PATH Annual Steering Committee Meeting

April 29, 2022



Housekeeping

- This call is being recorded to facilitate accurate minutes (recording will not be disseminated)
- Please enable video so we can see each other
- Use the chat for questions/comments or technical difficulties
- Keep yourself muted when not speaking. Click on the microphone button on the meeting controls (or dial *6 if using phone audio) to unmute
- If you are using computer audio and your connection becomes unstable, please try disabling video or dial in by phone (number is on agenda and in calendar appointment)



Agenda

- Welcome and Introductions
- PATH Updates
 - PATH overview
 - Review of priority hormone list
 - Educational and communications activities
 - Work with insurers
- Member Updates
 - ATA
 - CDC
 - Others



Introductions

- New participants
 - ATA: Vivian Lee Weiss, MD, PhD
 - Avalon Healthcare Solutions: Michael Lemieux, PhD
 - PCOS Challenge: Melanie Cree-Green, MD and Megan Murphy
 - Others?
- Attendees by organization



PATH Updates

PATH Overview

Dr. Hubert Vesper

PATH Vision

Improved patient care and public health through universal use of accurate and reliable hormone tests in healthcare and research.

PATH Mission

To advance the development of standardized hormone assays that are traceable to a single higher order reference material and method, and to advocate for the universal adoption of these assays in medical practice and research.



• Goal 1: Standardization

Increase the number of hormone assays that are standardized

• Goal 2: Education

Deepen the knowledge of relevant stakeholder about the importance of accurate and reliable hormone assays, and assay quality in patient care, research and public health

Goal 3: Implementation

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

• Goal 4: Sustainability

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

Further details are outlined in PATH's Strategic and Communication Plans



PATH Member Organizations and Observers (in alphabetical order)

American Association for Clinical Chemistry American Society for Bone and Mineral Research American Thyroid Association American Urological Association Androgen Excess and Polycystic Ovary Syndrome Society Association of Public Health Laboratories **Avalon Healthcare Solutions** Centers for Disease Control and Prevention College of American Pathologists **Endocrine Society** Food and Drug Administration International Society for Andrology

Laboratory Corporation of America Mass Spectrometry & Advances in the Clinical Lab National Association of Chronic Disease Directors National Polycystic Ovary Syndrome Association – PCOS Challenge NIH National Institute of Child Health and Human Development North American Menopause Society Pediatric Endocrine Society Quest Diagnostics Roche Diagnostics Corporation Siemens Healthineers

PATH welcomes its new members and looks forward to a productive collaboration!



PATH's work is addressing a long-standing critical need that is common across different organizations and stakeholders



Priority Hormone List

Dr. Hubert Vesper

PATH list of hormones with high need for standardization

- Adrenocorticotrophic hormone (ACTH)
- Aldosterone
- Anti-Mullerian hormone
- CEA
- Cortisol
- DHEAS
- D-dimer
- Estradiol
- Estrone
- Folate
- Follicle Stimulating Hormones (FSH)
- Growth hormone
- Inhibin B
- Insulin-like growth hormone 1 (IGF-1)

- Insulin-like growth factor binding protein-3 (IGFBP-3)
- Luteinizing hormone (LH)
- Parathyroid hormone
- Progesterone
- PSA
- Serum Albumin
- Testosterone, including free-testosterone
- Thyroglobulin
- Thyroid hormones (T3, T4), including free-T4
- Thyroid-stimulating hormone (TSH)
- Thyroid peroxidase (TPO) antibodies
- Vitamin D
- 17-Hydroxyprogesterone

PATH list of hormones with high need for standardization

- Creates awareness among PATH members and the public
- Assists with prioritization of standardization activities and resources
- PATH initially focused on testosterone only and has now activities on 15 hormones

PATH list of hormones with high need for standardization

- Adrenocorticotrophic hormone (ACTH)
- Aldosterone
- Anti-Mullerian hormone
- CEA
- Cortisol
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PATH Educational and Communications Activities

