



Meeting Summary  
PATH Annual Steering Committee Meeting  
April 29, 2022

**Participants**

***Members***

Doug Fesler, MAIA- ASBMR  
Robert Fitzgerald, PhD- AACC  
Luigi Garibaldi, MD- PES  
Laura Hickes, PhD- Roche  
Kelly Hoff, CAE- ATA  
Andrew Hoofnagle, MD, PhD- CAP  
Alex Katayev, MD- LabCorp  
Michael Lemieux, PhD- Avalon  
Alvin Matsumoto, MD- ASBMR  
James Meenan, MBA- Siemens  
Megan Murphy- PCOS Challenge  
Darius Paduch, MD, PhD  
Amanda Perl- ATA  
Robert Rej, PhD- APHL  
Nanette Santoro, MD- NAMS  
Andre Valcour, PhD, MBA, D(ABCC)- LabCorp  
Hubert Vesper, PhD- CDC  
Christina Wang, MD- ISA

Vivian Lee Weiss, MD, PhD- ATA  
Ronald Whitley, PhD- AACC  
Zengru Wu, PhD, DABCC, C(ADCP)<sup>CM</sup>, CCS- Quest

***Observers***

Marianela Perez-Torres, PhD- FDA

***Staff***

Mila Becker, JD- ES  
Laura DeStigter, MPH- NACDD  
Daphnie Loriston, MPH- NACDD  
Linde Parcels- CDC  
Fidelia Pokuah, MPH- CDC

***Guests***

Melanie Cree-Green, MD- PCOS Challenge  
Zahra Shajani-Yi, PhD, DABCC, FAACC- LabCorp

**Welcome, Introductions, and PATH Overview**

Dr. Hubert Vesper, PATH co-chair, reviewed the agenda for the day and welcomed new attendees. Participants introduced themselves. Dr. Vesper shared the vision, mission, goals, and member organizations of PATH, emphasizing the importance of bringing together diverse stakeholders to support the work. He shared a timeline of PATH's activities, demonstrating the progress that has been made since PATH was formed.

**PATH Updates**

***Review of Priority Hormone List***

Dr. Vesper reviewed the list of hormones in high need for standardization and asked that PATH members submit any other hormones that should be added to the list or that should be prioritized

within the current list. CDC is working on this list through their programs. They have new projects on thyroid hormones and will be working on free testosterone next year.

Inhibin B was suggested as a candidate for further prioritization, and the importance of looking at the full process—from collection of the sample through analysis—was noted. It was suggested that a paper could be developed, as was done with PTH, with considerations and recommendations to ensure a high-quality sample.

PTH was also suggested for further prioritization, as there are huge differences in results generated by different laboratories, which is greatly impacting clinical care. It was noted that IFCC is working to come up with a reference measurement procedure, which would provide a basis for building a program for PTH. Dr. Vesper shared that CDC is currently in the final stages of establishing a reference measurement procedure and developing primary reference materials and will be launching a standardization activity for PTH within the next year.

#### **ACTION ITEMS:**

- PATH Members: Send Laura DeStigter any hormones that should be added to the priority list or further prioritized within the list
- PATH Members: Contact Ms. DeStigter if interested in joining a working group to develop a paper with recommendations on Inhibin B.

#### ***Education and Communications Activities***

Mila Becker provided an overview of the development of the Endocrine Society's [Accurate Hormone Testing Series](#). The series includes 4 online modules and was conceptualized and outlined by PATH co-chair Dr. Alvin Matsumoto, with content developed and reviewed by members of PATH. The first module, on the importance of hormone measurements and assay standardization, was released in December 2020. The second module, on hormone types and the characteristics of an ideal assay, was released in May 2021. Module 3, released in August of 2021, focuses on methods used to measure hormones and judging the quality of a hormone assay. Module 4 covers factors affecting interpretation of hormone concentrations for diagnosis of endocrine disease and was completed in November 2021. Each module includes a presentation and case-based questions with a real-world scenario to test the learner's knowledge. CME credit is available.

Evaluations have been extremely positive. 98% of evaluated learners said the activity was clinically sound and evidence based and that they would recommend the course to a colleague. In addition, 98% said the activity expanded their medical knowledge and improved clinical practice skills, leading to benefits to patients. The first module has had 520 enrollees, and each subsequent module has had over 100 enrollees.

The Endocrine Society has promoted the series through their communications platforms and shared it with the Association of Program Directors in Endocrinology, who also promoted it. The American Society for Reproductive Medicine has also made this available to fellows in training. The Endocrine Society developed a [communications toolkit](#) (password: hormones) for promoting the module, which was shared with PATH member organizations.

