

Frequent inaccuracies in testosterone testing lead to call for standardization

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The use of testosterone assays for patient care and research is on the rise as new research links testosterone to a variety of diseases and conditions. Although the assays are heavily used, discrepancies and inaccuracies in measurements resulting from the various assays are widespread. Seeking to address this critical health issue, a multidisciplinary group of experts convened by The Endocrine Society and the US Centers for Disease Control and Prevention just issued recommendations for improving and standardizing testosterone testing in a consensus statement to be published in the October 2010 issue of The Endocrine Society's *Journal of Clinical Endocrinology & Metabolism (JCEM)*.

Testosterone assays are tests that measure [testosterone](#) levels which, in turn, are used to diagnose and treat patients with a number of disorders. These disorders may include: testicular or pituitary diseases in men potentially leading to erectile dysfunction and decreased sexual drive; polycystic ovarian syndrome which may cause menstrual disturbances and infertility in women; and early or late pubertal development in children.

"The development of this [consensus statement](#) has been a collaborative effort among key stakeholders including professional societies, laboratories and regulatory agencies," said William Rosner, MD, a lead author of the consensus statement and a member of The Endocrine Society. "Not only does this entire group benefit from better assays, but all bear some responsibility in working to improve accuracy."

Aimed at improving the quality of research, patient care and public health through broad implementation of standardized testosterone measurements that are accurate, reliable and comparable over time, the consensus statement recommends the following:

- All stakeholders should acknowledge the importance of testosterone assay standardization and work closely with the CDC to formulate plans to implement accuracy-based, calibrated testing across the community of assay providers and users;
- The expert scientific and medical communities should work to:
 - define performance criteria that cover the full range of expected values, from children to adult males and females;
 - define reference intervals for testosterone in adults and children of both sexes; and
 - develop guidelines and protocols to ensure uniform patient preparation and handling of samples before they are assayed.
- Third-party payers and health care organizations should promote the use of and enable payment for assays that have been standardized through the above mentioned efforts;
- Funding entities, journals and others involved in research should support the standardization of assays; and
- Manufacturers and laboratories should continue to develop new methodological approaches ensuring the sensitive, specific, accurate and cost-effective measurement of testosterone.

"The recommendations in this consensus statement emphasize the need for the research, medical and industry communities to each play their part in improving testosterone assays," said Rosner. "High quality testosterone testing will not only provide for better patient care outcomes but will rein in the cost of health care as they will lessen the need for frequent retesting."

The consensus statement has been endorsed by the following organizations:

- American Association for Clinical Chemistry
- American Association of Clinical Endocrinologists
- Androgen Excess/PCOS Society
- American Society for Bone and Mineral Research
- American Society for Reproductive Medicine
- American Urological Association
- Association of Public Health Laboratories
- The Endocrine Society
- Laboratory Corporation of America
- North American Menopause Society
- Pediatric Endocrine Society (formerly known as Lawson Wilkins Pediatric Endocrine Society)

The Coalition for Quality Testing, comprising most of the groups listed above and other interested organizations, has been formed to address the technical aspects of reference intervals and performance criteria; to develop guidelines and protocols; and to educate third-party payers, funding entities, journals and other relevant stakeholders.

The statement, "Toward Excellence in Testosterone Testing; A Consensus Statement," will appear in the October 2010 issue of *JCEM*.

Provided by The Endocrine Society

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