Washington State Health Care Authority

Agency Medical Director Comments

Testosterone Testing in Adult Men

G. Steven Hammond, PhD, MD, MHA
Chief Medical Officer
WA Department of Corrections

March 20, 2015

Background

- Testicular function is normally regulated by the hypothalamo-pituitary-testicular (HPT) axis
- Measurement of serum testosterone levels in men has been used for many years in clinical evaluation of HPT function
- Pathological conditions that disrupt HPT function may result in hypogonadism and androgen deficiency

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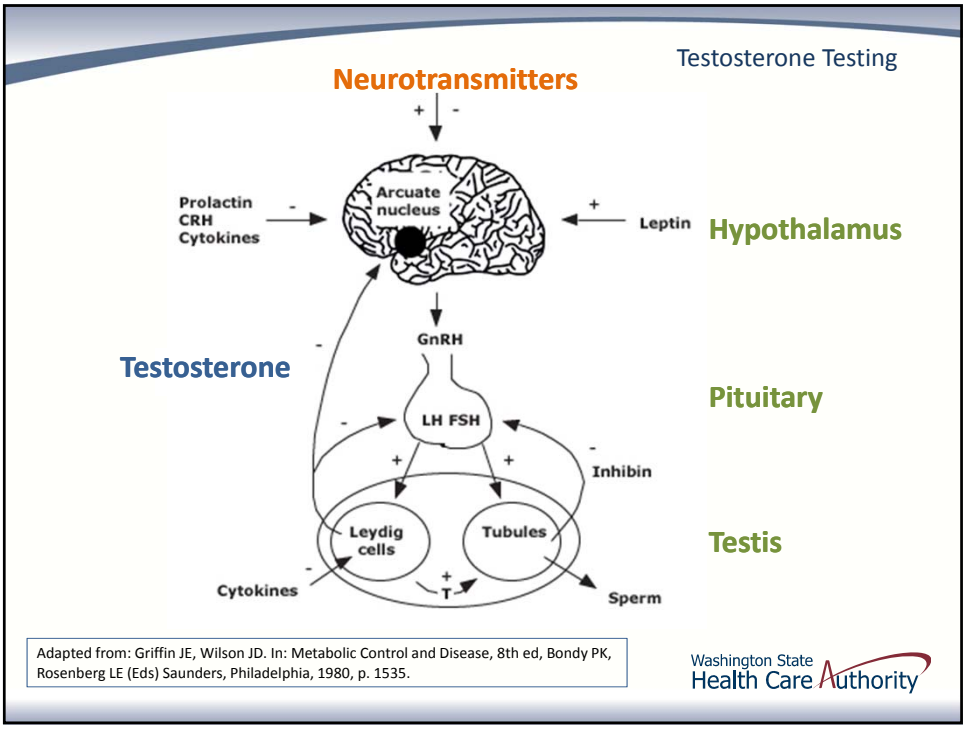
Testosterone Testing



Adapted from: Griffin JE, Wilson JD. In: Metabolic Control and Disease, 8th ed, Bondy PK, Rosenberg LE (Eds) Saunders, Philadelphia, 1980, p. 1535.

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Testosterone Testing

Hypogonadism - Classic vs. Putative

- Most well-defined clinical conditions of hypogonadism result in frank androgen deficiency with markedly decreased androgen levels
  - Primary hypogonadism such as with congenital abnormalities, destructive orchitis, or trauma
  - Secondary hypogonadism such as occurs with panhypopituitarism or mass effect of pituitary or suprasellar tumor
  - In these syndromes testosterone levels are often very low, (i.e., ½ to 1/10 of the lower limit of normal)
- In syndromes marked by severe androgen deficiency, testosterone replacement therapy yields well recognized benefits
  - Improvement in libido and sexual function
  - Maintenance/improvement of muscle strength and lean body mass
  - Maintenance/improvement of bone density and strength

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Testosterone Testing

Hypogonadism - Classic vs. Putative, cont.

- In recent years research has been conducted to study "late onset hypogonadism", i.e., a putative state of androgen deficiency associated with aging, characterized by lower testosterone levels, decreased libido and sexual function, and physical frailty
  - No clear etiology or pathogenesis of "late onset hypogonadism" has been established – other than simply an effect of aging and association with chronic illness
  - Benefits of testosterone therapy are less well established in the setting of "late onset hypogonadism"
  - Signals of risk, particularly for cardiovascular morbidity, of testosterone replacement therapy in older men have emerged

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Testosterone Testing

Testosterone Treatment – New and Old

- For many years, standard testosterone replacement therapy (TRT) was by intramuscular injection of depot-form testosterone every 1-4 weeks
- In the past 15 years transdermal testosterone gel preparations have been marketed; the price of the newer transdermal testosterone gel preparations is 10-20-fold (or more) higher than the older depot forms for intramuscular injection
- Since the transdermal gels have been marketed, mass media has been used to publicize "low T", a putative health condition characterized by lower testosterone levels, particularly in middle-aged and older men
  - Health benefits of testosterone treatment for age-related "low T" have not been demonstrated
  - Testosterone treatment of age-related "low T" is not FDA-approved and pharmaceutical companies are not allowed to claim benefits of testosterone treatment for age-related "low T"
  - However, pharmaceutical companies are allowed to support "Disease Awareness Campaigns" about "low T" that include encouraging men to talk to their doctors about it and have their testosterone level checked

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Testosterone Testing

Recent Trends in Testing & Treating

In this setting there has been marked increase in testosterone testing and prescribing of testosterone products in the USA and to a much lesser extent in the United Kingdom (see next slide)

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Testosterone Testing

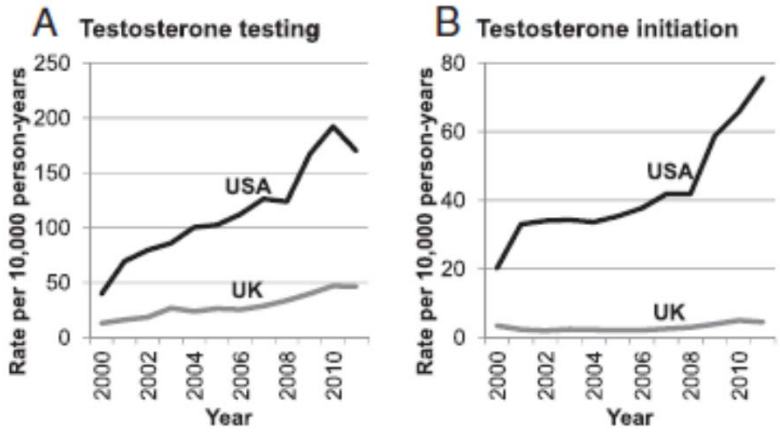

Figure 2. Trends of testosterone laboratory testing (A) and initiation (B) in the United States and United Kingdom, 2000 to 2011.

Layton et al., JCEM 2014

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Testosterone Testing

"Low T" or Normal Aging?

