AVALON HEALTHCARE SOLUTIONS
JULY WEBINAR

July 20, 2021

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OVERVIEW & INTRODUCTIONS

Barry Davis, Chief Growth Officer, Avalon

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Refreshed Website

WWW.AVALONHCS.COM

Resources tab for past webinars, news, research & reports

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Before we start

This meeting is being recorded

We will be **MUTING** everyone except the presenter to make sure the AUDIO is clean and clear

Q&A will be done by using the **“Questions” feature**

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Agenda

OVERVIEW AND INTRODUCTIONS

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WASHINGTON, D. C. POLICY UPDATE

Julie Barnes, Principal, Maverick Health Policy

TESTOSTERONE TESTING: Is It Accurate & Driving the Right Care?

Rahul Singal, M.D., Chief Medical Officer, Avalon

Hubert W. Vesper Ph.D., Director, Clinical Standardization Programs and Chief,
Protein Biomarker Laboratory and Lipid Reference Laboratory, Centers for Disease Control and Prevention

Alvin M. Matsumoto M.D., Professor Emeritus, Department of Medicine,
Division of Gerontology and Geriatric Medicine, University of Washington

CLOSING REMARKS

Rahul Singal, M.D., Chief Medical Officer, Avalon

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POLICY UPDATE

Julie Barnes, Principal, Maverick Health Policy

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Overview

- No Surprises Act Rule
- Update on Alzheimer's Drug
- Presidential Executive Order on Competition

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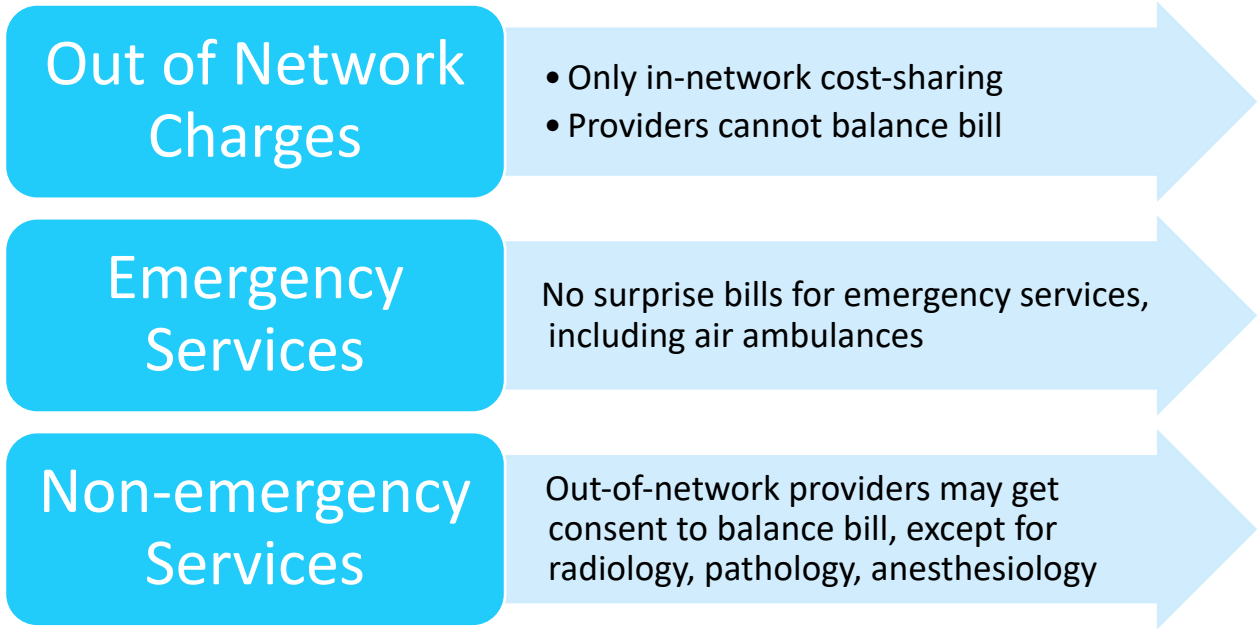
No Surprises Act – Interim Final Rule

When: Starting Jan 1, 2022

Who: All health plans, all hospitals

What:



- Rule includes notice requirements for plans and providers.
- Future rules on arbitration process, advance EOBs, price comparison tools, provider directory updates, enforcement

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Alzheimer's Treatment Update

FDA

- June 7: Approval over objections
- July 8: Narrowed eligibility from 6M to 1.5M
- July 9: FDA Commissioner calls for independent investigation

Price Controversy

- Biogen: $56,000 per year
- ICER: $3,000 to $8,400 per year

CMS

- National Coverage Determination analysis
  - Final decision in 9 months
  - Until then, coverage determinations are case-by-case

Industry

- Cleveland Clinic, Mount Sinai, Providence won't offer it
- Several BCBS health plans won't pay for it

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Executive Order:
Promoting Competition in the American Economy

- 72 recommendations and orders directing federal agencies to promote competition
- Creates White House Competition Council
- Targets hospital consolidation, non-competes, Big Tech
- Prioritizes price transparency, drug pricing, consumer privacy

Questions?

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Maverick Health Policy

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11

TESTOSTERONE TESTING: IS IT ACCURATE & DRIVING THE RIGHT CARE?