Mila Becker, JD Endocrine Society

Accurate Hormone Testing Course

Module	Title	Faculty	Released
1	The Importance of Hormone Measurements and Assay Standardization	Dr. Alvin Matsumoto	December 2020
2	Hormone Types Characteristics of an Ideal Assay	Dr. Christina Wang, Dr. Frank Stanczyk	May 2021
3	Methods Used to Measure Hormones Validation and Judging the Quality of a Hormone Assay	Dr. Rob Fitzgerald, Dr. Nanette Santoro	August 2021
4	Factors Affecting Interpretation of Hormone Concentrations for Diagnosis of Endocrine Disease	Dr. Jack Fuqua	November 2021

Peer-reviewers: Dr. Hubert Vesper, Dr. Rob Fitzgerald, Dr. Alvin Matsumoto



Process and Composition of Each Module

CASE-BASED QUESTIONS

Page 1 of 2

QUESTION 1

You are caring for a 35-year-old woman with Hashimoto thyroiditis. She had been taking 125 mcg of levolthyroxine dially for the previous 6 years. TSH Levels performed at your hospital tab had been stable in the 0.75-10 mU/L range for that time (and beness fatigue, coid intolerance, or abnormal menses. Because of insurance changes, she goes to her local lab for measurement of TSH and there 14, your find that her TSH is now 0.45 mU/L (reference interval 0.5-4.5 mU/L), with a stable free T4, and you becrease the levolthyroxine does to 112 mcg daily. Tow months later, the patient catios complaining of fatgue, heavy menses, and an enlarging gotter. You have her repeat the TFHs at your hospital lab and find that PTSH is now 35 mU/L.

Of the following, the most likely reason for the variable TSH results is:

CHOOSE ONE

A. Diurnal variation in TSH secretion.

B. Her local lab uses a non-commutable calibrator for its assay.

O C. She had transient production of a TSH receptor stimulating antibody.

D. The patient's pharmacy erred in filling her prescription.









Endocrine Society

certifies that

Maggie Graham

attended the educational activity titled

Accurate Hormone Testing - Module 1: The Importance of Hormone Measurements and Assay Standardization

on Tue, 12/08/2020 - 12:00pm - Sat, 12/31/2022 - 11:59pm.

The Endocrine Society is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Endocrine Society designates this activity for a maximum of 1.50 AMA PRA Category 1 CreditsTM.

Activity duration: Tue, 12/08/2020 - 12:00pm - Sat, 12/31/2022 - 11:59pm Certificate generated: April 23, 2021

Muhille L. Klink Michelle I. Klinke

Director, Education Endocrine Society

Evaluations So Far

- Module 1: 520 total enrollees, 149 evaluations
- Module 2: 189 total enrollees, 76 evaluations
- Module 3: 116 total enrollees, 48 evaluations
- Module 4: 112 total enrollees, 34 evaluations
- 98% of evaluated learners say the activity was clinically sound and evidence based, and that they would recommend the course to a colleague.
- Many learners found the content to be an important subject, unique, helpful, and welcome – and that the content addresses common issues in clinical practice.
- 98% said the activity has expanded medical knowledge and improved clinical practice skills, leading to benefits to patients.
- 62% said this would improve interpretation of testing results, and 78% said this would improve the accuracy of diagnosis.



What Learners Are Saying

"A much-needed topic that isn't taught during the fellowship."

"This is an important topic, and more should be dedicated to increase awareness."

"Thank you for taking the time to create this module! Very helpful as education at my current fellowship program is pretty limited and I am depending on utilizing secondary materials and sources."

"Good session with clear overview and practical points."

"Every clinical endocrinologist should be reviewing this info all the time."



How We're Promoting

FELLOWS TRAINING SERIES: SUPPLEMENTAL COURSES

VIEW EDIT REVISIONS CLONE

Thank you for your participation in FTS! In addition to the core curriculum we have developed, there are numerous Society resources that are designed specifically for fellows. Please see these additional courses below; if your fellows would benefit from this content, please share these courses with them.

Accurate Hormone Testing



New Releases in the Center for Learning

If you find yourself with some free time during this holiday season, take advantage of the new on-demand education opportunities in our Center for Learning. These sessions, available for viewing at any time, are a great way to catch up on the latest developments in endocrinology or to earn a few education credits before the end of the year.