- Serum testosterone levels in men decline with age, such that if "normal" levels are determined on the basis of the distribution of serum testosterone levels in younger men, a substantial proportion of older men will be reported by clinical laboratories as having "low" testosterone levels (see following slides), and thus may be uncritically diagnosed with "hypogonadism"
  - The serum total testosterone level is an imprecise test, the value being subject to inter-individual variability of sex hormone binding globulin levels, reducing signal-to-noise ratio in and near the normal range
  - Age-related decline in serum testosterone levels is particularly pronounced for free testosterone levels
  - Compounding the problem, when serum testosterone levels are measured later in the day than 10 AM they are lower than at the ~8 AM diurnal peak
  - "Low T" is not an accepted medical diagnosis

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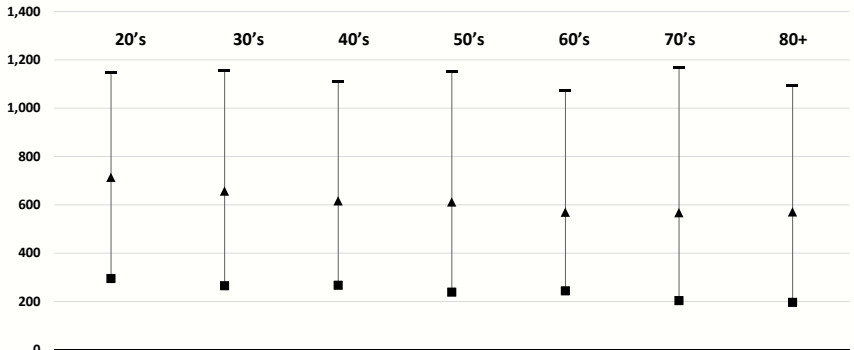
Testosterone Testing

Serum Total Testosterone Levels by Decades, Men (ng/dl)



	20-29 (N=220)	30-39 (N=660)	40-49 (N=872)	50-59 (N=788)	60-69 N=493)	70-79 (N=289)	80+ (N=26)
– 97.5th percentile	1146.2	1156.8	1111.8	1150	1071.6	1168.1	1093.6
■ 2.5th percentile	295	265.3	267.2	238.6	243.8	203.8	196.3
▲ Mean	713.24	656.23	616.1	611.47	569.03	567.09	570.2

Bhasin et al., JCEM 2011

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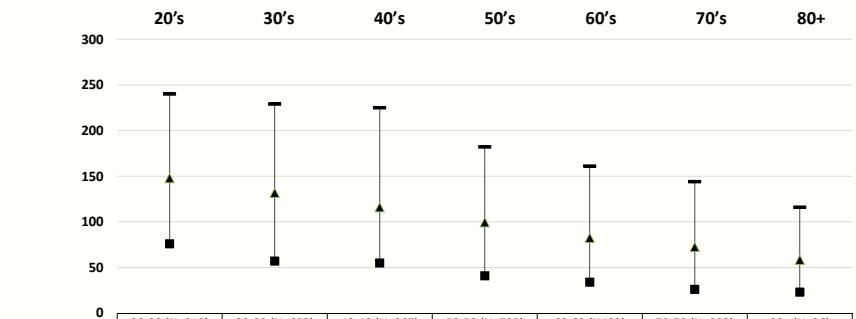
Testosterone Testing

Serum Free Testosterone Level by Decades, Men (pg/ml)



	20-29 (N=219)	30-39 (N=655)	40-49 (N=867)	50-59 (N=785)	60-69 (N492)	70-79 (N=288)	80+ (N=26)
━97.5th percentile	240.0	229.0	225.0	182.0	161.0	144.0	116.0
■2.5th percentile	76.0	57.0	55.0	41.0	34.0	26.0	23.0
▲Mean	147.9	131.7	116.0	99.5	82.4	72.5	58.5

Bhasin et al., JCEM 2011

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Testosterone Testing

What Is the Clinical Significance of Lower Testosterone Levels in Older Men?

- Without clinical correlates of known hypogonadal syndromes, low testosterone levels in older men are unlikely to be diagnostic of a known clinico-pathological condition
  - Given the known decline in testosterone levels in older men it may be more appropriate to develop age-related reference ranges
- Late onset hypogonadism is not a well-established clinical diagnosis; it is a putative diagnosis in the research setting
  - Neither ICD-9 nor ICD-10 recognize a specific diagnosis of "late onset hypogonadism"
- Given growing concerns about safety of testosterone treatment in older men, caution is warranted in diagnosing and treating late onset hypogonadism

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Testosterone Testing

Evidence of Cardiovascular Risk of Testosterone Treatment in Older Men

- An RCT on testosterone replacement therapy (TRT) for men over 65 with mobility limitations was terminated early because of increased CV adverse events associated with TRT – Basaria et al., NEJM 2010
  - TRT treatment course was 6 months, or less if terminated due to early termination of the trial
  - TRT raised hematocrit and thromboxane levels and decreased HDL cholesterol levels
- A retrospective national cohort study of 8709 US veterans with low testosterone levels showed a hazard ratio of 1.29 (1.04-1.58) for all-cause mortality or hospitalization for MI or CVA – Vigen et al., JAMA 2013

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Evidence of Cardiovascular Risk of Testosterone Treatment in Older Men, cont.

- A retrospective cohort study of 55,593 men in a large health-care database showed an increased incidence of MI within 90 days after TRT was prescribed, compared to the year prior to the prescription, ratio 1.36 (1.03-1.81) - Finkle et al., PLOS ONE 2014
  - Effect progressively greater in older men ($\geq$ 65)
  - Effect also seen in men < 65 with history of heart disease
  - No increase in MI among 167,279 patients prescribed sildenafil or tadalafil

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Testosterone Testing

Evidence of Cardiovascular Risk of Testosterone Treatment in Older Men, cont.

- A systematic review and meta analysis of 27 placebo controlled RCTs of TRT lasting ≥ 12 weeks that reported CV events, including 2994 subjects, mostly middle-aged or older, showed OR 1.54 (1.09-2.18) for all CV events and OR 1.61 (1.01-2.56) for serious CV events – Xu et al., BMC Medicine 2013
  - Pharmaceutical industry-funded RCTs (13 of 27) showed OR 0.89 (0.50-1.60) vs. non-pharmaceutical industry-funded RCTs (14 of 27) showing OR 2.06 (1.34-3.17)
  - Funnel plot suggested publication bias (i.e. less reported results of increased CV events with TRT)
  - Trim and fill adjustment for publication bias raised the calculated OR
  - Previous, smaller meta analyses that did not show statistically significant increase in CV events with TRT did show trends in this direction

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Testosterone Testing

Concerns Voiced at FDA

- Safety concerns prompted the FDA to convene an advisory panel in September, 2014 to address concerns about CV risks of testosterone treatment in older men
  - "There was overwhelming support that the use of TRT should exclude men with age-related testosterone decline. The panel voted 20 to 1 in favor of revising the current indication by limiting TRT to those with classic hypogonadism, and including in the label the potential for cardiovascular risk… and a statement that both the safety and efficacy of TRT in age-related hypogonadism had not been established." – Garnick, JAMA 2/10/15
  - As of 3/1/15 the FDA has not added a warning about increased CV risk associated with TRT

