



WHAT'S INSIDE



LETTER FROM THE CHAIR Dr. Keith Churchwell Chair, Advocacy Coordinating Committee



POLICY GUIDANCE ON COVID-19 VACCINE DISTRIBUTION http://bit.ly/AHACOVIDVaccine2020



EXPANDING ACCESS TO CARE THROUGH TELEHEALTH http://bit.ly/AHATelehealth2020



GUIDANCE TO REDUCE THE CARDIOVASCULAR BURDEN OF AMBIENT AIR POLLUTANTS http://bit.lu/AHAAIrQualitu/2020



REDUCING NON-TRAUMATIC LOWER EXTREMITY AMPUTATIONS BY 20% BY 2030

http://bit.ly/AHAPVD2021



AHA'S CALL TO ACTION FOR REDUCING THE GLOBAL BURDEN OF RHEUMATIC HEART DISEASE http://bit.ly/AHARHD2020

7

8



EVIDENCE BASED POLICY MAKING FOR PUBLIC HEALTH INTERVENTIONS: ASSESSING THE FEASIBILITY OF CONDUCTING TRIALS WITH "HARD" CLINICAL OUTCOMES

http://bit.ly/ EvidenceBasedPolicyMaking2020



RECOMMENDATIONS FOR REGIONAL STROKE DESTINATION PLANS IN RURAL, SUBURBAN AND URBAN COMMUNITIES FROM THE PREHOSPITAL STROKE SYSTEM OF CARE CONSENSUS CONFERENCE

http://bit.ly/AHAPreHospitalStroke2021

6

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3

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This past year has brought a lot of change, but we have been nimble, responsive and determined in our advocacy and policy work.

LETTER FROM THE CHAIR

As Chair of the American Heart Association's Advocacy Coordinating Committee (AdCC), I am pleased to present to you the Winter/Spring 2021 issue of the Policy Report.

In this edition you will find the most recent policy publications of the committee. The Report includes a look at recent policy guidance on COVID-19 vaccine distribution. This guidance discusses the need for equitable vaccine distribution to protect every person in the United States from the pandemic.

Expanding Access to Care Through Telehealth, provides guidance for ways in which telehealth has the potential to make quality health care accessible to more people, in the midst of the COVID-19 pandemic and beyond.

Reducing Non-traumatic Lower Extremity Amputations by 20% by 2030: Time to Get to Our Feet, describes the impact of amputation on patients and society, and proposes policy solutions to prevent limb amputation.

AHA's Call to Action for Reducing the Global Burden of Rheumatic Heart Disease, examines the global weight of rheumatic heart disease and pledges support in five key areas to reduce the burden.

Recommendations for Regional Stroke Destination Plans in Rural, Suburban and Urban Communities, is an important, multi-organizational statement that provides consensus recommendations from the Prehospital Stroke System of Care Consensus Conference for prehospital destination plans tailored to specific population environments.

Two other statements are our new policy positions on air quality, articulating the association's policy guidance on addressing this important cardiovascular disease risk factor and the evidence used for policy-making, especially from clinical trials.

This past year has brought a lot of change, but we have been nimble, responsive and determined in our advocacy and policy work. As we look toward a more hopeful Spring and Summer, we will continue our equity-focused work in support of the American Heart Association's 2024 Impact Goal – to advance cardiovascular health for all, including identifying and removing barriers to health care access and quality.

As always, we welcome your response and feedback on this Policy Report to uphold the American Heart Association's mission to be a relentless force for a world of longer, healthier lives. Please continue to contact us at **policyresearch@heart.org**.

Sincerely,

Dr. Keith Churchwell, FAHA Chair, Advocacy Coordinating Committee

HOW TO USE THIS REPORT

- Use data from the policy report in your internal communications to support statements regarding cardiovascular disease (CVD) and brain health.
- Send a copy to your professional contacts in the public, private and nonprofit sectors who support the Association's mission or have a stake in cardiovascular and brain health.
- Share with your connections in local media markets by referencing how Association policy translates into improved health outcomes and can be tied to broader health policy issues.
- Use social media icons to quickly share policy updates and statistics with your network.

