POSITION STATEMENT

Improving equity & access to pediatric testing

February 2025

Introduction

Achieving access to quality, affordable healthcare for children is critical for their development into healthy adults. Unfortunately, significant challenges hinder access to pediatric laboratory services, including limited test availability, insufficient age-specific technologies, and rising health costs. Children are often unable to express their healthcare needs, and parents or guardians may lack the necessary understanding to make informed decisions. Improving access will help children, particularly the most vulnerable, receive the care they need. Overcoming these inequities requires well-developed policies that bring together key parties—laboratorians, healthcare providers, and policymakers—to collaborate and ensure access to pediatric testing and healthcare services.

Considerations

Test availability and access

Children born in different states do not receive the same level of healthcare. For instance, newborn screening (NBS) varies significantly across the U.S., with some states like Louisiana and Montana screening for 33 inborn genetic conditions, while others such as Connecticut and California screen for over 70 conditions. As of January 2023, federal NBS recommendations include 38 core conditions and 26 secondary conditions. However, nine states still fail to meet these federal standards.

The availability of standard laboratory tests for children is also inconsistent. Most lab tests are validated using adult populations, with limited consideration for pediatric patients. As a result, pediatric tests may require excessive blood samples or lack appropriate reference intervals (commonly known as normal ranges), leading to inaccurate clinical decisions and suboptimal healthcare outcomes. There is also incomplete data available for pediatric reference intervals in the U.S., further complicating treatment decisions.

ADLM POSITION:

ADLM supports efforts to reduce barriers to pediatric testing and care. Partnerships between healthcare institutions, academic researchers, and industry are essential for improving access to pediatric-specific diagnostics and treatment. Investing in these efforts is crucial to ensuring that all children receive the laboratory testing needed to maintain and improve their health.

Potential harms resulting from limited access include:

- Conditions may go undiagnosed, resulting in delayed treatment, potentially leading to more severe health issues
- A lack of timely testing that exacerbates existing conditions, increasing the

 900 Seventh Street, NW, Suite 400, Washington, DC 20001 | 1.202.857.0717 | 1.800.892.1400 | 1.202.887.5093 fax | myadlm.org

risk of complications and mortality
- Anxiety and uncertainty for parents and guardians who cannot access lab tests to clarify their conditions affecting their children
- Disproportionate impact on vulnerable populations, exacerbating health disparities and inequities in care.

Access to essential tests is often limited by geography. Families in underserved areas, particularly those who live far from urban or regional laboratories, face significant barriers to obtaining follow-up testing. Travel distances, time off from work, and transportation costs further restrict access to necessary care. A 2024 study found that only a quarter of Texas' pediatric population lives within an hour of a regional hospital that can provide adequate pediatric care (3). Outreach centers and mobile clinics play a critical role in reaching families who might otherwise face barriers to accessing healthcare services, such as when timely access to regional hospitals is unrealistic.

Technology limitations

Technology limitations impact the accuracy, reliability, and accessibility of pediatric healthcare, contributing to disparities in outcomes. The lack of age-appropriate collection techniques and home-based specimen technology worsens these gaps, particularly in rural and underserved communities where families often travel long distances for testing.

Standard blood collection methods used for adults can be distressing and traumatic for children, leading to avoidance of necessary tests. Alternative methods, such as heel sticks or finger pricks, often yield inadequate or compromised samples, requiring retesting to ensure accuracy. These challenges highlight the need for the development and implementation of age-appropriate collection techniques to improve the quality and reliability of pediatric laboratory testing.

Although the use of pediatric telehealth has grown, technologies that enable remote specimen collection remain scarce. Investments in such as home-based testing technologies promise to expand access to care, particularly in underserved areas, as seen during the COVID-19 pandemic. However, these technologies are not widely accepted for standard clinical testing, and each laboratory must undergo the costly process of validating these specimens as laboratory-developed tests (LDTs), creating both technical and financial challenges that further limit access to essential services.

Education

Improving pediatric access to laboratory medicine requires a comprehensive educational strategy, both for healthcare providers and families. Nationally standardized, culturally appropriate education programs should be developed to help patients and guardians make informed healthcare decisions. These tools, adapted from adult care settings, can empower families and improve long-term outcomes by helping them better understand pediatric testing and treatment options.

While the 2021 Cures Act emphasizes patient access to test results, many families still lack the resources to interpret these results accurately. Misunderstanding test results can lead to unnecessary stress, missed follow-ups, and additional healthcare visits, all of which negatively impact a child's development and long-term health. Providing families with tools tailored to their health literacy levels and cultural backgrounds is essential to improving decision-making and reducing these risks (5).

Collaboration between laboratory professionals, medical organizations, and federal agencies is necessary to address these educational gaps. Initiatives could include interactive apps, dashboards, and animated videos designed to provide clear, accessible information. These tools should be standardized to ensure quality, relevance, and accessibility for diverse audiences.

Promoting health equity within the Centers for Medicare and Medicaid Services (CMS) framework, with a focus on language access, health literacy, and culturally tailored clinical services, can further improve access to vital healthcare information. Ensuring that digital resources are accessible to all populations will reduce barriers to understanding laboratory results and improve healthcare outcomes for children.

Science

Children have unique physical, biochemical, genetic, psychosocial, and developmental needs that require specialized research and testing approaches. Unfortunately, pediatric research and laboratory

testing remain underfunded and often overlooked. Addressing these research gaps is essential to improve pediatric healthcare for both current and future generations.

Despite the significant healthcare burden posed by pediatric diseases, federal research funding from agencies such as the National Institutes of Health (NIH) remains disproportionately low. Industry-sponsored funding is also limited, largely due to lower profitability and more stringent regulatory requirements for pediatric testing. These funding shortages hinder the development of pediatric-specific diagnostics and treatments.