JAMA 2/10/15 p. 564

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Testosterone Testing

PEBB/UMP

Testosterone Tests & Treatments, 2010-2013

	2010	2011	2012	2013	4 Yr Overall **	Avg Annual % Chg
Populations						
Avg Annual Members	213,487	212,596	212,684	222,339		1.4%
Men	96,435	96,283	95,581	101,144		0.2%
Testosterone Tests						
Paid $ 84402 [1]	$92,270	$66,432	$70,811	$75,560	$305,073	-10.0%
Paid $ 84403 [2]	$217,732	$190,031	$198,658	$195,132	$801,553	-5.4%
Testing Paid $ (PEBB Primary)	**$310,002**	**$256,463**	**$269,469**	**$270,692**	**$1,106,626**	**-6.6%**
Test Counts - 84402	2627	2678	2849	3343	11497	6.4%
Test Counts - 84403	6226	7133	7470	8353	29182	8.0%
Total Test Counts	**8,853**	**9,811**	**10,319**	**11,696**	**40,679**	**7.6%**
Count of Patients (Women)	1600	1520	1465	1611	4929	-1.2%
Count of Patients (Men)	2861	3231	3552	4075	9470	9.9%
Total Patient Counts	**4461**	**4751**	**5017**	**5686**	**14399**	**6.5%**
Avg Tests per patient	2.0	2.1	2.1	2.1	2.8	
Avg Tests per pt (Men)	2.0	2.0	2.0	2.0	2.9	
Avg Paid $ 84402(PEBB Primary -93%)	$36	$27	$26	$24	$28	-11.6%
Avg Paid $ 84403 (PEBB Primary)	$37	$29	$29	$26	$30	-10.9%
Testosterone Supplementation						
Paid $ Injections	$12,862	$14,497	$21,807	$24,623	$73,789	17.5%
Paid $ Testosterone Pharmaceuticals	$782,110	$972,702	$836,191	$1,153,242	$3,744,245	9.3%
Total Paid for Treatments (PEBB Prim.)	**$794,972**	**$987,199**	**$857,998**	**$1,177,865**	**$3,818,034**	**9.5%**
Avg Paid per pt (PEBB Primary)	$744	$841	$636	$749	$1,460	2.1%
Avg Paid per pt (PEBB Primary - Men)	$754	$852	$642	$754	$1,438	1.9%

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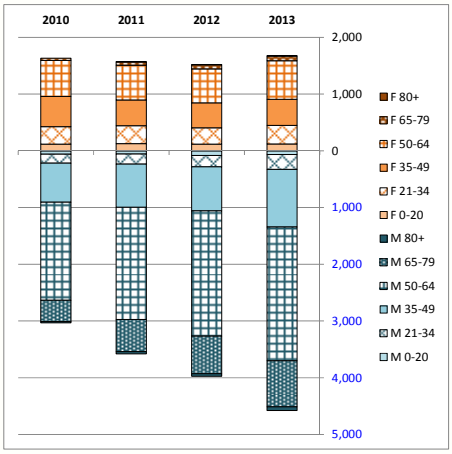
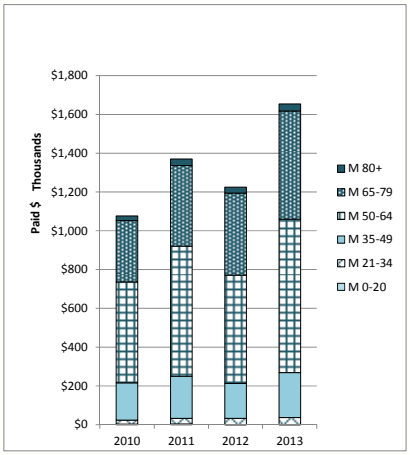
Testosterone Testing

Testosterone Test Patients by Age & Gender, 2010-2013



Testosterone Treatment Patients by Age, Men only, 2010-2013



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Testosterone Testing

Agency Medical Director Concerns

- **Safety = High**
- **Efficacy = High**
- **Cost = High**

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Testosterone Testing

Agency Medical Director Concerns

- Testosterone testing without additional clinical findings of hypogonadism is highly vulnerable to false positive findings of "hypogonadism", especially in older men, especially when reference ranges appropriate to men in their 20s are used for older men
  - Such testing exposes patients to risk of inappropriate diagnosis of "hypogonadism" and prescribing of testosterone therapy with attendant risks, particularly of adverse cardiovascular events
  - Efficacy of testosterone treatment in the absence of clear signs and symptoms of hypogonadism is unproven
  - Inappropriate testosterone testing is wasteful in itself and also likely leads to wasteful (and risky) prescribing

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Current State Agency Policy

- **Medicaid** and **PEBB** – covered without restrictions
- **L&I** and **DOC** – prior authorization required

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Agency Recommendation

Cover with Conditions:

- In setting of clinical findings well correlated with definable HPT axis pathology (objective physical examination or laboratory/imaging evidence of pituitary or primary gonadal dysfunction; osteoporosis; sexual dysfunction)
  - E.g., gynecomastia or testicular atrophy; hyperprolactinemia; laboratory evidence of hypopituitarism; pituitary macroadenoma; osteoporosis; sexual dysfunction
  - Agencies can further delineate
- "Fasting" (8 AM – 10 AM) blood draw for initial assessment of possible hypogonadism

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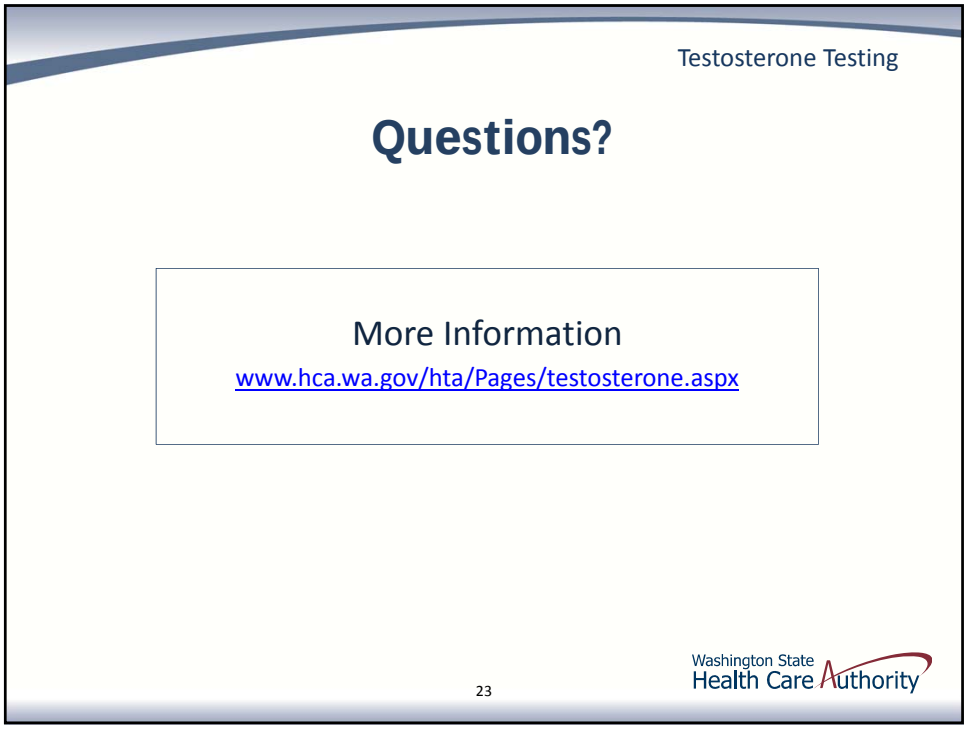
Testosterone Testing
Questions?
More Information
www.hca.wa.gov/hta/Pages/testosterone.aspx
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Health Technology Assessment

Order of Scheduled Presentations:

Testosterone Testing

	Name
1	
2	
3	
4	
5	
6	

No requests to provide public comment on the technology review were received.