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POLICY GUIDANCE ON COVID-19 VACCINE DISTRIBUTION



The COVID-19 pandemic has put a significant strain on the healthcare industry and laid bare socioeconomic disparities and unequal access to quality of care in the United States. These strains have disproportionately impacted racial and ethnic minority communities, immigrant communities, those who are older, those who are low-income, and the incarcerated. The unprecedented global investment in research dedicated to the development of COVID-19 vaccines has been remarkable, however equitable distribution will be integral in ultimately protecting every person in the United States from the pandemic. To maximize the benefit of the COVID-19 vaccine, AHA advocates that:

- Any vaccine distribution framework prioritize those who are at disproportionate vulnerability and exposure to COVID-19 and risk for severe illness caused by COVID-19 and ensure that no one is denied access based on a lack of privileged status.
- Public health infrastructure should be strengthened to engage diverse, cross-disciplinary stakeholders to plan for and execute COVID-19 vaccination campaigns and distribution, which should include robust transparency and education on the vaccines' manufacturers and development, evidence base, intended effects, potential side effects, and administration sites.
- All protocols and decisions for vaccine approval, distribution, and administration must be based only on scientific evidence, and meaningful effort should be made to mitigate the proliferation or exacerbation of disparities.
- Public and private investment in support of biomedical and health services research related to COVID-19 vaccines should be continued and expanded as a national priority.

3 THINGS TO KNOW

People with cardiovascular disease and risk factors are at much greater risk for severe illness from COVID-19.

Hesitancy and misinformation surrounding administration of a COVID-19 vaccine are significant barriers to vaccination rates.

A safe, effective, widely accessible vaccine in all countries and communities is essential to slowing the spread of COVID-19 and allowing fuller reopening of businesses, faith-based organizations, community centers and schools.

Cite

EXPANDING ACCESS TO CARE THROUGH TELEHEALTH

Principles for Telehealth

- Policies should be enacted that ensure everyone, regardless of their geographic location, race and ethnicity, gender, sexual orientation, or socioeconomic status, have access to telehealth services.
- 2 Clinical appropriateness, rather than payment policies, should determine whether telehealth is an acceptable method for healthcare delivery.
 - Providers, policymakers, and clinical researchers must continue to invest resources to expand the evidence base for telehealth and determine what types of healthcare it can safely and adequately deliver.
 - For services delivered via telehealth, coverage and payment should be comparable to healthcare delivered in person. For services that can only be delivered via telehealth, policymakers and other key stakeholders must develop fair and reasonable coverage and payment policies.
- 5 To avoid fragmentation of care and extract maximum value, telehealth should be incorporated into existing integrated healthcare delivery systems.
- 6 Telehealth should be implemented in ways that will strengthen community-based care.
 - Policies should be enacted to ensure that adequate broadband connectivity and telehealth technologies are affordable and widely accessible to everyone.
- 8 Telehealth design and implementation should be informed by human-centered design, cultural and linguistic adaptability, accessibility, and usability principles in order to ensure that all levels of technological acuity can benefit from it.
- 9 Whenever applicable, policies should be enacted that ensure all telehealth encounters adhere to the same principles that apply to in-person encounters with respect to data accuracy, patient safety, civil liberties, and privacy.



The outbreak of COVID-19 has put a strain on the healthcare industry and laid bare significant gaps in access to quality care in the United States. Issues such