Rahul Singal, M.D., Chief Medical Officer, Avalon

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Avalon – Promoting Quality and Standardization

- For the past 50 years, the CDC has programs to assure the quality and standardization of laboratory testing, especially in chronic conditions. Details are available at: https://www.cdc.gov/labstandards/index.html
- Avalon has become a member of the Partnership for the Accurate Testing of Hormones (PATH, www.hormoneassays.org). PATH is a multi-stakeholder group working to improve patient care through the universal use of standardized accurate and reliable hormone tests in healthcare and research. The CDC is one of the participating members.
- Avalon's quality and standardization program is led by Tatiana Souslova, PhD, DABCC, VP of Medical Policy.

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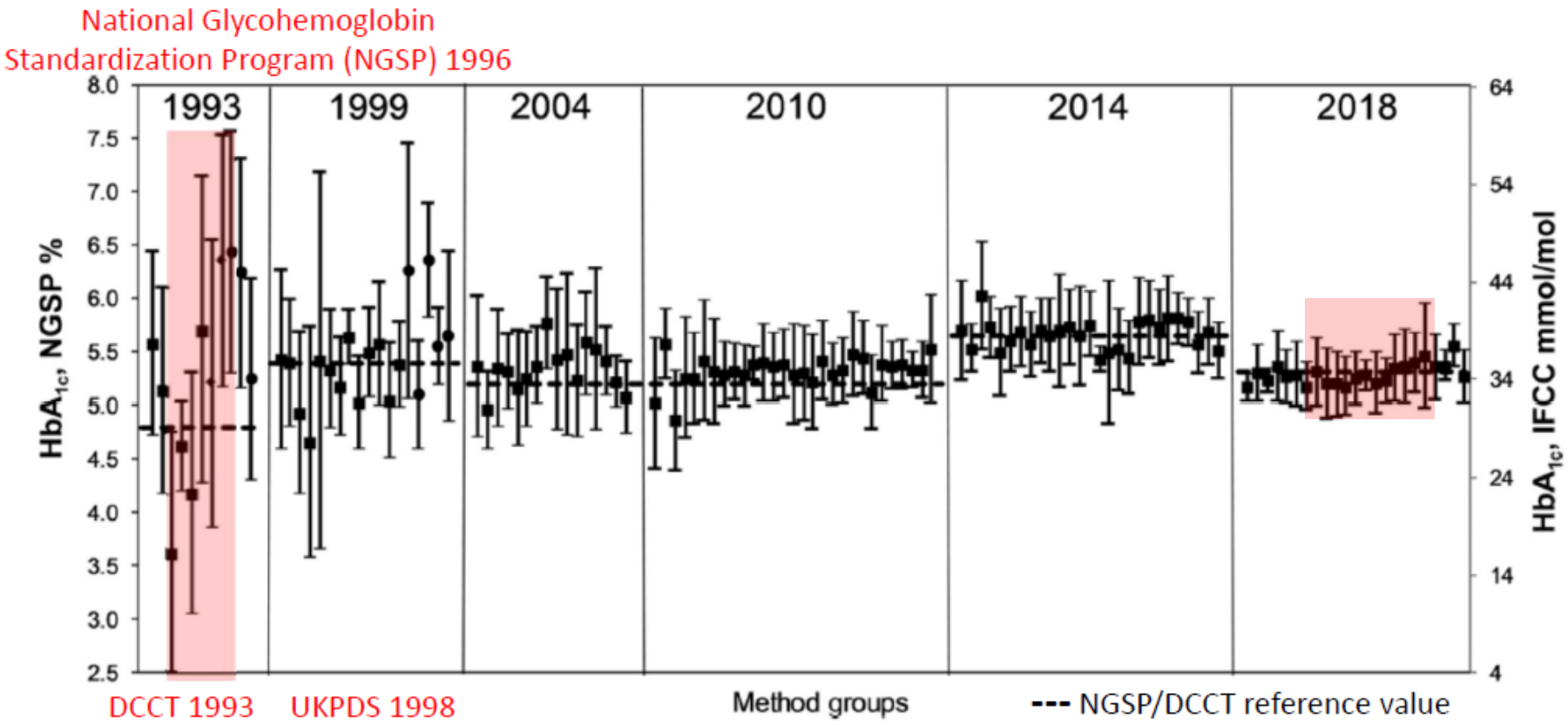
Example Lab Standard Program - Hemoglobin A1c

NATIONAL GLYCOHEMOGLOBIN STANDARDIZATION PROGRAM (NGSP) 1996



Little RR, et al, Clin Chem 65:839-848, 2019

- Breakthrough research results completed in 1990s that showed lower A1c results in fewer complications.
- However, in real world, huge variability existing in commercial labs in 1990s.
- NGSP began its standardization program in 1996.
- Reference samples variability dramatically decreased over next 10 years and continues to improve.

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Introductions

Hubert W. Vesper, Ph.D. Director, Clinical Standardization Programs and Chief, Protein Biomarker Laboratory and Lipid Reference Laboratory
Centers for Disease Control and Prevention

Alvin M. Matsumoto, M.D., Professor Emeritus , Department of Medicine, Division of Gerontology and Geriatric Medicine,
University of Washington School of Medicine

www.hormoneassays.org

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The Partnership for the Accurate Testing of Hormones (PATH)

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.

