



PARTNERSHIP for the ACCURATE
TESTING of HORMONES
Better Tests, Better Health

Strategic Plan 2019-2023

Approved May 3, 2019

Funding for this document was supported by the Grant/Cooperative Agreement number 6-NU38OT000286-01, funded by the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention or the Department of Health and Human Services.

The Problem

The analytical accuracy and performance of hormone measurements is critical for optimal and appropriate patient care and to effectively conduct implementable clinical research. Many laboratory assays used in patient care and clinical research do not have the accuracy and reliability to meet today's needs to ensure correct diagnosis and treatment and to effectively apply research findings in patient care and public health.

Incorrect assay accuracy and reliability can affect patient care by preventing detection of diseases or identifying people at risk for diseases, and thus can have major public health implications. They can also influence the outcomes of clinical trials and other research, making it difficult or impossible to use research data and findings to improve the health and care of people. Most importantly, inaccurate assay results drive up healthcare costs by causing some patients to receive incorrect diagnosis and unnecessary treatment, to potentially encounter avoidable complications, or to be under-diagnosed with potentially treatable conditions.

A major problem in this regard is the lack of laboratory assays not being calibrated to one commonly recognized standard and their analytical performance not being assessed for accuracy as well as reliability using criteria set forth by relevant stakeholders. Furthermore, a system is lacking to rigorously assess and monitor analytical assay performance. Exacerbating these technical problems is a general lack of awareness among physicians, payers and patients of the poor quality and non-interchangeability of the assays that are ordered and of activities and programs to address these problems.



PATH Vision & Mission

The Partnership for the Accurate Testing of Hormones (PATH) Steering Committee came together for a meeting at the Endocrine Society on April 22, 2018 and affirmed the vision and mission of PATH.

PATH Vision:

To have optimal and appropriate patient care and public health through the universal use of accurate and reliable hormone assays in healthcare and research.

PATH Mission:

To advance the development of accurate and reliable hormone assays that are traceable to a single, higher-order reference, demonstrate analytical performance characteristics suitable to meet clinical and public health needs, and to advocate for the universal adoption of these assays in medical practice and research.

PATH is a stakeholder organization bringing together public and private partners with a common vision and mission. Taken together, PATH member organization represent a very large proportion of health care professionals and researchers, who provide their broad range of knowledge and expertise to achieve PATH's vision and mission.

PATH demonstrated that it can accomplish more than each organization by itself: Ensuring that hormone assays have the analytical performance and capability to meet today's needs in patient care and research requires a special technical infrastructure to appropriately assess and evaluate clinical laboratory assays. This technical infrastructure exists with CDC's Hormone Standardization Program. PATH members developed analytical performance criteria for testosterone, which are used in CDC's Hormone Standardization Program to help laboratories and assay manufacturers meeting clinical and public health needs. Furthermore, PATH used its expertise to develop and implement approaches to educate health professionals and health policy officials through successful educational events and activities.

Building on the initial success, PATH is working to improve people's health by addressing more high priority hormones, further educating health professionals, and by promoting the use of standardized and thus accurate and reliable hormone assays.



PATH's Goal 1. Standardization

Increase the number of hormone assays that are standardized:

Increasing the number of assays that demonstrate through a rigorous, independent assessment that they meet analytical performance requirement set forth by PATH.

Objectives/Strategies

- Establish a list of priority hormones and update the list annually
- Develop new or endorse existing analytical performance criteria for hormone assays and update them as needs change
- Provide technical support, such as guidance on analytical performance criteria, to CDC's Hormone Standardization Program

PATH's Goal 2. Education

Deepen the knowledge of health care providers, health researchers and administrators, policy makers and payers about the importance of accurate and reliable hormone assays, and assay quality in patient care, research and public health

Objectives/Strategies

- Develop educational content customized for relevant audiences in collaboration with subject matter experts located in PATH member organizations
- Perform educational events at meetings of PATH member organizations for health care providers and researchers
- Conduct educational activities for policy makers and payers
- Maintain PATH website and review annually
- Establish an effective communication system using tools in place at PATH member organizations



PATH's Goal 3. Implementation

Increase the use of standardized assays in patient care, public health and research

Objectives/Strategies

- Promote the use of standardized assays in relevant guidelines and other publications
- Assist laboratories with selecting standardized assays
- Support manufacturers with developing new standardized assays
- Promote accuracy-based proficiency testing
- Establish use of assays with standardization certification as quality element in health care quality assessment
- Establish standardization certification as one criterion to demonstrate that assays are fit-for-purpose
- Facilitate the development of harmonized reference ranges and other data that can be used with standardized assays

PATH's Goal 4. Sustainability

Establish a sustainable system to standardize hormone assays and to keep hormone assays accurate and reliable

Objectives/Strategies

- Secure appropriate funding for PATH and its activities
- Establish broad technical support from stakeholders
- Increase PATH membership to include all relevant stakeholders
- Establish standardization certification in quality systems at health care organizations