Better Bones: A Course on Osteoporosis & Metabolic Bone Disease Each course is worth 1.0 AMA PRA Category 1 Credit[™] and 1.0 ABIM MOC Point.

Telehealth and Diabetes Technology: A New Approach to Patient Care 0.5 AMA PRA Category 1 Credit[™] and 0.5 ABIM MOC Point

Partnership for the Accurate Testing of Hormones (PATH): Module 1 1.5 AMA PRA Category 1 Credits™



On-Demand Education Study at Your Own Pace

If you are searching for learning opportunities that you can engage with on your own schedule, look no further than the on-demand education sessions in our Center for Learning. These courses are accessible for viewing any time and make for an excellent way to continue your education in endocrinology at your own pace. Take a look at a few of our offerings below and visit the <u>Center for Learning</u> to see a full listing of available modules.

Partnership for the Accurate Testing of Hormones (PATH): Module 1

1.5 AMA PRA Category 1 Credits[™] As part of a four-module series on hormone testing, Module 1 features Alvin M. Matsumoto, MD in a didactic presentation on the importance of hormone measurements and assay standardization.



PATH Member Feedback

- <u>https://www.hormoneassays.org/social-media-toolkit/</u>
- Other promotion opportunities
- Future opportunities to leverage module content
 - Adapt for meeting presentations
 - Share with primary care associations
 - Other ideas

PATH Communications Activities

PATH Website (www.hormoneassays.org)

PATH Quarterly Newsletter

PATH Member Communication Collaboration



PATH Website Activity: January 2021 – March 2022



Month	Unique visitors	Number of visits	Pages	Hits	Bandwidth
Jan 2021	831	1,465	8,988	12,245	13.08 GB
Feb 2021	762	1,369	7,447	10,404	11.65 GB
Mar 2021	741	1,315	6,428	9,428	11.92 GB
Apr 2021	709	1,218	6,442	8,684	7.71 GB
May 2021	813	1,471	6,702	10,355	20.00 GB
Jun 2021	800	1,367	6,291	10,334	21.11 GB
Jul 2021	1,154	1,724	8,064	16,041	80.81 GB
Aug 2021	965	1,734	29,310	33,693	32.60 GB
Sep 2021	871	1,523	13,100	15,117	13.18 GB
Oct 2021	1,082	1,914	7,199	8,478	5.68 GB
Nov 2021	806	1,753	7,116	8,288	5.57 GB
Dec 2021	963	1,895	7,774	9,878	10.49 GB
Total	10,497	18,748	114,861	152,945	233.80 GB



Month	Unique visitors	Number of visits	Pages	Hits	Bandwidth
Jan 2022	1,054	1,949	8,021	9,499	7.32 GB
Feb 2022	1,078	1,864	7,048	8,543	6.58 GB
Mar 2022	1,042	1,989	7,668	9,697	8.65 GB
Apr 2022	552	1,044	4,663	5,709	3.84 GB
May 2022	0	0	0	0	0
Jun 2022	0	0	0	0	0
Jul 2022	0	0	0	0	0
Aug 2022	0	0	0	0	0
Sep 2022	0	0	0	0	0
Oct 2022	0	0	0	0	0
Nov 2022	0	0	0	0	0
Dec 2022	0	0	0	0	0
Total	3,726	6,846	27,400	33,448	26.39 GB

PATH Member Engagement Opportunities

PATH Website

- Seeking workgroup members to assist with creating a userfriendly list of CDC-certified assays to include on the site
- Encourage your organizations to link to the site

PATH Newsletter

- Next issues May and July
- Encourage your organizations to contribute

Collaboration with PATH Member Communications Staff

- Opportunity to broaden PATH's messages and support members
- Encourage greater collaboration related to website, education, and meetings



Work with Insurers

Laura DeStigter, MPH NACDD



Avalon Healthcare Solutions has become a member of the <u>Partnership for the Accurate</u> <u>Testing of Hormones</u> (PATH), a national network of clinical, medical, laboratory and public health organizations and experts working to improve patient care through the universal use of standardized accurate and reliable hormone tests in healthcare and research.

