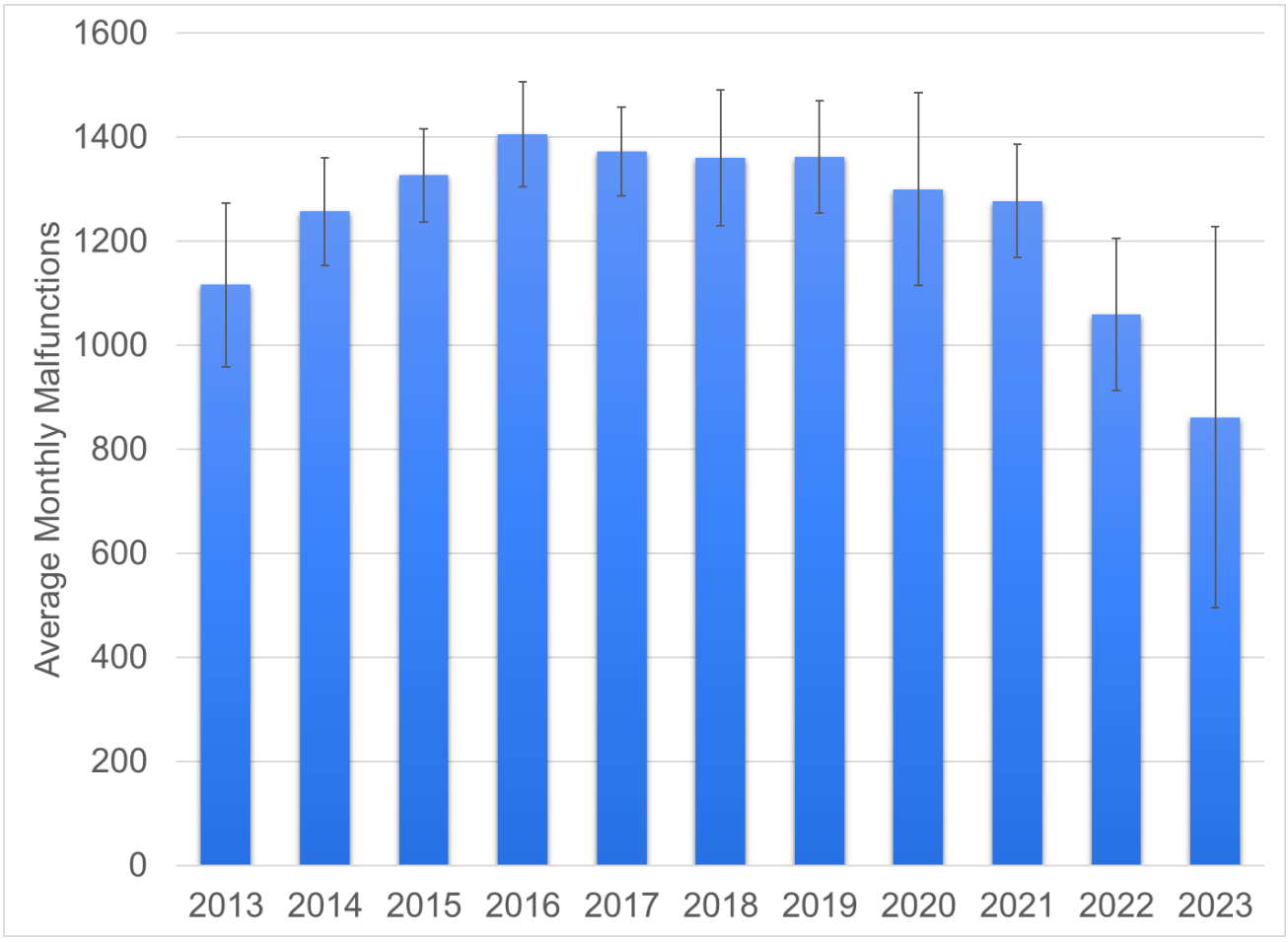

Figure 5: Data showing the average monthly malfunctions attributed to the MKJ product class from 2013-2023. Error bars represent standard deviation.

As previously mentioned, after collecting the data, we used t-tests to determine whether these fluctuations in the data over time were significant or not. For the NSAs, when we ran the t-test comparing monthly malfunctions in 2013 to 2014, there was a p value of 0.33, which is greater than 0.05, meaning that we cannot reject the null hypothesis, and the change in malfunctions from 2013 to 2014 was not significant. When we compared the monthly malfunctions in 2013 to 2015, the p value was 0.09, which is greater than 0.05, meaning that the change in malfunctions was not significant. When we compared the monthly malfunctions in 2016 and 2017 to 2013, both p values were less than 0.05, meaning that the change in malfunctions from 2013 to 2016 and 2017 were significant. However, the change in malfunctions from 2013 to 2018 was not significant, since the p value was significant. The change in malfunctions from 2013 to 2019-2023 were significant since the p value when comparing the monthly malfunctions from 2013 to 2019-2023 was less than 0.05. For the MKJ products, when we compared the monthly malfunctions in 2013 to 2014-2021, the p value was less than 0.05, so the change in malfunctions from 2013 to 2014-2021 was significant. However, the change in monthly malfunctions from 2013 to 2022-2023 was not significant, since both p values were less than 0.05.

