# Congress of the United States
## Washington, DC 20515

November 30, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Brooks La-Sure:

We write regarding a pervasive and longstanding diagnostic problem that negatively impacts our nationwide acute care hospital system: false positive blood tests used in the diagnosis of sepsis (known as blood cultures). As we discuss below, with decisive action by CMS, this preventable error can be largely solved across our nation's hospitals.

In addition to creating significant patient safety risks for well over one million Americans each year, false positive blood culture tests for sepsis drive unnecessary and inappropriate use of antibiotics. This, in turn, fuels the antimicrobial resistance crisis we are battling both nationally and globally while creating billions of dollars in wasted costs within the U.S. healthcare system each year.

Research released last February by CMS and others revealed that U.S. hospitals experienced a 40 percent increase in the rate of Medicare beneficiaries hospitalized with sepsis over the past seven years. In 2018 alone, the estimated cost of sepsis to Medicare was more than $41.5 billion.[1]

Complicating our fight against sepsis is the stark reality that more than 20 million Americans present with symptoms of sepsis in acute care hospitals annually.[2] Appropriately, these patients are treated under a "sepsis protocol" where blood culture tests are urgently drawn and used as the gold standard to diagnose bloodstream infections. The challenge, however, is that an average of 40 percent of the positive blood culture test results for sepsis are wrong (i.e., are falsely positive) due to blood sample contamination.[3] This has been a significant clinical challenge since the advent of blood cultures as a tool to diagnose infection more than a century ago.

Patients with false positive blood culture results are often subjected to unnecessary, inappropriate and prolonged antibiotic therapy and have extended hospital stays. This, in turn results in an increased

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[1] Buchman, Timothy G. PhD, MD1,2; Simpson, Steven Q. MD1,3; Sciarretta, Kimberly L. PhD1; Finne, Kristen P. BA4; Sowers, Nicole MPP5; Collier, Michael BA5; Chavan, Saurabh MBBS, MPH5; Oke, Ibijoke MPA5; Pennini, Meghan E. PhD1; Santhosh, Aathira MA5; Wax, Marie MBA1; Woodbury, Robyn PhD1; Chu, Steve JD6; Merkeley, Tyler G. MS, MBA1; Disbrow, Gary L. PhD1; Bright, Rick A. PhD1; MaCurdy, Thomas E. PhD5,7,8,9; Kelman, Jeffrey A. MD, MMSc6 Sepsis Among Medicare Beneficiaries: 1. The Burdens of Sepsis, 2012–2018*, Critical Care Medicine: March 2020 - Volume 48 - Issue 3 - p 276-288
doi: 10.1097/CCM.0000000000004224

[2] Rhee C, Dantes R, Epstein L, Murphy DJ, Seymour CW, Iwashyna TJ, Kadri SS, Angus DC, Danner RL, Fiore AE, Jernigan JA, Martin GS, Septimus E, Warren DK, Karcz A, Chan C, Menchaca JT, Wang R, Gruber S, Klompas M; CDC Prevention Epicenter Program. Incidence and Trends of Sepsis in US Hospitals Using Clinical vs Claims Data, 2009-2014. JAMA. 2017 Oct 3;318(13):1241-1249. doi: 10.1001/jama.2017.13836. PMID: 28903154; PMCID: PMC5710396.

[3] Zwang, O., et al. (2006). "Analysis of Strategies to Improve Cost Effectiveness of Blood Cultures." Journal of Hospital Medicine, 1(5): 272-276.

risk of hospital-acquired infections, preventable medical errors, and increased morbidity and mortality. Additionally, peer-reviewed studies[4,5] indicate that false positive blood culture tests for sepsis burden our healthcare systems with approximately $6 billion annually in completely avoidable costs.

Several methods are available to reduce blood culture contamination. These include disinfecting skin and the tops of blood culture vials, obtaining blood via venipuncture rather than catheters, and collecting an appropriate volume of blood. A new innovative approach involves actively diverting the first portion of blood, which can be easily accomplished through the use of a closed-system initial specimen diversion device. In fact, the FDA recently cleared the first initial specimen diversion device indicated to specifically reduce blood culture contamination in 2020. A comprehensive review of the problem of blood culture contamination was published in January 2020 in Clinical Microbiology Reviews, a leading peer-reviewed medical journal. The authors concluded: "…the use of initial specimen diversion devices as an alternative to standard blood specimen collection methods represents an exciting new advance that has the potential for reducing overall contamination rates to levels not previously considered to be attainable. In view of the foregoing, we believe that a new universal standard of less than 1 percent should be considered in defining allowable overall institutional blood culture contamination rates…".[6]

We are appreciative of CMS' ongoing efforts to address the growing burden of sepsis for the Medicare population. In light of new clinical evidence and the advent of technologies capable of significantly reducing overall blood culture contamination rates, we strongly encourage CMS to:

- Prioritize the development and implementation of a specific quality measure for blood culture contamination based on an allowable standard of <1% blood culture contamination rates for individual hospitals;
- Collaborate with the Centers for Disease Control and Prevention and National Quality Forum on the development, testing and implementation of the quality measure, with regular reporting to be conducted via the National Healthcare Safety Network in the same manner as other similar quality measures;
- Establish appropriate tracking mechanisms to quantify the impact of blood culture contamination on inappropriate antibiotic use nationwide and potential impacts on the problems of antimicrobial resistance and the emergence and persistence of multi-drug resistant organisms; and
- Evaluate programs and/or other innovative approaches to incentivize adoption and implementation of best practices to minimize blood culture contamination in hospitals nationwide.

We urge CMS to take meaningful action to reduce the preventable error of blood culture contamination which represents an immense and avoidable economic and public health burden. By prioritizing the development and implementation of a specific quality measure for blood culture contamination and appropriately incentivizing the use of clinical practices and technologies that are

[4] Geisler, B., et al. (2019). A Model to Evaluate the Impact of Hospital-Based Interventions Targeting False-Positive Blood Cultures on Economic and Clinical Outcomes. Journal of Hospital Infection. https://doi.org/10.1016/j.jhin.2019.03.012

[5] Skoglund, E., et al. (2019). Estimated clinical and economic impact through use of a novel blood collection device to reduce blood culture contamination in the emergency department: A cost-benefit analysis. J. Clin. Microbiol. 57: e01015-18.

[6] A Comprehensive Update on the Problem of Blood Culture Contamination and a Discussion of Methods for Addressing the Problem (https://cmr.asm.org/content/33/1/e00009-19)

proven to reduce (and nearly eliminate) contamination, CMS can directly and dramatically reduce the number of false positive blood tests for sepsis, one of the deadliest infections Americans confront.

Sincerely,

Gus M. Bilirakis
Member of Congress

Mike Levin
Member of Congress

Dan Newhouse
Member of Congress

Jaime Herrera Beutler
Member of Congress

John H. Rutherford
Member of Congress

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Larry Bucshon, M.D.
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