

levels of physical activity have been consistently associated, in a dose-dependent manner, with reduced ASCVD events and mortality risks after adjustment for major ASCVD risk factors.^{3,4} Although we agree with Dr Langland that the available evidence supports the view that a very highly active person with a CAC score ≥ 100 is at lower risk of ASCVD than a less active person with the same CAC score, the evidence regarding absolute risk for adverse cardiovascular outcomes in such patients is limited at present and should therefore be interpreted with caution. Statin therapy is associated with reduced incidence of ASCVD events across the spectrum of baseline risk, and, although risk may be lower in highly active individuals for a given level of CAC, it is uncertain whether risk of ASCVD events is low enough to justify withholding statin therapy in those with CAC scores ≥ 100 .² Clinical judgment and a clinician–patient dialog is required regarding the potential benefits and risks of statin therapy in highly active patients with borderline or intermediate estimated 10-year risk and CAC scores ≥ 100 .

Carl E. Orringer, MD

University of Miami
Miller School of Medicine
Miami, Florida

Kevin C. Maki, PhD

Department of Applied Health Sciences
Indiana School of Public Health
Bloomington, Indiana

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ORCID

Carl E. Orringer:  <https://orcid.org/0000-0002-1001-6781>

1. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a Report of

- the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2019;139(25):e1082–e1143.
2. Cholesterol Treatment Trialists' (CTT) Collaborators, Mihaylova B, Emberson J, et al. The effects of lowering LDL cholesterol with statin therapy in people at low risk of vascular disease: meta-analysis of individual data from 27 randomised trials. *Lancet*. 2012;380(9841):581–590.
3. Arnett DK, Blumenthal RS, Albert MA, et al. 2019 ACC/AHA guideline on the primary prevention of cardiovascular disease: Executive Summary: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2019;74(10):1376–1414.
4. 2018 Physical Activity Guidelines Advisory Committee. 2018 Physical Activity Guidelines Advisory Committee Scientific Report. Washington, DC: US Department of Health and Human Services; 2018. Available at: <https://health.gov/paguidelines/secondedition/report>. Accessed October 4, 2020.

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Aseptic Disposable Stethoscope Barrier: Acoustically Invisible and Superior to Disposable Stethoscopes



To The Editor: Health care-associated infections (HAIs) occur in ~ 1.7 million patients annually, and 100,000 patients die, at a cost of \$147 billion.¹ Overall, 85% of stethoscopes (the physician's third hand) are contaminated with the identical pathogens as found on the hands.² Although hand hygiene is emphasized, cleaning stethoscopes between patients occurs in as few as 10% of encounters.³

Unfortunately, Centers for Disease Control and Prevention (CDC) guidelines rely on outdated strategies, instructing providers to clean their own stethoscopes, an intervention that has repeatedly been a dismal failure. Contemporary methods to decrease stethoscope-mediated transmission of pathogens include single-use disposable aseptic diaphragm barriers placed on high-fidelity stethoscopes⁴ (Figure) or auscultation with a disposable single-use stethoscope. How these strategies affect the stethoscope's auscultatory function has not been previously described. Our purpose was to evaluate the auscultation impact of a disposable aseptic barrier and the physician's preferences vs a disposable stethoscope.

We performed an institutional review board-exempt prospective evaluation assessing the sound transmission effects of an aseptic barrier (DiskCover, AseptiScope Inc, San Diego, California) placed on a stethoscope diaphragm. Using the Littmann 3200 recording stethoscope (3M, Maplewood, Minnesota) and a simulation mannequin (iSTAN, CAE, Sarasota, Florida), 28 physicians performed auscultations in prespecified locations, for 15 seconds of respiratory wheezes, normal heart sounds, systolic murmurs, and diastolic murmurs. Physicians were blinded to the barriers' presence and received sounds in random order. Digital audio files



FIGURE. Stethoscope barrier dispenser and stethoscope with barrier.

were analyzed for amplitude differences (Logic Pro X, Apple Inc., Cupertino, California), with and without the barrier. Physicians reported subjective sound-quality differences. Unblinded physicians then used Littmann stethoscopes with barriers and disposable stethoscopes (Proscope 665, ADC Inc, Hauppauge, New York) without barriers, with auscultation accuracy recorded. To compare amplitude differences among groups, the Wilcoxon rank sum test was used, and McNemar's test was used to compare diagnostic accuracy.