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Health Technology Assessment

Testosterone Testing

Clinical Expert

Alvin M. Matsumoto, MD, FACP

Professor, Department of Medicine, University of Washington School of Medicine,

Acting Head, Division of Gerontology & Geriatric Medicine, Department of Medicine, University of Washington School of Medicine

Acting Chief, Gerontology Section, Department of Veterans Affairs Puget Sound Health Care System

Director, Board of Directors, Seattle Institute for Biomedical and Clinical Research

Director, Special Fellowship Program in Advanced Geriatrics, Department of Veterans Affairs Puget Sound Health Care System

Director, Clinical Research Unit, Department of Veterans Affairs Puget Sound Health Care System

Associate Director for Clinical, Geriatric Research, Education and Clinical Center, Department of Veterans Affairs Puget Sound Health Care System

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		X
2.	Equity interests such as stocks, stock options or other ownership interests.		X
3.	Status or position as an officer, board member, trustee, owner.		X
4.	Loan or intellectual property rights.		X
5.	Research funding.	X	
6.	Any other relationship, including travel arrangements.		X

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

AbbVie - Testosterone and placebo gel for multi-center study
GlaxoSmithKline - Dutasteride and placebo, and research support for investigator initiated study

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		X

If yes to #7, provide name and funding Sources: _____

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X [redacted] 3/18/2014 [redacted]

Signature *Date* *Print Name*

For questions contact: Christine Masters
Health Technology Assessment
PO Box 42712
Olympia, WA 98504-2712
360-725-5126

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August 18, 2014

CURRICULUM VITAE

ALVIN M. MATSUMOTO, MD, FACP

1. PERSONAL DATA

Date of Birth:	March 22, 1949
Place of Birth:	Honolulu, Hawaii, United States
Citizenship:	United States
Marital Status:	Married, 3 Children

2. EDUCATION

Medical School:

1971-75 University of Washington School of Medicine, Seattle, WA, M.D., June, 1975

College:

1967-71 University of Washington, Seattle, WA, B.S., Chemistry, with Distinction, Magna Cum Laude, June, 1971

3. POSTGRADUATE TRAINING

Fellowship:

1979-82 Senior Fellow in Medicine/Endocrinology and Metabolism, University of Washington School of Medicine, Veterans Administration Medical Center, Seattle, WA

Residency:

1978-79 Chief Resident in Internal Medicine, United States Public Health Service Hospital, University of Washington School of Medicine, Seattle, WA

1976-78 Resident in Internal Medicine, University of Washington Affiliated Hospitals, Seattle, WA (Traditional Program)

Internship:

1975-76 Intern in Internal Medicine, University of Washington Affiliated Hospitals, Seattle, WA (Traditional Program)

4. FACULTY POSITIONS HELD

1997- Professor, Department of Medicine, University of Washington School of Medicine, Seattle, WA

1989-97 Associate Professor, Department of Medicine, University of Washington School of Medicine, Seattle, WA

1983-89 Assistant Professor, Department of Medicine, University of Washington School of Medicine, Seattle, WA

1978-79 Acting Instructor of Medicine, University of Washington School of Medicine, Seattle, WA

5. DEPARTMENTAL AND HOSPITAL POSITIONS HELD

2012- Acting Head, Division of Gerontology & Geriatric Medicine, Department of Medicine, University of Washington School of Medicine, Seattle, WA

2010- Acting Chief, Gerontology Section, Department of Veterans Affairs Puget Sound Health Care System, Seattle, WA
2007- Director, Board of Directors, Seattle Institute for Biomedical and Clinical Research (SIBCR), Seattle, WA
2001- Director, Special Fellowship Program in Advanced Geriatrics, Department of Veterans Affairs Puget Sound Health Care System, Seattle, WA
2000- Director, Clinical Research Unit, Department of Veterans Affairs Puget Sound Health Care System, Seattle, WA
1993- Associate Director for Clinical, Geriatric Research, Education and Clinical Center, Department of Veterans Affairs Puget Sound Health Care System Seattle, WA
1993-00 Chief, Gerontology, Department of Veterans Affairs Puget Sound Health Care System, Seattle, WA
1993-98 Associate Chief of Staff for Geriatrics and Extended Care, Department of Veterans Affairs Puget Sound Health Care System, Seattle, WA
1993-00 Director, Geriatric Evaluation and Management Unit, Department of Veterans Affairs Puget Sound Health Care System, Seattle, WA
1986- Staff Physician, Geriatric Research, Education and Clinical Center, Department of Veterans Affairs Medical Center, Seattle, WA
1983-86 Research Associate, Veterans Administration Medical Center, Seattle, WA
1981-83 Associate Investigator, Veterans Administration Medical Center, Seattle, WA
1978-79 Staff Physician, Primary Care Department, United States Public Health Service Hospital, Seattle, WA

6. HONORS AND AWARDS

2015 Chair, Laureate Awards Committee, The Endocrine Society
2014-18 Associate Editor, Journal of Clinical Endocrinology and Metabolism
2014- Appointed, Chair-Elect, Laureate Awards Committee, The Endocrine Society
2013- Appointed, Co-Chair, Partnership for the Accurate Testing of Hormones (PATH)
2013 Outstanding Reviewer Recognition Award, The Journal of Clinical Endocrinology & Metabolism, The Endocrine Society
2012 Sidney H. Ingbar Distinguished Service Award, The Endocrine Society
2010- Appointed, Member, Partnership for the Accurate Testing of Hormones (PATH) (previously known as Coalition for Quality Testing), The Endocrine Society, American Society for Bone and Mineral Research Representative
2008- Appointed, Member, Scientific Advisory Board, Partnership for Clean Competition (United States Anti-Doping Agency, United States Olympic Committee, National Football League, Major League Baseball and other professional sports leagues)
2008 Elected as Fellow, American College of Physicians
2008-10 Appointed as Clinical Science Chair, Bridge Grant Review Committee, The Endocrine Society
2007-11 Appointed as Chair, Hormone Foundation Committee, The Endocrine Society
2007- Member, Board of Directors, Seattle Institute for Biomedical and Clinical Research
2006 Robert G. Petersdorf Teaching Award, VA Puget Sound Health Care System