Because there is a well-established Centers for Disease Control and Prevention (CDC) standardization program, numerous standardized assays available, and a harmonized reference range for total testosterone, Avalon strongly recommends that providers and payers respectively order and reimburse only standardized total testosterone assays for laboratory evaluation of patients.

Overview

- Collaborated with Avalon Healthcare Solutions
 - Updated 3 medical policies to strongly recommend use of CDC HoSt certified assay
 - Developed an educational "Snippet"
 - Presented on webinar
- Additional activities planned
 - Continue work with Avalon
 - Outreach to Beacon LBS
 - Potential focus group

Member Suggestions

 What other activities should we consider for next project year (Aug. 1, 2022-July 30, 2023)?



BREAK



Member Updates 📩



ATA Presentation

Kelly Hoff & Amanda Perl

ATA Highlights

April 29, 2022





Vision - Optimal Thyroid Health For All



Mission - Transforming care through clinical excellence, education, scientific discovery, and advocacy in a diverse, collaborative community



Key initiatives and Lab Focused Resources/Priorities





Guidelines and Statements Update Guidelines In-progress: -Differentiated Thyroid Cancer (DTC) -Thyroid Nodules -Pediatric Thyroid Cancer -Medullary Thyroid Cancer (MTC) Systemic Therapies -Thyroid and Pregnancy

Consensus Statement (to be published in May): -ATA & ETA Consensus Statement on Management of Thyroid Orbitopathy

Statements In-progress:

-Thyroid Function Tests -Ablation Techniques for Benign Nodules -Molecular Testing of Thyroid Nodules



ATA Monthly Thyroid Health Blog

Member Posts Discussing Thyroid Conditions and Thyroid Cancer Topics Published to ATA Website and Social Media https://www.thyroid.org/category/thyroid-health-blog/



Thyroid Health Blog: Obesity and Thyroid Function Tests in Children Blog Post



Thyroid Health Blog: An Individualized Approach to Thyroid Hormone Replacement in Thyroid Cancer Patients Blog Post



Thyroid Health – Management of Hypothyroidism During Pregnancy: When and how to treat? Blog Post



Thyroid Health Blog: w to Congenital Hypothyroidism awareness: The importance of newborn screening Blog Post



Thyroid Health Blog: Is Prescription Levothyroxine Really an Artificial Hormone? Blog Post



Thyroid Health Blog: Thyroid Disruption and Triclosan in Consumer Products – Is the threat contained? Blog Post



Thyroid Patient Information

ATA's Patient Information Portfolio includes 50+ downloadable patient brochures for adult and pediatric audiences and their families in both English and Spanish. https://www.thyroid.org/thyroid-information/

AMERICAN THYROID ASSOCIATION WWW.thyroid.org Thyroid Function Tests Wat Is the Market and Association and Association Wat Is the Market and Association and Association	C AMERICAN THYROID ASSOCIATION www.thyroid.org	C AMERICAN THYROID ASSOCIATION NYWW.thyroid.org Iodine Deficiency	Rrand and Generic Medication Evolained	2022 Brochure Updates
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2022 Annual Meeting **Program Co-Chairs:** Christopher McCabe, PhD & Maria Papaleontiou, MD

Plenary sessions

- Radiation-Related Genomic Profile of Papillary Thyroid Carcinoma After the Chernobyl Accident
- Precision Thyroid Care: Avoiding Over-and Under Treatment of Thyroid Cancer

• New in 2022

- Diversity, Equity, and Inclusion Networking Sessions
- Poster tracks pediatrics and surgical
- Women in Thyroidology Plenary & Networking
- Interesting Clinical Cases (Non-Cancer)
- Standardization of Thyroid Hormone Tests Symposium & Workshop

Event Website: https://www.thyroid.org/91st-annual-meeting-ata/

Highlighted Symposia

- Highlighting Disparities in Access to Care for Patients With Thyroid Disease and Cancer
- Molecular landscape of pediatric thyroid cancer
- Thyroid Disease in Women: Understanding Sex-based Differences
- Living Beyond Thyroid Cancer: Improving Thyroid Cancer Survivorship
- Surgical Approach to Thyroid Cancer Informed by Molecular Testing
- Universal Screening for Thyroid Dysfunction
- Management of Graves' Ophthalmopathy and New Monoclonal Treatments
- Thyroid Disease, Endocrine Disruptors, Nutrition and Health



ATA'S LAB RELATED PUBLICATIONS AND EDUCATIONAL CONTENT



Laboratory Services Library

Home » Professionals Portal » Laboratory Services Library

ABOUT

The Laboratory Services Committee of the American Thyroid Association (ATA) conducted a survey of ATA members to identify areas of member interest for education in pathology and laboratory medicine. In response to the results of the survey, the Lab Service Committee developed a series of educational materials to share with the ATA membership. The topics below were ranked as high educational priorities amongst the membership.