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
- Association for 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

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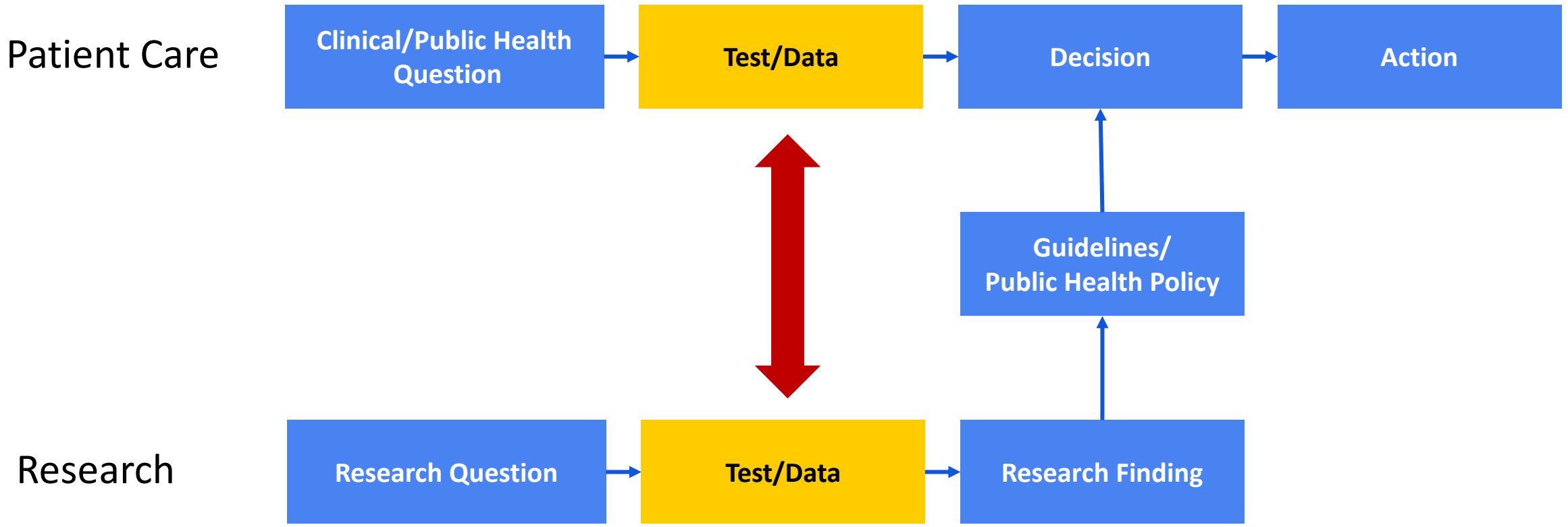
In-vitro Diagnostic Tests Used in Clinical Research and Patient Care Need to Produce Comparable Results to Effectively Diagnose Patients



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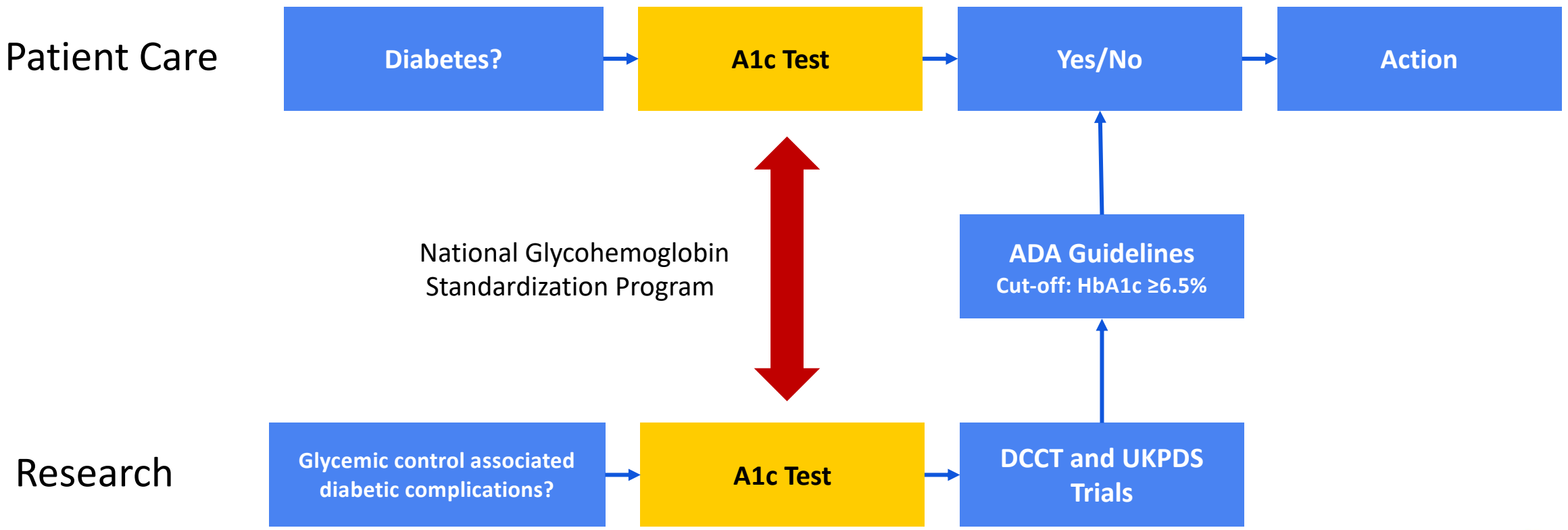
Example: Accurate and Comparable (=Standardized) A1c Tests Allow for Consistent and Reliable Diagnosis of Diabetes