as large populations of uninsured and underinsured, primary and specialty care shortages, hospital closures, and the disproportionate impact of chronic disease on minority ethnic and racial populations have been magnified exponentially by the outbreak. Additionally, many states and local communities have implemented stay-at-home edicts, thereby further restricting patients' access to traditional healthcare. The crisis has forced healthcare systems and regulatory bodies to turn to telehealth to provide healthcare. Telehealth has enabled patients, healthcare providers and health systems to communicate through virtual channels in in-patient, ambulatory, and non-healthcare environments. In March 2020, the federal government temporarily lifted restrictions on Medicare reimbursement for telehealth. Various state governments did the same with Medicaid. The new measures have facilitated significant changes in the way healthcare is provided, enabling patients to access healthcare in the privacy of their own residence regardless of their geographical location. However, while telehealth has the potential to make quality health care accessible to more people, the increased emphasis on it amid the COVID-19 pandemic has exposed additional inequities in the United States healthcare system that have not been previously addressed. Therefore, the American Heart Association (AHA) recognizes the potential impact of telehealth on access to quality care and supports policies that ensure healthcare providers are adequately reimbursed for it and that patients have access to its benefits when it is clinically appropriate. The AHA has developed the guiding principles for expanding access to care through telehealth.

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Cite

GUIDANCE TO REDUCE THE CARDIOVASCULAR BURDEN OF AMBIENT AIR POLLUTANTS

In 2010, the American Heart Association published a statement concluding that the existing scientific evidence was consistent with a causal relationship between exposure to fine particulate matter and cardiovascular morbidity and mortality, and that fine particulate matter exposure is a modifiable cardiovascular risk factor. Since the publication of that statement, evidence linking air pollution exposure to cardiovascular health has continued to accumulate and the biological processes underlying these effects have become better understood. This increasingly persuasive evidence necessitates passing and implementing policies to reduce harmful exposures and the need to act even as the scientific evidence base continues to evolve.

The new policy statement, "Guidance to Reduce the Cardiovascular Burden of Ambient Air Pollutants," builds on the evidence presented in our scientific statements and provides policy guidance for lawmakers at the local, state, and federal levels to improve the health of our communities. The guidance is intended to reduce the negative and inequitable health impacts of air pollution and to improve standards for air quality, vehicle emissions, and energy generation. In addition to public policy, industry innovation and public-private partnerships are also critical to achieving these goals.



" Policy change is essential to reducing exposure to air pollution and reversing the negative impact of poor air quality on heart health," said Joel Kaufman, M.D., M.P.H., lead author of the policy paper and professor at the University of Washington's School of Public Health and School of Medicine. "We have made big progress in improving air quality in the U.S. over the last 50 years, but inequities still exist, and we need to consider clean air a right for all communities. This policy statement highlights ways we can improve heart health by reducing environmental inequalities."

$\mathbf{3}$ things to know

The American Heart Association supports public policies, private sector innovation, and public-private partnerships to reduce the adverse impact of air pollution on current and future cardiovascular health for all people living in the United States.

Environmental regulations and policies have been successful in improving air quality, but more than 130 million people in the United States still live in counties that were not in compliance with one or more of the federally regulated air quality standards.

Black and Hispanic people and individuals with low incomes are more likely to be exposed to higher concentrations of air pollution.

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REDUCING NON-TRAUMATIC LOWER EXTREMITY AMPUTATIONS BY 20% BY 2030: TIME TO GET TO OUR FEET

TOP 3 THINGS TO KNOW

Lower-extremity peripheral artery disease (PAD) affects more than 200 million adults worldwide and 8-10 million adults in the US; non-traumatic lower-extremity amputation is a devastating complication of peripheral artery disease (PAD) with high mortality and medical expenditure.

There are significant racial/ ethnic and geographic disparities in lower limb amputation which may be due to limited health insurance coverage, inadequate access to advanced PAD care in many areas of the country and other social determinants of health including poverty.

This statement describes the impact of amputation on patients and society, summarizes medical approaches to identify PAD and prevent its progression, and proposes policy solutions to prevent limb amputation.



Non-traumatic lower-extremity amputation is a devastating complication of peripheral artery disease (PAD) with high mortality and medical expenditure. There are ~150,000 non-traumatic leg amputations every year in the US, and most cases occur in patients with diabetes. Among diabetic patients, after a ~40% decline between 2000 and 2009, amputation rates increased by 50% from 2009 to 2015. There are a number of evidence-based diagnostic and therapeutic approaches for PAD that can reduce amputation risk. Yet, their implementation and adherence are suboptimal. Racial/ ethnic minorities have elevated risk of PAD, but less access to high-quality vascular care, leading to increased rates of amputation. To stop, and indeed reverse, the increasing trends of amputation, actionable policies that will reduce incidence of critical limb ischemia and enhance delivery of optimal care are needed.