Lab Services Library for Professionals

https://www.thyroid.org/professionals/laboratory-services-library/



Recently Published Articles

Thyroid, Just Accepted

Serum Thyroglobulin Measurement Following Surgery without Radioactive Iodine for Differentiated Thyroid Cancer: A Systematic Review

Dr. Roger Chou 🖂, Ms. Tracy Dana, Dr. Gregory A Brent, Dr. Whitney Goldner, Dr. Megan R. Haymart, Dr. Angela M. Leung, Dr. Matthew D Ringel, and Dr. Julie Ann Sosa

Published Online: 12 Apr 2022 | https://doi.org/10.1089/thy.2021.0666

Thyroid, Vol. 31, No. 9 | Original Studies

🔂 Open Access | 🕝 🛊

Measurement of Reverse Triiodothyronine Level and the Triiodothyronine to Reverse Triiodothyronine Ratio in Dried Blood Spot Samples at Birth May Facilitate Early Detection of Monocarboxylate Transporter 8 Deficiency

Hideyuki Iwayama ⊡, Hiroki Kakita, Masumi Iwasa, Shinsuke Adachi, Kyoko Takano, Masahiro Kikuchi, Yasuko Fujisawa, Hitoshi Osaka, Yasumasa Yamada, Akihisa Okumura, Khemraj Hirani, Roy E. Weiss, and Samuel Refetoff Published Online: 7 Sep 2021 | https://doi.org/10.1089/thy.2020.0696

Thyroid, Vol. 31, No. 8 | Original Studies

Biotin Interference in Assays for Thyroid Hormones, Thyrotropin and Thyroglobulin

Dorina Ylli, Steven J. Soldin, Brian Stolze, Bin Wei, Girum Nigussie, Hung Nguyen, Damodara Rao Mendu, Mihriye Mete, Di Wu 💿 Cristiane J. Gomes-Lima, Joanna Klubo-Gwiezdzinska, Kenneth D. Burman, and Leonard Wartofsky 🖂

Published Online: 3 Aug 2021 | https://doi.org/10.1089/thy.2020.0866

Thyroid, Vol. 31, No. 5

🔂 Open Access | 💿 🛊 😒

Thyroid Laboratory Testing and Management in Women on Thyroid Replacement Before Pregnancy and Associated Pregnancy Outcomes

Patricia Lemieux, Jennifer M. Yamamoto, Kara A. Nerenberg, Amy Metcalfe, Alex Chin, Rshmi Khurana, and Lois Elizabeth Donovan 🖂

Published Online: 3 May 2021 | https://doi.org/10.1089/thy.2020.0609



2022 Lab Focused Education

- 2022 Sawin Lecture: Neonatal Screening for Congenital Hypothyroidism
- 2022 Publication in *Thyroid*[®] Expected for Special Article on *Thyroid Function Tests*
- ATA 2022 Annual Meeting Program planned for Sunday, October 23:

Updates on Thyroid Testing: Symposium & Workshop



Laboratory Advances & Challenges

Vivian Weiss, MD, PhD, Vanderbilt University Medical Center Chair, ATA Lab Services Committee





THANK YOU!

ATA Website <u>www.thyroid.org</u>





CDC Updates

Dr. Hubert Vesper

CDC Clinical Standardization Programs (CSP)

Hubert W. Vesper, Ph.D.