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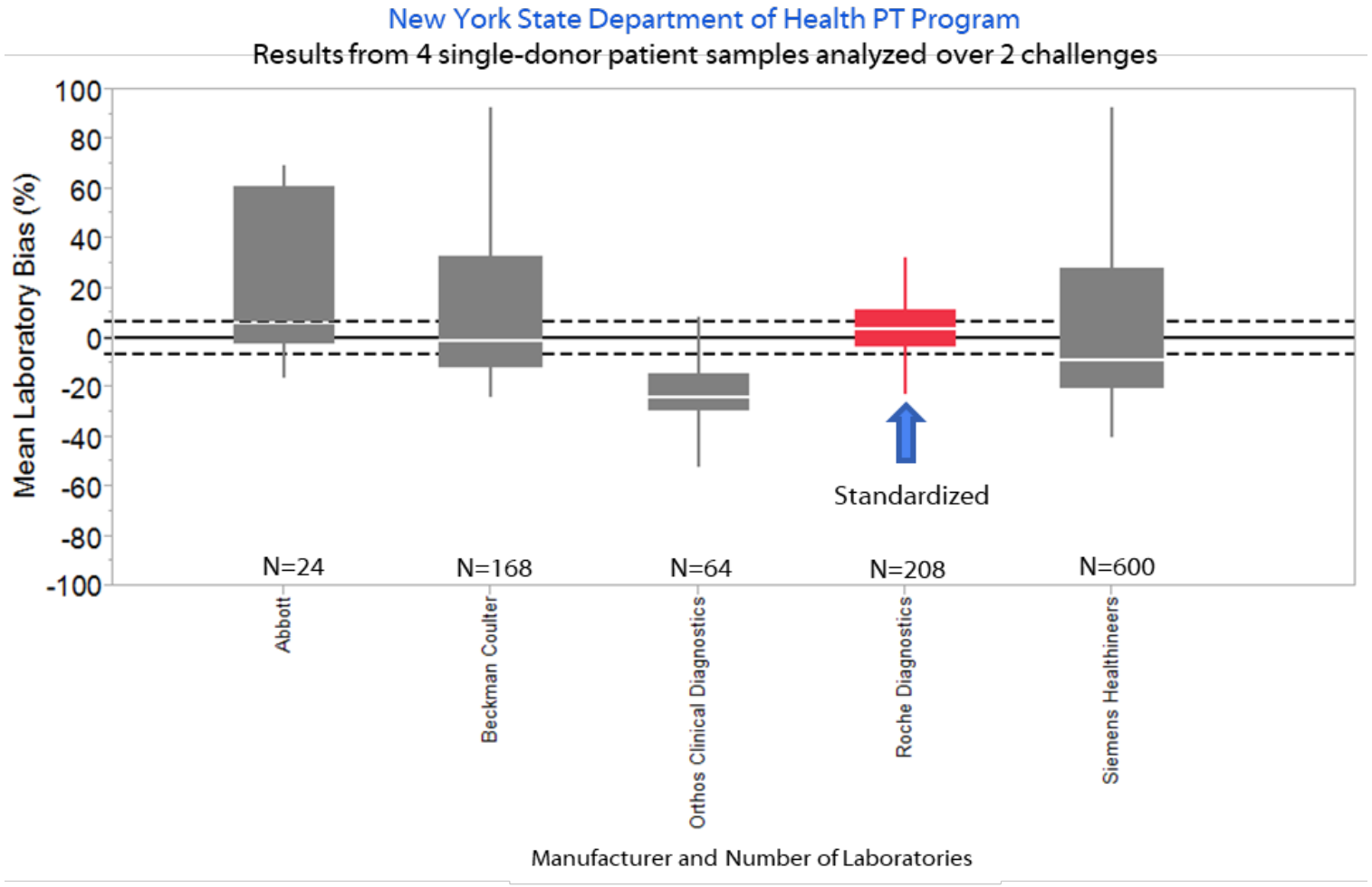
Standardized and Non-Standardized Testosterone Tests Are Currently Used in Patient Care



