

Improving Children's Health Through Better Pediatric Reference Intervals

When making a diagnosis, the pediatrician evaluates a laboratory test value within the context of a reference interval – a range of numeric values that would be expected in a healthy child. Reference intervals are integral in determining whether a blood test value is normal, and many of these intervals change throughout life, most markedly in childhood. Pediatric laboratory professionals have long recognized that reference intervals in children differ not only from those in adults, but also amongst children themselves, as the intervals vary at different developmental stages.

Pediatric laboratory professionals strive to provide clinicians with precise reference intervals to assess the children under their care.

The best reference intervals are those established using blood samples from healthy children.

Unfortunately, the development of more precise pediatric reference intervals (PRIs) is hindered by the limited access to blood samples from healthy children. The establishment of robust pediatric reference intervals is critical to ensure accurate diagnosis and treatment of children.

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Congress initially recognized the need to improve PRIs in report language accompanying the fiscal year (FY) 2020 budget:

Clinicians use a spectrum of values, referred to as reference intervals, to evaluate whether a child's test result is normal or indicates a problem that requires medical attention. Without accurate reference intervals physicians may misdiagnose a condition that could result in harm to the child. The Committee recommends that CDC develop and submit a plan for improving pediatric reference intervals, including the resources necessary for carrying out this initiative in the fiscal year 2021 C.J. (Page 73, S.R. 116-000)

The infrastructure for advancing this effort is already in place. CDC responded to Congress stating that its Environmental Health Laboratory would need an additional \$10 million to initiate and coordinate this vital work. ADLM and its partners call on Congress to provide this funding.

- The CDC's National Center for Health Statistics, through the National Health and Nutrition Examination Survey (NHANES), can obtain consent and collect and store specimens from children and adults for health research. Simple expansion of this work to include enough children ages 1-18, along with additional health information, would provide a rich source of samples from healthy children.
- The CDC Environmental Health Laboratory, which has experience in developing reference intervals using highly accurate tests, can perform the testing on NHANES samples to generate more accurate PRIs based on age, stages of development, ethnicity, and gender.
- ADLM would partner with the agency to disseminate the improved PRIs to the laboratory community.

Report language supporting this initiative was included in the House of Representatives FY 2022 Labor, Health and Human Services, Education, & Related Agencies appropriations bill: *Improving Pediatric Reference Intervals.*—The Committee encourages CDC to initiate efforts to improve the accuracy of pediatric reference intervals. (Page 97, H.R. 117-000)