2005-11 Appointed as Chair of the Men's Health Task Force, The Endocrine Society
2005-07 Appointed as Program Chair, American Society of Andrology, 32nd Annual Meeting 2007
2005 The Endocrine Society & Pfizer, Inc. International Award for Excellence In Published Clinical Research in The Journal of Clinical Endocrinology & Metabolism in 2004
2000-01 Appointed as Clinical Chair, The Endocrine Society Annual Meeting 2001
1999 Elected to Western Association of Physicians
1997-00 Elected to Executive Council, American Society of Andrology
1995 Elected to Western Society for Clinical Investigation
1988 Endocrine Society Travel Award to attend 8th International Congress of Endocrinology, Kyoto, Japan, July 17-23, 1988.
1983-86 Veterans Administration Research Career Development Award: Research Associate
1981-83 Veterans Administration Research Career Development Award: Associate Investigator
1974 Alpha Omega Alpha (Medical Honorary)
1971-72 Medical Scientist Training Fellowship (Institutes of General Medical Sciences, National Institutes of Health)
1971 Phi Beta Kappa
1971 Phi Lambda Upsilon (National Chemistry Honorary)
1970-71 Dow Chemical Company Scholarship, University of Washington
1970-71 University Students Club Scholarship, University of Washington
1970 President's Certificate of High Scholarship, University of Washington
1970 National Science Foundation Summer Fellowship-Undergraduate Research Participation Program, Department of Chemistry, University of Washington
1969-70 Dow Chemical Company Scholarship, University of Washington
1969 National Science Foundation Summer Fellowship-Undergraduate Research Participation Program, Department of Chemistry, University of Washington
1968-69 Dow Chemical Company Scholarship, University of Washington
1967-68 Seattle Japanese American Citizens League Scholarship

7. BOARD CERTIFICATION

Nov 1981 Diplomate, American Board of Endocrinology and Metabolism (64276)
Sep 1978 Diplomate, American Board of Internal Medicine (64276)
May 1976 Diplomate, National Board of Medical Examiners

8. CURRENT LICENSE TO PRACTICE MEDICINE

Mar 1977 State of Washington (0015733)

9. PROFESSIONAL ORGANIZATIONS

Western Association of Physicians
Western Society for Clinical Investigation
American Federation for Clinical Research
Chairman, West Coast Endocrine Club 1986
The Endocrine Society
Associate Editor, Journal of Clinical Endocrinology and Metabolism, 2014-2018

Chair, Laureate Awards Committee, 2015
Chair-Elect, Laureate Awards Committee, 2014
Co-Chair, Partnership for the Accurate Testing of Hormones (PATH) (previously known as Coalition for Quality Testing), 2013-present
Member, Laureate Awards Committee, 2013-2017
Working Group, Primary Care Clinical Practice Guidelines for Testosterone Therapy in Men with Androgen Deficiency Syndrome, 2013- present
Working Group, Guys' Guide to Testosterone (formerly the Testosterone Tour): an Interactive Online Tool for Men Interested in Testostoerone Therapy, Hormone Health Network, 2012-2013
Working Group, Myth vs. Fact: Male Menopause, Hormone Health Network, 2012-2013
Editorial Board, Journal of Clinical Endocrinology and Metabolism, January, 2012-December, 2016
Partnership for the Accurate Testing of Hormones (PATH) (previously known as Coalition for Quality Testing), American Society for Bone and Mineral Research Representative, 2010-present
Task Force, Androgen Deficiency Performance Improvement Module, 2011-2013
Task Force, Evidence-Based Guidelines for Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes, Revision 2010
Member, Testosterone Therapy Performance Measure Set Committee, 2008-2010
Clinical Science Chair, Bridge Grant Review Committee, 2008-2010
Chair, Hormone Foundation Committee, 2007-2011
Chair, Men's Health Task Force, 2007-present
Hormone Foundation Committee, 2005-2007
Task Force, Evidence-Based Guidelines for Evidence-Based Guidelines for Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes, 2004-2006
Meetings & Educational Programs Committee, 2002-2005
Program Committee, Clinical Endocrinology Update, 2002
Annual Meeting Steering Committee, 1998-2001
Clinical Chair, Annual Meeting Steering Committee ENDO 2001

American College of Physicians
Fellow, 2008

Society for the Study of Reproduction

American Society of Andrology
Member, Awards Committee 2012-2014
Member, Program Committee 2006-2008
Chair, Program Committee 2005-2007
Member, Program Committee 2003-2005
Chair, Local Arrangements Committee 2002
Member, Program and Post-Graduate Course Committee 2001-2002
Member, Executive Council 1997-2000
Member, Post-Graduate Course Committee 1999-2000
Member, Program Committee 1997-1999
Chair, Nominating Committee 1997-1998
Nominating Committee 1995-1997
Chairman, Post-Graduate Committee 1992-1993

Program Committee 1992-1993
Awards Committee 1992-1994

American Society for Bone and Mineral Research
Representative, Partnership for the Accurate Testing of Hormones (PATH) (previously known as Coalition for Quality Testing), The Endocrine Society, 2010-present
Representative, CDC Testosterone Measurement Consensus Conference, 2010

American Geriatrics Society
Gerontological Society of America
King County Medical Society

10. TEACHING RESPONSIBILITIES

A. Students

Fourth-Year Students:

Teach clinical geriatric medicine while attending on Transitional Care Unit (TCU) at VAPSHCS (Chronic Care Clerkship-Geriatrics, Conjoint 694). 4 weeks yearly. August 1-15, 2014

Transitional Care Unit (TCU) Teaching Conferences on Core Topics at VAPSHCS. August 1-15, 2014
"Vitamin D deficiency", August 4, 2014
"Osteoporosis in older adults: not just a problem in older post-menopausal women", August 12, 2014

B. Housestaff/Fellows

Teach clinical geriatrics to R-l's while attending on Transitional Care Unit (TCU) at VAPSHCS. 4 weeks yearly. August 1-15, 2014

Transitional Care Unit (TCU) Teaching Conferences on Core Topics at VAPSHCS. August 1-15, 2014
"Vitamin D deficiency", August 4, 2014
"Osteoporosis in older adults: not just a problem in older post-menopausal women", August 12, 2014

Present at Geriatric Grand Rounds, "Osteoporosis in men: not just a problem in postmenopausal women", Harborview Medical Center, August 30, 2013

Present at Reproductive Endocrinology Research Conference, University of Washington, "Osteoporosis in veterans: diagnosis, evaluation and management", October 8, 2013

Present at Chief of Medicine Rounds, VAPSHCS, Seattle, WA, "Male hypogonadism", October 9, 2013

Present at Geriatric Medicine/Psychiatry Fellows Conference, VAPSHCS, Seattle, WA, "Thyroid disorders in older adults", January 29, 2014

Present at GRECC, Associate Directors for Clinical Teleconference, "VA Clinical Demonstration Projects at VA Puget Sound Healthcare System, GRECC, February 10, 2014

Present at GRECC Research Seminar, VAPSHCS, Seattle, WA, "Testosterone treatment in older men: where are we now?", February 10, 2014

Present at SPORE Clinical Studies Seminar, Fred Hutchinson Cancer Research Center, "Important issues and state of knowledge in male hormone hormone replacement therapy: whoa T for low T", February 27, 2014

Present at Northwest Geriatric Education Center (NWGEC), Geriatric Health Series, Seattle, WA, "Thyroid disorders in older adults", May 13, 2014