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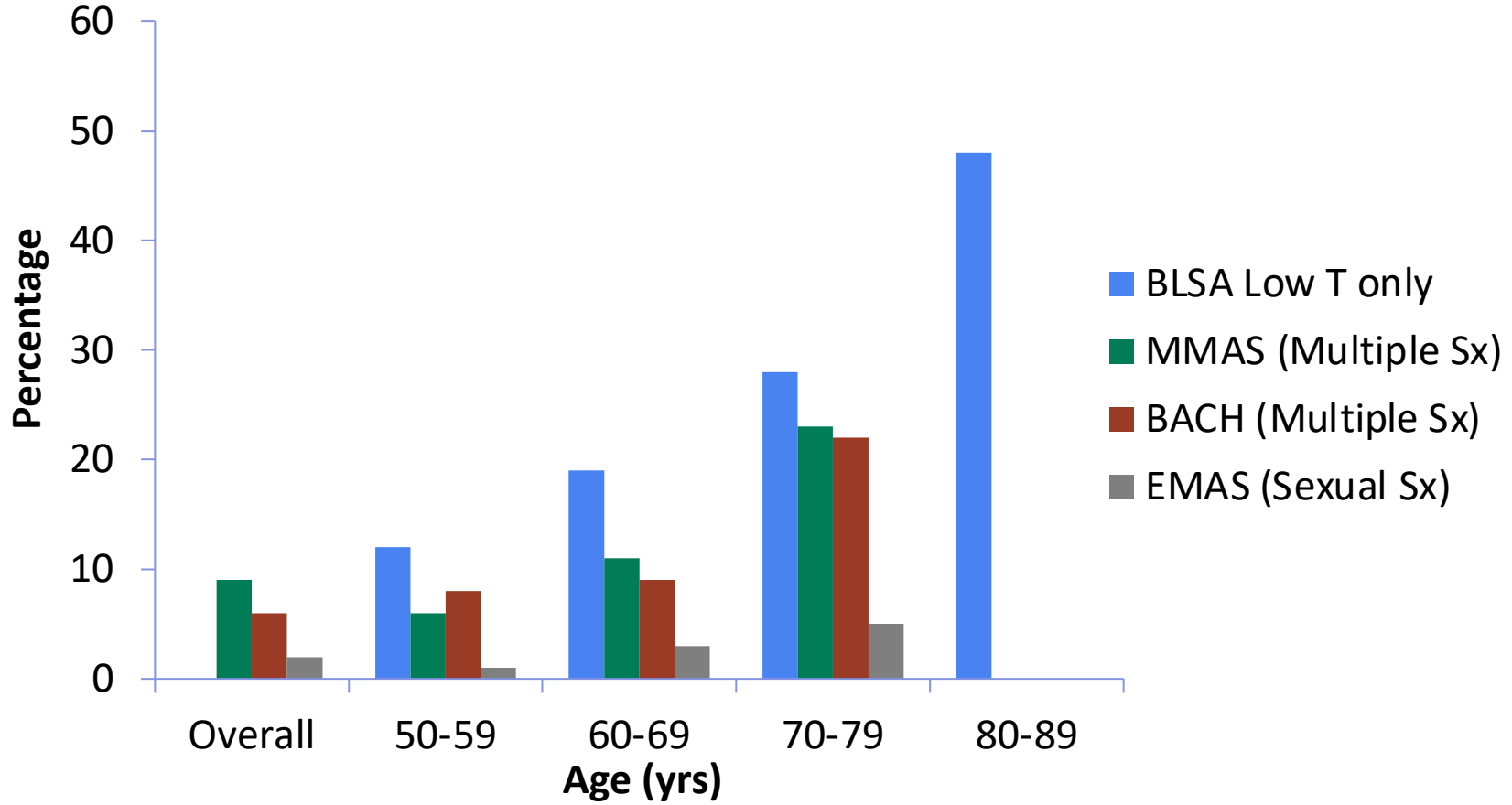
Prevalence of Low T Alone Much Greater Than Low T with Symptoms



Harman SM, et al, J Clin Endocrinol Metab 86:724-731, 2001; Araujo A, et al, J Clin Endocrinol Metab 89:5920-5926, 2004; Araujo A, et al, J Clin Endocrinol Metab 92:4241-4247, 2007; Wu FC, et al, N Engl J Med 363:123-135, 2010

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Most Total T Tests Are Not Standardized and Inaccurate
Clinical Consequences

- Over- and under-diagnosis and treatment of hypogonadism
  - Total T values and reference ("normal") ranges differ from test to test→ extreme variability
  - Inappropriate treatment with T and exposure to potential side effects of T treatment
  - Need for repeat T testing with change in practitioner
- Increased health care costs
- Inconsistent clinical practice guidelines
  - Inability to translate research findings to patient care