PATH members suggested several options for broadening dissemination, including:

- Promoting through the Society of Andrology
- Promoting at the annual meeting of the International Society of Endocrinology

- Promoting at the monthly Andrology Fellowship Directors Meeting
- Having PATH members use the content to give presentations at Grand Rounds and other meetings
- Including a slide about the modules among the slides shown at Endocrine Society meetings when waiting for talks to begin
- Adapting one of the modules for primary care providers, ideally pediatric focused with case examples

#### **ACTION ITEMS:**

- PATH Members: Contact Ms. Becker if you are interested in assisting with developing a module for primary care providers.
- PATH Members: Encourage your organization to [promote](#) the online modules.
- PATH Members: Contact Ms. Becker with a list of meetings you would be able to present at.
- Ms. Becker will create a PowerPoint that can be used for these presentations.

Ms. Becker shared traffic statistics on the PATH website, which receives about 700-1,000 unique visitors each month. The number of visits goes up when there is new content shared (for example, there has been an increase in traffic when modules are released). She encouraged PATH members to contribute news items and to have their organization link to the PATH website in order to increase traffic.

An upcoming activity will be creating a user-friendly version of the list of CDC-certified assays to include on the PATH website. This list is housed on the CDC website, but there are limitations on how the information can be presented and it is very technical. Workgroup members are needed to assist with adapting the list and making it easier for providers, patients, insurers, and researchers to use.

Ms. Becker also encouraged PATH members to contribute to the PATH newsletter. This is an opportunity for organizations to connect to a broader audience and increase visibility. Examples of items to share include new practice guidelines, white papers, and educational offerings. Ms. Becker reaches out directly to communications staff at the member organizations, but it would be helpful if PATH members could help elevate those requests.

#### **ACTION ITEMS:**

- PATH Members: Contact Ms. Becker if you are interested in helping to create the user-friendly list of CDC-certified assays.
- PATH Members: Talk with your organization's communications team about linking to the PATH website and contributing to the PATH newsletter.
- Ms. Becker will share with PATH members her list of communications contacts at each organization for review and updating.

#### ***Work with Insurers***

Laura DeStigter summarized PATH's work with insurers. In the 2020-2021 project year, PATH had a productive partnership with Avalon Healthcare Solutions. Avalon updated 3 medical policies to strongly recommend the use of CDC HoSt certified assays, developed an educational brief on the importance of standardized assays, and hosted a webinar for their network on the importance of standardized testosterone tests that featured Drs. Matsumoto and Vesper. In the coming year, the PATH project team

will explore opportunities to continue to partner with Avalon and is planning a focus group with several insurers to help inform future activities in this sector.

### ***Other Discussion***

The need for post-market manufacturing for big manufacturers was raised. Many manufacturers do not want to update their calibration, as they've already been approved by FDA, and this affects accuracy over time.

## **Member Updates**

### ***American Thyroid Association***

Kelly Hoff shared information about the ATA and provided an overview of current initiatives related to the work of PATH. Key initiatives include the development of clinical practice guidelines and statements, a monthly thyroid health blog, patient resources, and publications and education. ATA currently has 5 guidelines, a consensus statement, and 3 statements that are in the process of being developed or updated. PATH members are invited to engage through the monthly [blog](#). Over 50 downloadable patient [brochures](#) are available, with 6 being updated this year. Multiple sessions at the 2022 ATA Annual Meeting will relate to PATH's work, including a symposium and workshop on standardization of thyroid hormone assays. ATA also maintains a lab services [library](#) for professionals and publishes research articles.

Dr. Vivian Weiss spoke further about ATA's upcoming symposium on advances and challenges of thyroid function testing and special publication on thyroid function tests. These will include information on the clinical utilities of TSH, T4, and T3 measurements and factors to consider when choosing an assay method, as well as the analytic performance and limits of thyroid testing. To date, international harmonization and standardization of thyroid testing has not yet been implemented, and ATA is excited to present a global perspective on this issue.

### ***CDC***

Dr. Vesper provided an update on the CDC's clinical standardization programs for hormones. The CDC works with both assay manufacturers and clinical laboratories on a voluntary basis to ensure accurate and reliable patient results. Dr. Vesper provided an overview of CDC's program components, which correspond to each step in the standardization process: CDC reference laboratories, certification programs, and monitoring programs.

CDC's programs have shown notable improvements in the accuracy of hormone tests used in patient care and public health. They continue to develop new reference methods and programs, and are expanding to include the development of reference intervals for their standardized assays as well as to cover new technologies, such as point of care devices.

Dr. Vesper closed the meeting and encouraged members to share additional updates with Ms. Becker to include in the newsletter.