C. Mentorship of Research Trainees (last 5 years)

Mara Roth (Lang), MD, 7/07-6/10, Assistant Professor, Division of Metabolism, Endocrinology and Nutrition, Department of Medicine, University of Washington School of Medicine, Seattle, WA

Christin Snyder, MD, 7/07-6/10, Private Practice, Endocrinology & Metabolism, Portland, OR

Lianne Hirano, MD, 7/09-6/10, Acting Instructor, Division of Gerontology & Geriatric Medicine, University of Washington

Serena Lo, MD, 7/10-6/12, Special Fellowship Program in Advanced Geriatrics, Senior Fellow, Division of Gerontology & Geriatric Medicine, Department of Medicine, University of Washington School of Medicine
School of Medicine, Seattle, WA

Katya Rubinow, MD, 7/11-6/13, Assistant Professor, Division of Metabolism, Endocrinology and Nutrition, Department of Medicine, University of Washington School of Medicine, Seattle, WA

Lori Cooper, MD, 7/12-6/14, Senior Fellow, Division of Metabolism, Endocrinology and Nutrition, Department of Medicine, University of Washington School of Medicine, Seattle, WA

Katherine Ritchey, DO, 7/14-present, Senior Fellow, Division of Gerontology & Geriatric Medicine, Department of Medicine, University of Washington School of Medicine, Seattle, WA

Beverly Kocarnik, MD, 9/14-present, Senior Fellow, Division of Metabolism, Endocrinology and Nutrition, Department of Medicine, University of Washington School of Medicine, Seattle, WA

D. Director, Department of Veterans Affairs, Special Fellowship Program in Advanced Geriatrics. This is a national two-three year fellowship for research training in gerontology, geriatric medicine and geriatric psychiatry. As Director, I serve as academic career mentor for these fellows.

Serena Lo, MD, 7/10-6/12, Senior Fellow, Division of Gerontology & Geriatric Medicine, Department of Medicine, University of Washington School of Medicine

Deborah Huang, MD, 8/10-7/13, Senior Fellow, Division of Gerontology & Geriatric Medicine, Department of Medicine, University of Washington School of Medicine

Lori Cooper, MD, 7/13-present, Senior Fellow, Division of Metabolism, Endocrinology and Nutrition, Department of Medicine, University of Washington School of Medicine, Seattle, WA

Katherine Ritchey, DO, 7/14-present, Senior Fellow, Division of Gerontology & Geriatric Medicine, Department of Medicine, University of Washington School of Medicine, Seattle, WA

Beverly Kocarnik, MD, 9/14-present, Senior Fellow, Division of Metabolism, Endocrinology and Nutrition, Department of Medicine, University of Washington School of Medicine, Seattle, WA

E. Continuing Medical Education

Present at Geriatric Grand Rounds, “Osteoporosis in men: not just a problem in postmenopausal women”, Harborview Medical Center, August 30, 2013

Present at Northwest Geriatric Education Center (NWGEC), Geriatric Health Series, “Thyroid disorders in older adults”, University of Washington, Seattle, WA, May 13, 2014

Present at American Society for Men's Health, American Urological Association, Annual Meeting, "Testosterone replacement: a balanced clinical perspective", Orlando, FL, May 19, 2014

Present at Skyline at First Hill [Resident Lecture Series], "Testosterone and aging", Seattle, WA, June 26, 2014

Present at American Association of Clinical Endocrinologists, Heartland Chapter, 5th Annual Meeting, "Testosterone and cardiovascular disease: what do I do now?", Omaha, NE, August 24, 2014

Present at Clinical Endocrinology Update 2014, The Endocrine Society, "Androgen Deficiency Maintenance Of Certification (MOC) Live Learning Session", San Francisco, CA, September 3, 2014

Present at Endocrine Essentials Live for Primary Care, The Endocrine Society, "Low testosterone: when to treat", Manhattan Beach, CA, November 15, 2014

Present at Endocrine Essentials Live Pro, The Endocrine Society, "Diagnosis and management of hypogonadism", Manhattan Beach, CA, November 15, 2014

Present at Meet-the-Professor Session, "Evaluation of men with hypogonadotropic hypogonadism: clinical, laboratory and imaging", The Endocrine Society 97th Annual Meeting, San Diego, CA, March 6, 2015

Present at Controversies in the Diagnosis and Treatment of Male Hypogonadism Symposium, "Testosterone measurements to confirm the diagnosis of male hypogonadism", The Endocrine Society 97th Annual Meeting, San Diego, CA, March 7, 2015

Present at Meet-the-Professor Session, "Assessing and managing tesotosterone abnormalities in all your patients", American College of Physicians Annual Meeting Internal Medicine 2015, Boston, MA, April 30, 2015

11. EDITORIAL RESPONSIBILITIES

Associate Editor, Journal of Clinical Endocrinology and Metabolism, January, 2014-December, 2018

Editorial Board, Journal of Clinical Endocrinology and Metabolism, January, 2012-December, 2016

Outstanding Reviewer Recognition Award, The Journal of Clinical Endocrinology & Metabolism, The Endocrine Society 2013

Editor, UpToDate, Male Reproductive Endocrinology, January, 2007-present

Member, Faculty of 1000 (F1000) Biology, June, 2006-present

Editorial Quality Review Board, UpToDate, Endocrinology, January, 2003-December, 2006

Editorial Board, American Journal of Medicine, January, 2002-December, 2004

Editorial Board, Journal of Andrology, January, 1999-December, 2003

Editorial Board, Endocrine Reviews, January, 1999-December, 2002

Editorial Board, Journal of Clinical Endocrinology and Metabolism, January, 1995-December, 1999

Editorial Board, Journal of Andrology, January 1, 1990-December 31, 1992

12. SPECIAL NATIONAL RESPONSIBILITIES

Member, New Geriatric Research, Education and Clinical Center Review Committee, Office of Geriatrics and Extended Care, Department of Veterans Affairs, March 13-14, 2014, Washington, DC.

Member, Laureate Awards Committee, The Endocrine Society, 2013-2017; Chair-Elect, 2014-2015; Chair, 2015-2016

Member, Task Force, Primary Care Clinical Practice Guidelines for Testosterone

Therapy in Men with Androgen Deficiency Syndrome, The Endocrine Society,2013- present

Co-Chair, Steering Committee, Partnership for the Accurate Testing of Hormones (PATH), formerly the Coalition for Quality Testing, The Endocrine Society, 2013-2015

Working Group, Guys' Guide to Testosterone (formerly the Testosterone Tour): an Interactive Online Tool for Men Interested in Testostoerone Therapy, Hormone Health Network, 2012-2013

Working Group, Myth vs. Fact: Male Menopause, Hormone Health Network, 2012-2013

Member, Androgen Deficiency Performance Improvement Module Task Force, The Endocrine Society, 2011-2013

Member, Expert Working Group, World Anti-Doping Agency, "Medical Information to Support Therapeutic Use Exemption Committees Decision on Androgen Deficiency/Male Hypogonadism", 2011

Member, Steering Committee, Partnership for the Accurate Testing of Hormones (PATH), formerly the Coalition for Quality Testing, The Endocrine Society, American Society for Bone and Mineral Research Representative, 2010-present