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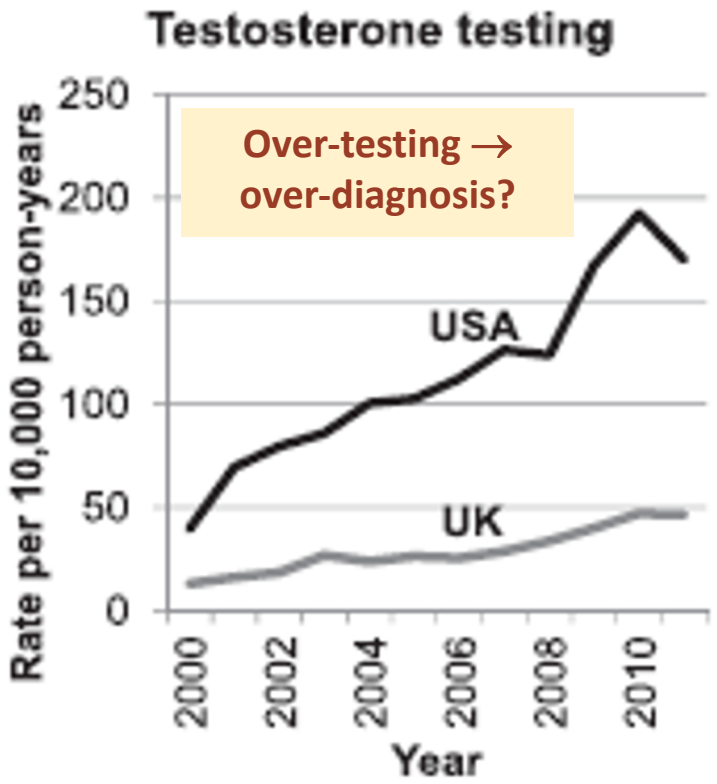
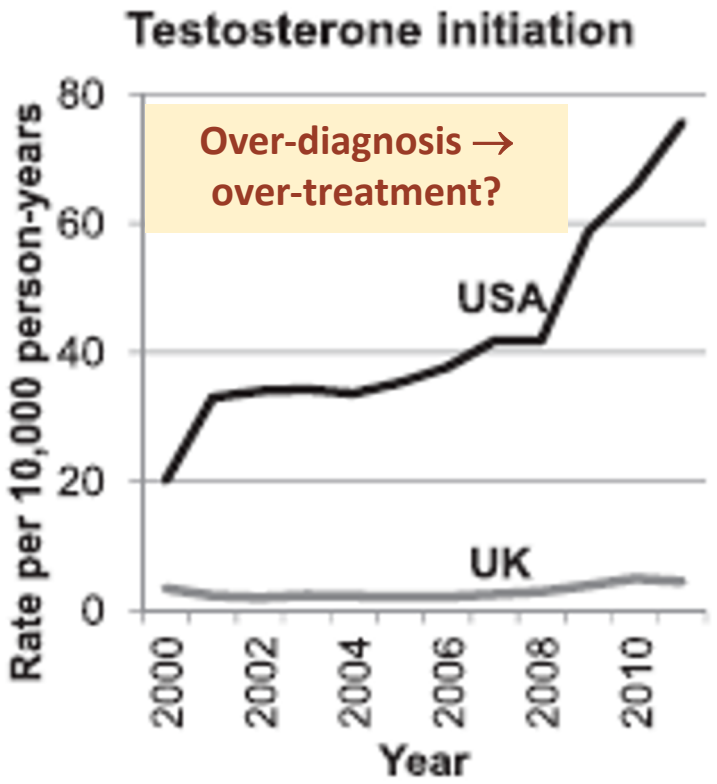
Trends in Testosterone Testing and Initiation in USA vs UK





Layton JB, et al, J Clin Endocrinol Metab 99:835-842, 2014

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T Levels in Test A vs. Test B Manufacturer
Clinically Significant Discrepant Measurements on Same Sample

Patient	Manufacturer (A) Initial T (ng/dL) (230-793 ng/dL)	Manufacturer (B) Repeat T (ng/dL) (187-950 ng/dL)
J.D	94 Low	233 Normal
L.M.	157 Low	218 Normal
M.M	155 Low	192 Normal
A.Y.	197 Low	277 Normal
K.W.	206 Low	282 Normal

Personal communication, 2019

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Extreme Variability in T Test

Serum Sample	Test Method	Number of Labs	Median T (ng/dL)	Low T (ng/dL)	High T (ng/dL)
Hypogonadal male	Immunoassays#	1133	87	45	365
	Mass Spectrometry	5	69	60	77

College of American Pathologists Test-Specific Proficiency Testing 2007

#Mostly automated platform immunoassays

Rosner W, et al, J Clin Endocrinol Metab 92:405-413, 2007

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Health Care Cost of an Initial Inaccurate Low T → Misdiagnosis of Hypogonadism

Initial Serum T Concentration

Inaccurate test	**$50**	**Accurate test**	**$50-100**
Low T		**Normal T**	

Follow-Up

Repeat T, LH, FSH, hematocrit	$175
Visit^ (discuss benefits/risks), PSA	$200

Treatment and Monitoring x 3 Months

Generic AndroGel* (w/ coupon)	$320
Visit (discuss efficacy/safety)	$150
Repeat T, hematocrit, PSA	$125

Total	**$970**

Follow-Up

Repeat T Test	$50-100

Total	**$100-200**

https://www.privatemdlabs.com ; ^ Blue Cross Blue Shield Massachusetts; * https://www.goodrx.com

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Clinical Practice Guidelines
Total T Level Threshold to Confirm Hypogonadism

- Endocrine Society
  - **CDC-standardized tests:** T < 264 ng/dL (9.2 nmol/L) x 2
    - Harmonized reference range in nonobese, young men 264-916 ng/dL [9.2-31.8 nmol/L)
  - **For non-CDC-standardized Tests:** T < lower limit of reference range may not accurately diagnose hypogonadism
- American Urological Association
  - T < 300 ng/dL (10.4 nmol/L) x 2, **irrespective of the test used**
  - BUT in 120 US labs, lower limit of T ranges 160 to 300 ng/dL
  - Used by many clinicians

Bhasin S, et al, J Clin Endocrinol Metab 103:1715-1744, 2018; Mulhall J, et al, J Urol 200:423-432, 2018; Le M, et al, J Urol 195:1556-1561, 2016

CDC's Clinical Standardization Programs Ensure That High Priority Clinical Tests Are Accurate and Reliable

CDC Standardized Tests are:

Accurate: Test calibration is appropriate and verified to be comparable to the CDC reference standard

Reliable: Analytical precision is tested to meet clinical needs

Comparable: Measurements in the same sample are similar in different tests and over time

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Centers for Disease Control and Prevention (CDC) Total Testosterone Standardization Program (HoSt TT)