Director, Clinical Standardization Programs

Division of Laboratory Sciences

PATH Meeting April 29, 2022

National Center for Environmental Health Agency for Toxic Substances and Disease Registry Division of Laboratory Sciences

CDC engages in standardization/harmonization activities to ensure that laboratory test measurements are accurate and reliable

CDC CSP Goal

Improve diagnosis, treatment, and prevention of selected diseases by standardizing clinical laboratory measurements

CDC CSP Objective

Create measurement results that are traceable to one accuracy basis and thus are comparable across methods, location, and over time

Standardization is a process in which the accuracy, precision, and other relevant analytical performance parameters of a laboratory test are improved and maintained to meet certain clinical needs

A standardized laboratory test has demonstrated through a thorough, independent assessment that its analytical performance meets relevant analytical performance goals

CDC's Clinical Standardization Programs

provide unique services at every step in the standardization process



CDC's Clinical Standardization Programs provide unique services at every step in the standardization process

CDC Reference Laboratories	Reference Methods Total testosterone Free testosterone by ED new Estradiol Free thyroxine (fT4) by ED new 25-OH Vitamin D2 and D3 PTH (fall 2022) Glucose TC, HDLC, LDLC, TG, Lp(a) (spring 2023)	Reference Materials CDC Single Donor Sera: Total testosterone, Estradiol, Vitamin D, fT4 Lp(a) Traditional reference materials (pooled sera): NIST 971a (Testosterone, Progesterone) NIST 1949 (FT4, prenatal serum) NIST 1595 (tripalmitin)	
CDC Standardization - Certification Programs	CDC Programs HoSt – Testosterone HoSt – Estradiol HoSt – free Thyroxine VDSCP CRMLN	CDC Supported Programs IFCC Committee for Standardizing Thyroid Function Tests (TSH, fT4) IFCC – Committee on Bone Metabolism (Vitamin D, PTH) National Glycohemoglobin Standardization Program (A1c)	
CDC Laboratory Monitoring Programs	CDC Programs AMP – Testosterone AMP – Vitamin D LSP	CDC Supported Programs CAP accuracy-based surveys: ABS (steroids), ABTH (thyroid), ABVD (Vitamin D) ABGIC (glucose), ABU (creatinine), ABL (Lipids)	

CDC Programs: Accuracy-based Monitoring Program (AMP); Cholesterol Reference Method Laboratory Network (CRMLN); Hormone Standardization (HoSt); Vitamin D Standardization-Certification Program (VDSCP); Lipid Standardization Program (LSP)

CDC Clinical Standardization Programs 2021 Activities in Numbers



10 Routine Methods (CLIA compliant) operational6 Routine Methods in development80,000 measurement results generated

Summary

CDC Clinical Standardization Programs

- Show notable improvements in accuracy of hormone tests used in patient care and public health
- Develop new reference methods and standardization programs to further improve patient care
- Expand activities to include development of reference intervals that can be used by laboratories operating assays standardized by CDC
- Expand to include new technologies (such as Point-of-Care Testing Devices)

Acknowledgements

CDC CSP Team

Hubert Vesper, PhD Uliana Danilenko, PhD Hui Zhou, PhD Li Zhang, PhD Alicia Lyle, PhD William Perry, PhD Karie Robertson, PhD Lumi Duke, MS Fidelia Pokuah, MPH Douglas Wirtz, MS Ashley Ribera, BS Otoe Sugahara, BS Komal Dahya, BS Paul Kim, BS Lynn Collins, BS Clark Coffman, BS Clark Coffman, BS Tatiana Buchannan, BS Bianca Smith, BS Alex Doty, BS Janet Thonkulptak, BS Tessa Szalkowski, MS Owen Glogovsky, BS Sydney Taylor BS Norma Vazquez, BS Zachary D'Zio, BS

Thank you!

For further information, please contact <u>standardization@cdc.gov</u> or visit

www.cdc.gov/labstandards/vdscp.html

Hubert W. Vesper, PhD Director, Clinical Standardization Programs <u>hvesper@cdc.gov</u>

For more information, contact NCEH/ATSDR 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348 www.atsdr.cdc.gov v Follow us on Twitter @CDCEnvironment

www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Use of trade names and commercial sources is for identification only and does not constitute endorsement by the U.S. Department of Health and Human Services, or the U.S. Centers for Disease Control and Prevention.



Wrap-up



THANK YOU