Of 800 matched observations, with and without DiskCover barriers, there were no differences in sound amplitude ($P=1.0$), and this was consistent for all sounds. Diagnostic accuracy of 110 auscultations using the Littman/DiskCover barrier was 100%. However, 110 disposable Proscope stethoscope auscultations had an error rate of 10.9% (12 of 110), with misinterpretation of 9 systolic murmurs as occurring during diastole and 3 diastolic murmurs identified as occurring during systole. In subjective evaluation, 95% of physicians reported a preference for their personal stethoscope with a DiskCover barrier vs the disposable Proscope stethoscope.

Ultimately, the advantages of the DiskCover barrier are significant when it is considered that stethoscopes are dirty, and the bacteria

cultured from them routinely carries significant pathogens.⁵ Our findings that the DiskCover is acoustically invisible and does not alter high-fidelity auscultation must be considered as an aseptic barrier costs only a few cents compared with several dollars for a disposable stethoscope. Our selection of a stethoscope barrier is restricted to only those with published infection-control efficacy. As no other barrier has published demonstration of performance, our acoustic results are limited to the DiskCover barrier.

Sarathi Kalra, MD, MPH

Rich F. Garri, MD

University of South Alabama
Mobile, Alabama

Jitesh B. Shewale, BDS, MPH, PhD

The University of Texas
MD Anderson Cancer Center
Houston, Texas

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ORCID

Sarathi Kalra:  <https://orcid.org/0000-0002-5619-3396>

1. Marchetti A, Rossiter R. Economic burden of healthcare-associated infection in US acute care hospitals: societal perspective. *J Med Econ*. 2013;16(12):1399-1404.
2. Longtin Y. Contamination of stethoscopes and physicians' hands after a physical examination. *Mayo Clin Proc*. 2014;89(3):291-299.

3. Boulée D, Kalra S, Haddock A, Johnson TD, Peacock WF. Contemporary stethoscope cleaning practices: what we haven't learned in 150 years. *Am J Infect Control*. 2019;7(3):238-242.
4. Vasudevan R, Shin JH, Chopyk J, et al. Aseptic barriers allow a clean contact for contaminated stethoscope diaphragms. *Mayo Clin Proc Innov Qual Outcomes*. 2020;4(1):21-30.
5. Zachary KC, Bayne PS, Morrison VJ, Ford DS, Silver LC, Hooper DC. Contamination of gowns, gloves, and stethoscopes with vancomycin-resistant enterococci. *Infect Control Hosp Epidemiol*. 2001;22(9):560-564.

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Minority Representation in Clinical Trials in the United States: Trends Over the Past 25 Years



To The Editor: All members of society need to be represented in medical research, but there is major underrepresentation of racial and ethnic minorities in clinical trials.¹ The National Institutes of Health (NIH) Revitalization Act was created in 1993 to increase the inclusion of diverse populations in clinical research to decrease health care disparities.² Even though the 2018 US Census Bureau population estimates report that non-Hispanic white Americans represent 60.7% of the US population, non-Hispanic whites of European ancestry comprise more than 90% of the population in clinical trials.³

This imbalance in clinical research inclusion leads to limitations

TABLE. Comparison of Ethnic/Racial Make-Up of Manuscripts Involving Minorities in 1993 and 2018

	All n=254,535		Non-NIH n=194,958		NIH n=59,577	
	1993 (n=4439)	2018 (n=7506)	1993 (n=3648)	2018 (n=5822)	1993 (n=791)	2018 (n=1684)
All minorities	1.51% (n=67)	4.85% (n=364)	1.23% (n=45)	3.04% (n=177)	2.78% (n=22)	11.11% (n=187)
Alaskan Native	0% (n=0)	0.05% (n=4)	0% (n=0)	0.02% (n=1)	0% (n=0)	0.18% (n=3)
Asian American	0.14% (n=6)	1.04% (n=78)	0.14% (n=5)	1.1% (n=64)	0.13% (n=1)	0.83% (n=14)
African American	0.97% (n=43)	2.23% (n=167)	0.71% (n=26)	1.13% (n=66)	2.15% (n=17)	6% (n=101)
Pacific Islander	0% (n=0)	0.04% (n=3)	0% (n=0)	0.02% (n=1)	0% (n=0)	0.12% (n=2)
Hispanic or Latino	0.18% (n=8)	1.24% (n=93)	0.11% (n=4)	0.5% (n=29)	0.51% (n=4)	3.8% (n=64)
Native American	0.09% (n=4)	0.31% (n=23)	0.08% (n=3)	0.17% (n=10)	0.13% (n=1)	0.77% (n=13)