CDC's Program Components

CDC Reference Laboratories

Reference Methods and Standards

CDC Standardization - Certification Programs

Calibrate and Verify Tests

Testosterone: Calibration bias ≤6.4% of reference value
Individual sera from male and female donors
Quarterly assessments

CDC Laboratory Monitoring Programs

Accuracy-based PT Programs
CDC Monitoring Programs

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CDC's Clinical Standardization Programs Use a Unique Design to Assess and Improve the Accuracy and Reliability of Tests

Design Parameters	CDC Clinical Standardization Programs	Proficiency Testing/External Quality Assurance Programs	Materials from Metrological Institutions
Specimen used	Single donor specimens	Pooled and/or modified specimens	Pooled specimens
# of samples/challenge, frequency and replicates	10 samples per challenge 4 challenges per year 2 replicates on 2 days	2 - 4 samples per challenge 2 - 12 challenges per year single measurements	1 - 5 samples # of challenges defined by lab # of replicates defined by lab
# of samples per evaluation	40	4 - 24	1 - 5
Performance evaluation performed by	CDC	PT/EQA Providers	User/Laboratory
Performance criteria based on	Clinical needs	Regulatory requirements and/or peer group distribution	User/Laboratory specification

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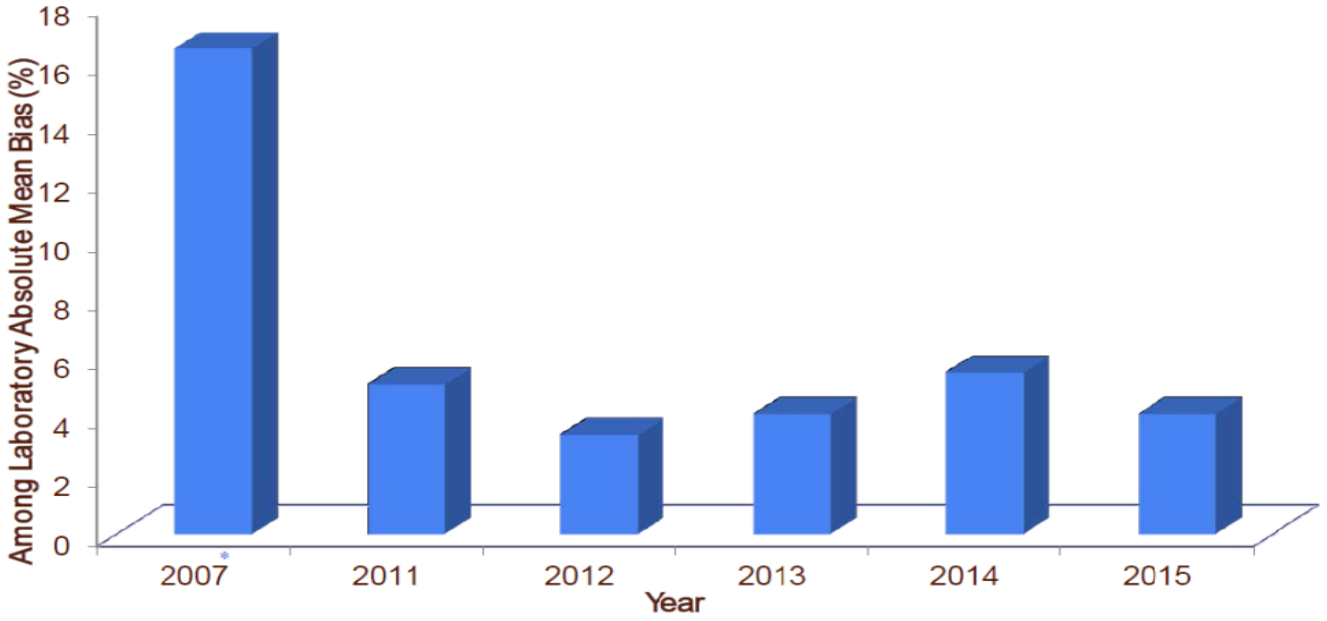
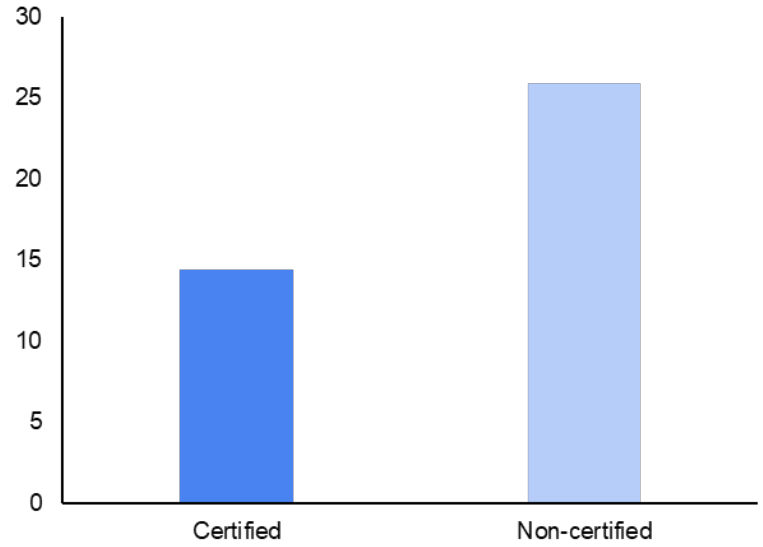
Improved Accuracy of Testosterone Tests After Enrollment in CDC Testosterone Standardization Certification Program

