



# PARTNERSHIP for the ACCURATE TESTING of HORMONES

STEERING COMMITTEE NEWSLETTER October 25, 2019

## PATH UPDATES



Members of the PATH Steering Committee during 2019 [annual meeting](#) last May.

- **Working Group on Training Curriculum** – As we noted during the May meeting, Dr. Matsumoto is looking for volunteers to identify case studies that can be part of a new training curriculum. If you are interested in working with him on a fellows curriculum, please contact [mbecker@endocrine.org](mailto:mbecker@endocrine.org).
- **Estradiol Meeting** – PATH helped support the September 23-24 Workshop on Normal Ranges for Estradiol organized by the North American Menopause Society (NAMS). The aim of this workshop was to review existing analytical methodologies for measuring

estradiol in postmenopausal women and to assess existing data and study cohorts of postmenopausal women for their suitability to establish postmenopausal reference ranges for estradiol and estrone. Workshop participants agreed that reference intervals for postmenopausal women should be established using an accurate and reliable assay such as a CDC certified assay – an approach that is consistent with the PATH mission and objectives. In addition, the participants agreed to use a methodology of harmonization similar to the one PATH employed for testosterone will be used. Please see attached DRAFT Workshop Summary Recommendations prepared by Dr. Richard Santen. Workshop participants are currently developing a “white paper” to detail the recommendations and hope to complete it in the next two months. For additional details, please contact Dr. Santen or PATH Steering Committee members Alvin Matsumoto, JoAnn Pinkerton, Nanette Santoro, Frank Stanczyk, and Hubert Vesper who led sessions during the Workshop.

## NEWS FROM STEERING COMMITTEE MEMBERS

- **ATA** – ATA formed a working group to review current analytical performance criteria for free thyroid hormones and to revise them as needed. The 89<sup>th</sup> Annual Meeting of the American Thyroid Association (ATA), October 30 – November 3, 2019 at the Sheraton Grand Chicago, Chicago, Illinois. The ATA Annual Meeting is open to the community of endocrinologists, internists, surgeons, oncologists, basic scientists, nuclear medicine professionals, pathologists, trainees, nurses, physician assistants, nurse practitioners and other healthcare professionals who wish to broaden and update their knowledge of the thyroid gland and thyroid cancer. Program and Registration Information Available at: <https://www.thyroid.org/89th-annual-meeting-ata/>
- **CDC** – CDC is addressing standardization of analytes considered high priority by PTH: it is working on launching a certification program for free thyroxine mid-2020 and is developing reference methods for measurement parathyroid hormone by mass spectrometry. Also, CDC continues to make available lists of certified laboratories for Vitamin D, estradiol, and testosterone procedures. These are available on the PATH [website](#).
- **Endocrine Society** – The Endocrine Society continues to promote the use of standardized hormone tests through recommendations in clinical practice guidelines and position statements. Last month, the Society’s Journal of Clinical Endocrinology and Metabolism (JCEM) published a [Global Consensus Position Statement on the Use of Testosterone Therapy for Women](#). Highlighting the importance of accurate and reliable tests in such documents is an indication of the success of the educational work done by PATH and is a major accomplishment for our coalition. The Endocrine Society’s monthly magazine, Endocrine News, also recently highlighted the need to create pediatric reference intervals and the advocacy work AACC and others are doing to urge Congress to provide funds to the CDC for a program to establish these intervals. The full article can be found at: <https://bit.ly/2p0INgu>

- **NACDD** – NACDD plays a critical role supporting PATH through funding of its Biomarker Project. Effective last month, Laura DeStigter, MPH, will be taking over management of the Biomarker project for NACDD. She replaces Leslie Best who acted as project manager until her retirement. We very much look forward to continuing to work with NACDD with Laura!
- **PCOS Challenge** – PCOS Challenge, more formally known as the National Polycystic Ovary Syndrome Association, is the leading patient support and advocacy organization globally that is advancing the cause of PCOS. A challenge in the diagnosis of PCOS and other hyperandrogenic syndromes is having an accurate standardized reference range for free testosterone in women. Therefore, PCOS Challenge is very interested in PATH’s work in this area. PCOS Challenge is driving the PCOS legislative advocacy efforts at the U.S. federal and state level. Most recently, PCOS Challenge led the effort and worked in partnership with a coalition of over 70 national and international organizations, including the Endocrine Society, to recognize the seriousness of PCOS; recognize the need for increased research and improved treatment and care options; and to officially designate September as PCOS Awareness Month through the U.S. Congress. PCOS Challenge invites healthcare providers and researchers to get involved with advocacy and awareness efforts to improve outcomes for PCOS patients. To learn more about PCOS Challenge and how to become involved, go to [pcoschallenge.org](https://pcoschallenge.org).

## CDC FUNDING NEWS

Last month, the Senate Labor, Health and Human Services, Education, and Related Agencies Subcommittee released its fiscal year 2020 appropriations report, which outlines the panel’s spending priorities. Included in the report is language that supports one of the laboratory community’s legislative priorities – improving pediatric reference intervals (PRIs). The draft Labor HHS report states:

*Pediatric Reference Intervals—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 references intervals, including the resources necessary for carrying out this initiative in the fiscal year 2021 CJ.*

A key objective of this effort is to ensure measurements are standardized and reference intervals will be usable to laboratories standardized to CDC. Release of the language moves the laboratory community one step closer to securing federal funding for the Centers for Disease Control and Prevention (CDC) to develop better PRIs. AACC, the Endocrine Society, and their partners will work to have the language included in any end-of-the-year spending package

brought before Congress. The community will work to obtain funding for improving PRIs in the fiscal year 2021 budget.

**If your organization has news to share about what it is doing related to hormone testing, please send to [mbecker@endocrine.org](mailto:mbecker@endocrine.org) so we can post it on the PATH website, forward to the PATH Steering Committee and/or include in our next newsletter.**

**VISIT THE PATH WEBSITE [WWW.HORMONEASSAYS.ORG](http://WWW.HORMONEASSAYS.ORG)**