4. Discussion

In summary, the FDA MAUDE data reveal that reported malfunctions for over-the-counter AEDs (product class NSA) declined from 2013 to 2023, whereas reported malfunctions for prescription AEDs (product class MKJ) increased from 2013 to 2021, and then declined again in 2022 and 2023. There are multiple factors that could result in reported adverse events for AEDs. One factor could be that individuals using over-the-counter AEDs have varying levels of experience, leading to possible incorrect use. Since AEDs are found in all commonplaces, this means that any person can use them, regardless of whether or not that individual is a medical professional [11]. Individuals in the community who are using AEDs may not have been trained on proper usage of the device. This could lead to the defibrillator being used incorrectly, as well as device wear-and-tear, thus leading to the defibrillator malfunctioning. The observed decline in reported malfunctions for AEDs could therefore represent improved training and experience with AEDs among members of the public. Another factor that could result in adverse events is the defibrillators may be producing the incorrect type of shock needed to treat cardiac arrest. This means that the defibrillator could either deliver a shock that is too weak to get the heart beating again, or deliver a shock that is too powerful, which can ultimately lead to death. The observed decline in reported malfunctions for AEDs could represent design improvements by manufacturers to prevent errors in defibrillation. Lastly, a major factor that most likely influenced these changes is the COVID-19 virus. Because of COVID-19, hospitals prioritised caring for people who had the COVID-19 virus over people with cardiovascular disease. Studies show that the number of cardiovascular deaths increased after the onset of the pandemic in 2020 [12]. Medical professionals likely focused on COVID-19 over other less immediate diseases due to the severity and uncertainty of the virus. The observed decline for reported malfunctions for AEDs in 2022 and 2023 could thus represent overall improvements in cardiovascular care in the post-pandemic era.

Across 2013-2023, the MKJ product class of AEDs had substantially more reported malfunctions than the NSA product class. This difference could be the result of different usage patterns, design differences, or underlying patient health. The number of AED malfunctions could be minimised by ensuring that there are instructions and training with each AED, so that there is a lower risk of human error. Regulatory oversight of manufacturing and testing of AEDs is also necessary to prevent malfunctions. The facilitators of all AED locations should perform regular checks to ensure the equipment functionality. As the COVID-19 pandemic has ended and individuals are finding a new normal, it is critical for medical professionals and community members to become more aware of available medical devices in public to ensure device safety and to help save lives.

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References

[1] Monsuez J. J. (2020). Cardiology practice in the COVID-19 era. European journal of preventive cardiology, 27(11), 1133–1135. https://doi.org/10.1177/2047487320929780

[2] Kiss, P., Carcel, C., Hockham, C., & Peters, S. A. E. (2021). The impact of the COVID-19 pandemic on the care and management of patients with acute cardiovascular disease: a systematic review. European heart journal. Quality of care & clinical outcomes, 7(1), 18–27. https://doi.org/10.1093/ehjqcco/qcaa084

[3] Wosik, J., Clowse, M. E. B., Overton, R., Adagarla, B., Economou-Zavlanos, N., Cavalier, J., Henao, R., Piccini, J. P., Thomas, L., Pencina, M. J., & Pagidipati, N. J. (2021). Impact of the COVID-19 pandemic on patterns of outpatient cardiovascular care. American heart journal, 231, 1–5. https://doi.org/10.1016/j.ahj.2020.10.074

[4] Takata, T. S., Page, R. L., & Joglar, J. A. (2001). Automated external defibrillators: Technical considerations and clinical promise. Annals of internal medicine, 135(11), 990-998. https://doi.org/10.7326/0003-4819-135-11-200112040-00011

[5] Delhomme, C., Njeim, M., Varlet, E., Pechmajou, L., Benameur, N., Cassan, P., Derkenne, C., Jost, D., Lamhaut, L., Marijon, E., Jouven, X., & Karam, N. (2019). Automated external defibrillator use in out-of-hospital cardiac arrest: Current limitations and solutions. Archives of cardiovascular diseases, 112(3), 217–222. https://doi.org/10.1016/j.acvd.2018.11.001

[6] Hoke, R. S., Heinroth, K., Trappe, H. J., & Werdan, K. (2009). Is external defibrillation an electric threat for bystanders?. Resuscitation, 80(4), 395–401. https://doi.org/10.1016/j.resuscitation.2009.01.002

[7] U. S. Food and Drug Administration (2023 December 31). MAUDE - Manufacturer and User Facility Device Experience. U.S. Department of Health and Human Services. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

[8] U. S. Food and Drug Administration (2024a January 15). Product Classification. U.S. Department of Health and Human Services. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

[9] U. S. Food and Drug Administration (2024b January 15). Over-The-Counter Automated External Defibrillator. U.S. Department of Health and Human Services. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=949

[10] U. S. Food and Drug Administration (2024c January 15). Automated External Defibrillators (Non-Wearable. U.S. Department of Health and Human Services. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?id=91

[11] U.S Centers for Disease Control and Prevention. Public access defibrillation. (2020, August 28) https://www.cdc.gov/dhdsp/policy_resources/pad.htm#:~:text=Public%20access%20defibrillation%20(PAD)%20programs,and%20where%20they%20are%20needed

[12] Wadhera, R. K., Shen, C., Gondi, S., Chen, S., Kazi, D. S., & Yeh, R. W. (2021). Cardiovascular Deaths During the COVID-19 Pandemic in the United States. Journal of the American College of Cardiology, 77(2), 159–169. https://doi.org/10.1016/j.jacc.2020.10.055