Absolute bias among laboratories participating in CDC HoSt TT



Absolute mean bias for testosterone of 3 survey samples in the 2018 CAP Accuracy Based Steroids (ABS) Survey



Courtesy of HW Vesper, CDC, 2018

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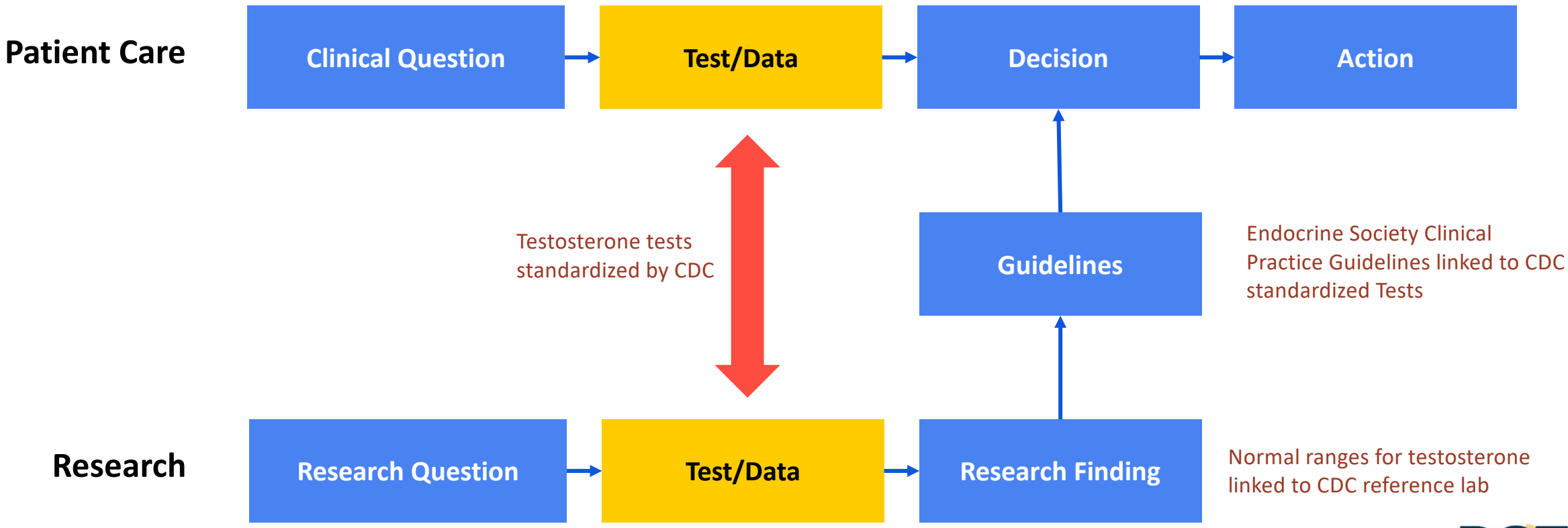
PATH, in Collaboration with the Endocrine Society and CDC, Created All Tools for Effective Evidence-Based Clinical Decision Making When Treating Hypogonadism



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Summary

- FDA-cleared tests used in CLIA-certified laboratories are not always sufficient to ensure correct diagnosis and appropriate patient care
- CDC Clinical Standardization Programs increase the accuracy and reliability of testosterone and other chronic disease biomarker tests to improve the diagnosis and treatment of patients
- PATH supported research and promotion of CDC-certified testosterone tests enabled evidence-based clinical decision making to diagnose hypogonadism
- More education is needed as standardized and non-standardized tests are used in patient care without distinction and clinical practice guidelines and standardized laboratory tests are not appropriately utilized

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Additional References and Resources

- The Partnership for the Accurate Testing of Hormones (PATH) - www.hormoneassays.org
- CDC, Standardizing Hormone Measurement: https://www.cdc.gov/labstandards/pdf/hs/HoSt_Brochure.pdf
- Endocrine Society, CME webinars for physicians - https://education.endocrine.org/content/accurate-hormone-testing-module-1-importance-hormone-measurements-and-assay-standardization
- Harmonized Reference Ranges for Circulating Testosterone Levels in Men of Four Cohort Studies in the United States and Europe, Journal of Clinical Endocrinology and Metabolism, https://academic.oup.com/jcem/article/102/4/1161/2884621
- Laboratory Quality Assurance and Standardization Programs - ttps://www.cdc.gov/labstandards/index.html

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CLOSING REMARKS

Rahul Singal, M.D., Chief Medical Officer, Avalon

Avalon Lab Insights

CRITICAL INSIGHTS AT EACH STEP TO DELIVER VALUE-DRIVEN CARE

RIGHT TEST

- Evidence-based lab policies
- Policy enforcement
- Prior authorization
- Lab network

RIGHT DATA

- Lab results capture
- Digitized lab results, across network in real time
- Prior authorization and payment decisions

RIGHT INTEL

- Advanced analytics & rules engine
- Early detection of disease
- Performance reporting
- Clinical decision support

RIGHT CARE

- Lab-informed treatment
- Clinical pathway adherence
- Optimized outcomes
- Lower healthcare costs

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Thank you

Look out for an invitation to our next webinar

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