Member, Scientific Advisory Board, Partnership for Clean Competition (United States Anti-Doping Agency, United States Olympic Committee, National Football League, Major League Baseball and other professional sports leagues), 2008-present

Member, Therapeutic Use Exemption Review Committee, United States Anti-Doping Agency, 2008-present

Clinical Science Chair, Bridge Grant Review Committee, The Endocrine Society, 2008-2010

Chair, Hormone Foundation Committee, The Endocrine Society, 2007-2011

Chair, Men's Health Task Force, The Endocrine Society, 2005-present

Member, Hormone Foundation Committee, The Endocrine Society, 2005-2007

Chair, Program Committee, American Society of Andrology, 32nd Annual Meeting 2007

Member, US Anti-Doping Agency (USADA), Research Policy Advisory Committee (RPAC), 2005-2008

Member, NICHD Reproductive Medicine Network (RMN) Review Committee, NICHD, NIH, 2004-2005

Member, The Endocrine Society Guidelines Committee, Task Force: Evidence-Based Guidelines for the Use of Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes, 2004-2006

Planning Committee, VA Cooperative Study Program CSP #561 entitled "Evaluation of an Electronic Chart Reminder for Prevention and Treatment of Glucocorticoid-Induced Osteoporosis" (Principal Proponent, RA Adler, Richmond VA Medical Center) 2005

Member, Meetings & Educational Programs Committee, The Endocrine Society, 2002-2005

Clinical Chair, The Endocrine Society Annual Meeting, ENDO 2001

Member, Population Research Subcommittee, NICHD Initial Review Group, NICHD, NIH, July 1, 1996-June 30, 2000

Member, Executive Council, American Society of Andrology, 1997-2000

Member, NICHD Special Review Committee, NIH, September 4-6, 1996

Member, Reproductive Endocrinology Study Section, NIH, July 1, 1990-June 30, 1994

Chairman, Special Reproductive Endocrinology/Biology Study Section, October 6, 1991

Member, Special Reproductive Endocrinology/Biology Study Section, June 18, 1991; October 4, 1992

13. SPECIAL LOCAL RESPONSIBILITIES

VAPSHCS	Chair, Research Education Committee, Seattle Institute of Biomedical and Clinical Research (SIBCR), 2012-present
VAPSHCS	Member, Clinical Executive Board, 2010-present
VAPSHCS	Member, VAPSHCS Research Task Force, 2010
VAPSHCS	Member, Research Space Subcommittee, 2009-2012
VAPSHCS	Director, Board of Directors, Seattle Insitute for Biomedical and Clinical Research (SIBCR), 2007-present
VAPHSCS	Chair, Research Conflict of Interest Subcommittee, 2006-2013
VAPHSCS	Chair, Clinical Research Unit Advisory Committee, 2000-present
UW	Member, General Clinical Research Center Education Committee, 2005-2009
VAPSHCS	Member, Research Space Committee, 2005-2007
UW	Senator, University of Washington Faculty Senate, 2003-2005
VAPSHCS	Member, Research and Development Education Committee, 2003-2009
VAPSHCS	Chair, Institutional Animal Care and Use Committee, 2001-2002
VAPSHCS	Member, Research and Development Committee, 2001-2002
VAPSHCS	Director, VA Special Fellowship Program in Advanced Geriatrics, 2000-present
VAPSHCS	Member, Geriatrics and Extended Care Operations Committee, 1998-2000
VAPSHCS	Member, Primary Care Council, 1997-2000
VAPSHCS	Chairman, Geriatrics and Extended Care Advisory Board, 1995-1998
VAPSHCS	Member, Clinical Executive Board, 1994-1998
VAPSHCS	Chairman, Research and Development Committee, 1998-1999
VAPSHCS	Member, Research and Development Committee, 1997-1998
VAPSHCS	Member, Research Space Subcommittee, 1997-1999
VAMC	Member, Health Care Reform Advisory Committee, 1994-1995
VAMC	Chairman, Extended Care Committee, 1994-1995
VAMC	Member, Research Space Subcommittee, 1993-1995
VAMC	Chairman, Research and Development Committee, 1992-1993
VAMC	Member, Research Space Subcommittee, 1988-1990
VAMC	Chairman (1988) and Member, Scientific Review and Evaluation Committee, 1986-1988
VAMC	Member, Research and Development Committee, 1984-1986
VAMC	Member, Animal Studies Subcommittee, 1983-1985

14. RESEARCH FUNDING

A. <u>ACTIVE GRANT SUPPORT</u>

1. National Institutes of Health

Co-Investigator, Executive Committee, Cognitive Function Working Group Leader (11.5% effort, PI Peter Snyder) NIA/NINDS grant proposal entitled, "Testosterone Trial", $30,701,066 (5/15/09-4/30/15) UO1 AG030344.

Site PI, Alvin M. Matsumoto (8% effort), $2,178,864 5/15/09-4/30/15)

The aim of this grant is to investigate the effects of testosterone treatment

on physical function and performance, sexual function, cognitive function and vitality/quality of life in older men with clinical manifestations of hypogonadism and unequivocally low serum testosterone levels, in a multicenter, randomized, double-blind, placebo-controlled study.

Site PI, Alvin M. Matsumoto, Cardiovascular Sub-Study, $136,480 (5/15/10-4/30/15)

This a sub-study of The Testosterone Trial to investigate the effects of testosterone treatment on coronary artery calcification by CT angiography and cardiovascular risk factors, including visceral adiposity.

Co-Investigator (2.5% effort) of project entitled, "Male hormonal contraception and metabolic health" (Project 4, Project Leader, Stephanie T. Page), $1,948,298 (7/1/12-6/30/17), $428,488 (7/1/12-6/30/13) in NICHD Cooperative Contraceptive Research Center (U54 HD42454) grant entitled, "Male contraception research center grant", P.I. William J. Bremner, University of Washington School of Medicine, $9,624,759 (9/17/12-6/30/17) U54 HD42454.

The aim of this project is to investigate the effects of hormonal contraceptive regimens on risk factors for cardiovascular disease in healthy normal men.

Co-Investigator (5% effort, PI Molly Shores) of project entitled, "Adverse Events Associated with Testosterone Treatment in Hypogonadal Men", $360,000 (8/12/12-7/31/14) RO1 AG 042934.

The aim of this project is to assess the effects of testosterone treatment of hypogonadal men on combined cardiovascular events and incident aggressive prostate cancer using the national VA database.

Consultant (0% effort, PI Stephanie Page) of project entitled "Dose-response relationships between circulating and intraprostatic androgens in men", $1,621,917 (7/1/10-6/30/15), $215,962 (7/1/12-6/30/13) R01 AG037603

The aim of this grant is to determine the dose-response effects of testosterone administration alone or in combination with a 5 alpha-reductase inhibitor (to block conversion of testosterone to dihydrotestosterone) and adrenal androgen precursors on intraprostatic androgen concentrations and cell-specific gene expression in older men.

2. Other

P.I. (10% effort) of GlaxoSmithKline Investigator-Initiated Grant entitled, "Testosterone Replacement and Dustasteride Effectiveness (TRADE)" $474,900 (6/1/04-12/31/14) GSK #000272.