Conducting pediatric trials presents additional challenges. Informed consent is often complex in pediatrics, and many pediatric diseases are rare, making it difficult to recruit enough participants. Pediatric trials also suffer from high dropout rates, with only 40% of these studies sharing data or publishing results in peer-reviewed journals. This lack of data transparency slows progress and reduces opportunities for innovation.

To close these gaps, increased federal and industry support is necessary. Granting agencies should fund recruitment efforts for pediatric studies and offer incentives for data sharing and publication. In addition, targeted federal aid should be directed toward addressing the unique needs of pediatric laboratory testing and supporting interventions and outcome-based therapies that can improve long-term health for children.

Cost of pediatric healthcare

The rising cost of healthcare and a lack of price transparency can make essential laboratory tests unaffordable for many families. Approximately 28 million people in the U.S. are uninsured, including over 4 million children. Even for families with insurance, high-deductible plans lead to significant out-of-pocket expenses, with 43% of insured patients facing prohibitive costs that often prevent them from seeking necessary pediatric care. The support provided by the Children's Health Insurance Program (CHIP) is often a vital lifeline for families seeking care, especially for underserved and specialized pediatric populations.

Knowledge of test costs can help guide patients to select necessary and affordable tests, and transparency about costs can further help identify disparities in access, helping to inform policy interventions to support underrepresented or low-income populations. Recent efforts, such as the CMS 2021 Hospital Price Transparency Final Rule and the 2023 Lower Costs, More Transparency Act, aim to make healthcare pricing information more accessible. However, significant barriers remain. Many hospitals and labs are not fully compliant with the agency's Final Rule, and when information is available, it is often presented in non-standardized formats that are difficult for patients to interpret. Hospitals often struggle to address these issues due to complex pricing systems, and the overabundance of tools—such as machine-readable files, cost estimators, and Good Faith Estimates – often leading to patient confusion. Maintaining and updating these tools may further pose a significant burden on hospitals, limiting the effectiveness of transparency initiatives.

Positions

ADLM emphasizes the critical need to address the challenges in pediatric access to healthcare, particularly in laboratory services. Ensuring that all children receive the quality and affordable care necessary for healthy development requires eliminating barriers in several areas. These include the ability to understand care needs, access appropriate tests, address technological limitations, provide adequate education, and manage the high cost of care. Focusing on these factors can create a more equitable healthcare landscape for children.

Test availability and access

- Federal funding should be expanded to ensure all states are compliant with the Recommended Uniform Screening Panel (RUSP) for newborns.
- Legislators should increase funding for the Children's Health Insurance Program (CHIP) and regional hospitals that provide care for underserved and specialized pediatric populations. Additional funding for outreach centers and mobile clinics will also benefit families who might otherwise face barriers to accessing healthcare services.
- Congress should provide the Centers for Disease Control and Prevention funding to establish and maintain pediatric reference intervals, and ensure laboratories have the necessary resources to conduct studies in different age and gender and specialized populations.

Science and technology

Government agencies, healthcare organizations, and the medical industry must prioritize bridging technological and diagnostic gaps in pediatric laboratory medicine. Investments should be directed toward developing pediatric-specific collection devices, conducting clinical trials, and establishing comprehensive pediatric reference intervals. The active involvement of laboratorians is essential to ensure these initiatives are tailored to meet the unique needs of children, ultimately improving diagnostic accuracy and care.

Education

Government support should be provided to enhance health literacy, making information accessible to diverse populations and promoting informed decision-making, empowering families to better understand their healthcare options and navigate the system effectively.

Cost of pediatric healthcare

- The Hospital Price Transparency Final Rule should be streamlined to reduce patient confusion while minimizing regulatory burdens.
- Patient advocacy groups, healthcare providers, and payers – should collaborate to ensure price transparency policies are patient-centered without adding unnecessary cost.

References

1) Gattermann, D. P., Langford, W. S., & Hay, W. W., Jr. (2018). The uncertain fate of the National Institutes of Health (NIH) pediatric research portfolio. Pediatric Research, 84(3), 328–332.

2) Brewster, R., Thomason, S. S., Vora, A., Zhang, Y., & Li, J. S. (2022). Early discontinuation, results reporting, and publication of pediatric clinical trials. Pediatrics, 149(3), e2021052557.

3) Centers for Medicare & Medicaid Services (CMS). (2020). Hospital price transparency final rule. Federal Register, 45 CFR Parts 180.

4) U.S. House of Representatives. (2023). H.R. 5378 - Lower Costs, More Transparency Act, 118th Congress. Congress.gov.

5) Gaughan, A. (2023). Developing and validating a laboratory test utilization dashboard. Journal of Applied Laboratory Medicine, 8(5), 1102–1110.

6) Hill, S. (2023). A strategy for boosting equitable access to digital healthcare. Clinical Laboratory News.

7) Centers for Medicare & Medicaid Services. (2022). CMS framework for health equity 2022–2032.

8) West Health. (2023). America's healthcare affordability crisis is growing larger and deeper. West Health News.

9) Health Literacy Solutions. (2021). Legally speaking: The 21st Century Cures Act draft legislation – Giving a voice to health literacy.

10) Texas Community Health News. (2024). A new pediatric hospital provides greater access in the Valley, but challenges remain for South Texas families.

11) Health Resources and Services Administration (HRSA). (2024). Newborn screening in your state.

12) American Academy of Pediatrics. (2024). Telehealth: Opportunities to improve access, quality, and cost in pediatric care. Pediatrics.

13) Children's Hospitals. (2024). Mobile health clinics close gaps in care.

14) Children's Health Fund. (2023). 20 million children lack sufficient access to health care. Physicians for a National Health Program.