VDSP: So Far and Plans for the Future

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for the
Vitamin D Standardization Program (VDSP)
A Brief Chronology

2004: Mary Francis Picciano (1946-2010) and NIST collaboration (Karen Phinney, lead): RMP and SRM 972 & 2972

2005: Collaborations Graham Carter (DEQAS) & Linda Thienpont at Ghent University.

2007: Vitamin D and Health in the 21st Century

2009: Release of SRMs 972 and 2972

2010: 1st VDSP meeting, Bethesda, MD (15 Nov)
A Brief Chronology

- 2011: JCTLM approval of NIST & Ghent RMPs
  VDSP Interlaboratory & commutability (Oct)
- 2012: CDC Standardization-Certification Program
  DEQAS becomes Accuracy-Based EQA
- 2013: CAP nominates representative to VDSP
- 2013: VDSP Meeting, Nov 14 - sponsorship by AACC, IFCC and PATH
VDSP Reference Measurement System Components

- NIST & Ghent RMPs
- NIST Standard Reference Materials (SRM)
- CDC Vitamin D Standardization-Certification Program
- Accuracy-Based Quality Assurance Programs
- Study designs for standardizing completed studies
Plans for the Future #1

• Publish:
  • NIST and Ghent Comparison
  • Interlaboratory Comparison Study Results
  • Commutability Results
  • Baseline data from DEQAS on accuracy and precision among assays
  • Standardized results from national health and nutrition surveys
Plans for the Future #2

- Continue analytical methods development
- Search for ways to improve serum samples used in calibration
- Promote standardization of completed studies
- Work with medical and professional societies to promote standardization in both clinical laboratories and in funded research
Work with individual:

- **Assay manufacturers** to help them improve accuracy and precision
- **Laboratories** through PT/EQA programs to help improve their accuracy and precision
Standardization Does Not Require a Single Analytic Approach

* Measurement Procedure
Calibration Traceability Scheme*

Reference procedure (LC-IDMS or GC-IDMS) Reference Laboratories

Primary Calibrator

Calibration

Single Donor Samples

Calibration

Commmutable SRM

Accuracy-Based PT/EQA

Commmutable Samples

Assay Manufacturer

Clinical Laboratory

* Adapted from: Myers G. Steroids 2008;73:1293-1296
Steps You Can Take to Achieve Standardization

- NIST SRMs: 972a and 2972
- CDC’s Vitamin D Standardization-Certification Program -
  - Immunoassay manufacturers
  - Commercial and large clinical laboratories
- Accuracy-Based Quality Assurance Programs:
  - CAP
  - DEQAS
  - NIST-NIH VitDQAP
- Send us your suggestions for improving VDSP
**Suggested Assay Performance Limits Based on Biological Variation**

<table>
<thead>
<tr>
<th>Measurements</th>
<th>CV (%)</th>
<th>Bias (%)</th>
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</thead>
<tbody>
<tr>
<td>Reference Labs</td>
<td>≤ 5%</td>
<td>≤ 1.7%</td>
</tr>
<tr>
<td>“Routine” Labs</td>
<td>≤ 10%</td>
<td>≤ 5%</td>
</tr>
</tbody>
</table>

Ask yourself?

- What’s your assay’s %CV? Is it ≤ 10%
- What’s your assay’s Bias? Is it ≤ 5%
Thank you!
Thank you - NIST!
Thank you sponsors - AACC, IFCC, PATH!
Thank you - Moderators, Speakers & Discussants!
Thank you - VDSP Members!
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  - Joyce Merkel
  - Mary Frances Picciano*
  - Christopher Sempos**
  - Paul Thomas
  - Anne Thurn
  - Elizabeth Yetley

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Thank you - Meeting Attendees!