This statement describes the impact of amputation on patients and society, summarizes medical approaches to identify PAD and prevent its progression, and proposes policy solutions to prevent limb amputation. Among the actions recommended are improving public awareness of PAD and greater use of effective PAD management strategies (e.g., smoking cessation, use of statins, and foot monitoring/care in diabetic patients). To facilitate the implementation of these recommendations, the AHA proposes several regulatory/ legislative and organizational/institutional policies such as adoption of quality measures for PAD care, affordable prevention, diagnosis, and management, regulation of tobacco products, and clinical decision support for PAD care, professional education, and dedicated funding opportunities to support PAD research. If these recommendations and proposed policies are implemented, it may be possible to achieve the goal of reducing the rate of non-traumatic lowerextremity amputations by 20% by 2030.

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THE AMERICAN HEART ASSOCIATION'S CALL TO ACTION FOR REDUCING THE GLOBAL BURDEN OF RHEUMATIC HEART DISEASE

Rheumatic heart disease (RHD) affects approximately 40 million people and claims nearly 300,000 lives around the world each year. The historic passing of a World Health Assembly resolution on RHD in 2018 now mandates a coordinated global response. The American Heart Association is committed to serving as a global champion and leader in RHD care and prevention. In this call to action, AHA examines the global burden of RHD and its contributing factors, reviews existing efforts to achieve RHD control, and pledges support in 5 key areas: (1) professional healthcare worker education and training, (2) technical support for the implementation of evidence-based strategies for rheumatic fever/RHD prevention, (3) access to essential medications and technologies, (4) research, and (5) advocacy to increase global awareness, resources, and capacity for RHD control. In bolstering the efforts of the American Heart Association to combat RHD, we hope to inspire the global health community to give RHD the attention and funding proportional to the disease burden, and encourage collaboration, communication, clinical capacity building, and coordinated research and advocacy efforts.



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3 THINGS TO KNOW

Addressing rheumatic fever and rheumatic heart disease in the United States was among AHA's foundational missions and greatest successes.

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Rheumatic heart disease remains a significant and persistent global health problem affecting nearly 40 million people and accounting for nearly 300,000 deaths each year.

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We call on the global health community to give RHD attention and funding proportional to the disease burden and to support research, clinical capacity building, and advocacy efforts.

Cite

EVIDENCE-BASED POLICY MAKING FOR PUBLIC HEALTH INTERVENTIONS: ASSESSING THE FEASIBILITY OF CONDUCTING TRIALS WITH 'HARD' CLINICAL OUTCOMES

Policy makers often question whether additional research, especially randomizedcontrolled trials (RCTs), are needed to "prove" that prevention policies are effective. Despite the prominent role of RCTs in health care, it is not always feasible to conduct these kinds of studies for public health interventions with hard outcomes due to logistical and ethical considerations. Currently, there is insufficient guidance for policymakers charged with establishing evidence-based policy to determine whether an RCT with hard outcomes is needed prior to legislation or regulation.

This paper summarizes a case study and analysis looking at the feasibility of conducting an RCT on sodium reduction for cardiovascular outcomes. Based on the analysis, a trial using any of the designs considered would require tens of thousands of participants and cost hundreds of millions of dollars, which is prohibitively expensive, and these estimates may be conservative. The authors propose a robust framework that can guide policy makers when establishing evidencebased public health interventions in the absence of trials with hard clinical outcomes.



3 THINGS TO KNOW

The estimated total cost for a randomized controlled trial for sodium reduction in a high-risk population would be approximately \$408 million and \$891 for a low-risk population. Even if researchers were able to reduce costs by half, such a trial would be prohibitively expensive.

When a randomly-controlled trial is not possible, there are other evidence reviews used by organizations that more fully consider other types of evidence, including observational and practice-based evidence.

