Newborn Screening for Critical Congenital Heart Disease: Appropriately Evaluating This Public Health Program

Matthew E. Oster^{1,2} · Gerard R. Martin³

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It was with great interest that we read “Pulse Oximetry Screening Has Not Changed the Timing of Diagnosis or Mortality of Critical Congenital Heart Disease” by Campbell et al. [1]. The authors have done an admirable job of describing how newborn screening for critical congenital heart disease (CCHD) has affected surgical outcomes *at their center*. However, we advise caution in interpreting these findings as an assessment of the overall impact of this public health program.

First, using clinical data from a single referral center is not an ideal way to evaluate a public health program. A true public health assessment would be population-based, would be indexed to the birth rate for the period in question, and would identify not just those referred for surgery but also those missed by screening (false negatives). Indeed, many state agencies are trying to perform such assessments, but further help is needed in capturing the necessary data [2].

Second, the study lacked statistical power to detect significant differences due to the very small numbers of CCHD cases that could have benefited from screening at ~24 h. Approximately 77% of the cases were detected prenatally, and many of the remaining 23% were likely detected prior to 24 h of age. We estimate that their sample size afforded them at most 4%, 7%, and 16% power to detect 1-year mortality decreases of 10%, 25%, and 50%, respectively. Furthermore, the authors had no way of accounting for cases that failed screening but died prior to presenting for surgical repair. The authors acknowledge these limitations in their manuscript, but these major limitations underscore the importance of using data from multiple centers or, ideally, an entire population-defined area.

Finally, the authors’ critique that the study by Abouk et al. could not account for the impact of improvements in

clinical management on improved survival is misleading. The difference-in-differences analysis by Abouk et al. used contemporary controls to account for both state-specific and time-variant factors [3]. Only if there were a strong temporal association between implementation of state CCHD screening mandates and clinical improvements specific to CCHD management varying by state could clinical improvements have affected the results.

Newborn screening for CCHD has been a public health success [4]. Yet, as with any program, its impact is expected to vary between centers and states. Thus, using population-level data to assess outcomes of population-wide interventions is preferable to using single-center data using historical controls.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

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✉ Matthew E. Oster
osterm@kidsheart.com

¹ Emory University School of Medicine, Atlanta, GA, USA

² Children’s Healthcare of Atlanta, Atlanta, GA, USA

³ Children’s National Hospital, Washington, DC, USA