These and other evidence grading systems can be used to evaluate the effect of prevention policy not only in terms of the quality of evidence, but whether there is health and equity impact, scalability, and sustainability.

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RECOMMENDATIONS FOR REGIONAL STROKE DESTINATION PLANS IN RURAL, SUBURBAN AND URBAN COMMUNITIES FROM THE PREHOSPITAL STROKE SYSTEM OF CARE CONSENSUS CONFERENCE



In 2015, studies of endovascular therapy (EVT) in selected patients with acute ischemic stroke demonstrated significant benefit. As a result, in 2019 the American Heart Association and American Stroke Association (AHA/ASA) released an update of its 2005 recommendations for stroke systems of care, reiterating the importance of delivering intravenous thrombolysis to all eligible patients, providing access to EVT, and reflecting the full range of stroke center certifications. However, there remains uncertainty concerning the optimal acceptable additional transport time to a Comprehensive Stroke Center (CSC) or Thrombectomy-capable Stroke Center (TSC). A multidisciplinary committee of acute stroke experts was convened to develop a set of consensus recommendations for prehospital destination plans tailored to specific population environments. The committee identified the need for regional customization of stroke systems of care (SSOC) to address differences in resources, hospital certifications, geography, and population density, and to educate providers on new models of acute stroke care and how they impact SSOC. This statement summarizes the Prehospital SSOC Consensus Conference recommendations.

"With the advent of new treatments for stroke such as thrombectomy, the American Stroke Association recognized the need for a national consensus approach to acute stroke prehospital triage that considers differences in regional plans in urban, suburban and rural environments. In time-critical conditions, the capabilities of the first destination hospital can strongly influence clinical outcomes, so it is vital to integrate both speed of transport with level of stroke care required for definitive treatment. This new statement, developed through consensus of leading professional organizations focused on stroke, provides needed recommendations to local communities and regions to improve their stroke systems of care. "

- Lee H. Schwamm, MD Chair, American Stroke Association Advisory Committee



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RECOMMENDATIONS FOR REGIONAL STROKE DESTINATION PLANS IN RURAL, SUBURBAN AND URBAN COMMUNITIES FROM THE PREHOSPITAL STROKE SYSTEM OF CARE CONSENSUS CONFERENCE

(Continued)

This statement will help to maximize patient access to evidence-based acute stroke therapies by providing state and regional policymakers, EMS agencies, and stroke advisory committees with recommendations for stroke systems of care tailored to population density, geography, health care resources and other considerations. More specifically, the statement:

 Provides common definitions of rural, suburban and urban environments leveraging the widely used US Census Bureau's rural-urban commuting area (RUCA) code system;

- Identifies a common set of principles that should apply to all SSOCs, regardless of geographic classification; and
- Recommends modifications to SSOCs for rural, suburban, and urban environments. Most notably, the statement includes recommendations for identifying the most appropriate first hospital transport destination depending on the type of stroke suspected, degree of severity based on validated scales and availability of specific levels of certified stroke centers.

3 THINGS TO KNOW

The proven benefit of endovascular therapy (EVT) for patients with large vessel occlusion (LVO) has created the need for more specific guidance for updating regional stroke systems of care (SSOC) plans. The recommendations can help ensure that acute stroke patients are triaged to the right place in the right amount of time for the most appropriate intervention, including intravenous thrombolysis and EVT. Selected patients with suspected stroke due to LVO should be preferentially triaged to the nearest EVT-capable stroke center.

With varying levels of stroke center certifications and unique regional and geographic considerations, local public health agencies are the organizations best suited to determine the most appropriate acute stroke destination plans that are simple, balanced, and actionable.

When a stroke facility with a lower certification level is closest, there is uncertainty concerning the acceptable additional transport time to a more comprehensive stroke facility. This paper provides local and regional Emergency Medical Services (EMS) agencies and stroke advisory committees with guiding principles and recommendations for how to integrate the elements of a stroke system of care in three key regional settings: urban, suburban, and rural settings.

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