The aim of this study is to determine the effect of testosterone in combination with the 5 alpha-reductase inhibitor, dutasteride, compared to testosterone alone on prostate size, symptoms of benign prostatic hyperplasia (BPH), intraprostatic steroid hormone concentrations and global prostate gene expression in hypogonadal men with mild to moderate BPH.

B. PENDING GRANT SUPPORT

None

15. BIBLIOGRAPHY (* 5 most significant publications)

A. PEER REVIEWED PUBLICATIONS OF ORIGINAL WORK

1. Bremner WJ, **Matsumoto AM,** Sussman AM, Paulsen CA. Follicle stimulating hormone and human spermatogenesis. J Clin Invest 1981;68:1044-1052. PMID: 6793629

2. Sandblom RE, **Matsumoto AM,** Schoene RB, Lee KA, Giblin E, Bremner WJ, Pierson DJ. Obstructive sleep apnea syndrome induced by testosterone administration. N Engl J Med 1983;308:508-510. PMID: 6823267

3. Karpas AE, **Matsumoto AM,** Paulsen CA, Bremner WJ. Elevated serum follicle stimulating hormone levels in men with normal seminal fluid analyses. Fertil Steril 1983;39:333-336. PMID: 6402388

4. **Matsumoto AM,** Paulsen CA, Hopper BR, Rebar RW, Bremner WJ. Human chorionic gonadotropin and testicular function: stimulation of testosterone, testosterone precursors, and sperm production despite high estradiol levels. J Clin Endocrinol Metab 1983;56:720-728. PMID: 6833460

*5. **Matsumoto AM,** Karpas AE, Paulsen CA, Bremner WJ. Reinitiation of sperm production in gonadotropin-suppressed normal men by administration of follicle stimulating hormone. J Clin Invest 1983;72:1005-1015. PMID: 6411766

6. **Matsumoto AM,** Bremner WJ. Modulation of pulsatile gonadotropin secretion by testosterone in man. J Clin Endocrinol Metab 1984;58:609-614. PMID: 6421864

7. **Matsumoto AM,** Paulsen CA, Bremner WJ. Stimulation of sperm production by human luteinizing hormone in gonadotropin-suppressed normal men. J Clin Endocrinol Metab 1984;59:882-887. PMID: 6434586

8. Gross KM, **Matsumoto AM,** Southworth MB, Bremner WJ. Evidence for decreased luteinizing hormone releasing hormone pulse frequency in men with selective elevations of follicle-stimulating hormone. J Clin Endocrinol Metab 1985;60:197-202. PMID: 3917266

9. **Matsumoto AM,** Bremner WJ. Stimulation of sperm production by human chorionic gonadotropin after prolonged gonadotropin suppression in normal men. J Androl 1985;6:137-143. PMID: 3922931

10. **Matsumoto AM,** Sandblom RE, Schoene RB, Lee KA, Giblin EC, Pierson DJ, Bremner WJ. Testosterone replacement in hypogonadal men: effects of obstructive sleep apnea, respiratory drives, and sleep. Clin Endocrinol 1985;22:713-721. PMID: 4017261

11. Gross KM, **Matsumoto AM,** Berger RE, Bremner WJ. Increased frequency of pulsatile LHRH administration selectively decreases FSH levels in men with idiopathic azoospermia. Fertil Steril 1986;45:392-396. PMID: 3081382

*12. **Matsumoto AM,** Karpas AE, Bremner WJ. Chronic human chorionic gonadotropin administration in normal men: evidence that follicle-stimulating hormone is necessary for the maintenance of quantitatively normal spermatogenesis in man. J Clin Endocrinol Metab 1986;62:1184-1192. PMID: 3084535

13. **Matsumoto AM**, Karpas AE, Southworth MB, Dorsa DM, Bremner WJ. Evidence for activation of the central nervous system-pituitary mechanism for gonadotropin secretion at the time of puberty in the male rat. Endocrinology 1986;119:362-369. PMID: 3522211

14. Gross KM, **Matsumoto AM,** Bremner WJ. Differential control of luteinizing hormone and follicle stimulating hormone secretion by luteinizing hormone releasing hormone pulse frequency in man. J Clin Endocrinol Metab 1987;64:675-680. PMID: 3102545

15. MacCalla DL, Clifton DK, **Matsumoto AM,** Steiner RA. Role of the central ascending noradrenergic system in the regulation of LH responsiveness to testosterone negative feedback in the adult male rat. Biol Reprod 1987;37:33-38. PMID: 3115323

16. Tenover JS, Dahl KD, Hseuh AJW, Lim P, **Matsumoto AM,** Bremner WJ. Serum bioactive and immunoactive follicle-stimulating hormone levels and the response to clomiphene citrate in healthy young and elderly men. J Clin Endocrinol Metab 1987;64:1103-1108. PMID: 3106393

17. Tenover JS, **Matsumoto AM,** Plymate SR, Bremner WJ. The effects of aging in normal men on bioavailable testosterone and luteinizing hormone secretion: response to clomiphene citrate. J Clin Endocrinol Metab 1987;65:1118-1126. PMID: 3119649

18. Petrie EC, **Matsumoto AM,** Bremner WJ. Modulation of LH pulse amplitude by the frequency of LHRH stimulation and by testosterone in castrate, hypothalamic-lesioned male rats. Biol Reprod 1988;38:143-149. PMID: 3130108

19. Alexander MJ, Clifton DK, **Matsumoto AM,** Steiner RA. Evidence that noradrenergic activity does not mediate the inhibition of luteinizing hormone secretion caused by vasoactive intestinal peptide. Brain Res 1988;445:247-253. PMID: 3130956

20. McLachlan RI, **Matsumoto AM,** Burger HG, deKretser DM, Bremner WJ. Relative roles of follicle-stimulating hormone and luteinizing hormone in the control of inhibin secretion in normal men. J Clin Invest 1988;82:880-884. PMID: 3138288

21. Tenover JS, **Matsumoto AM,** Clifton DK, Bremner WJ. Age-related alterations in the circadian rhythms of pulsatile luteinizing hormone and testosterone secretion in healthy men. J Gerontol:Med Sci 1988;43:M163—M169. PMID: 3183306

22. **Matsumoto AM.** Is high dosage testosterone an effective male contraceptive agent? Fertil Steril 1988;50:324-328. PMID: 3396702

23. Sheckter CB, McLachlan RI, Tenover JS, **Matsumoto AM,** Burger HG, deKretser DM, Bremner WJ. Stimulation of serum inhibin concentrations by gonadotropin releasing-

hormone in men with idiopathic hypogonadotropic hypogonadism. J Clin Endocrinol Metab 1988;67:1221-1224. PMID: 3142917

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27. **Matsumoto AM.** Effects of chronic testosterone administration in normal men: safety and efficacy of high-dosage testosterone and parallel dose-dependent suppression of luteinizing hormone, follicle-stimulating hormone, and sperm production. J Clin Endocrinol Metab 1990;70:282-287. PMID: 2104626

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weight, intra-abdominal adiposity, and plasma leptin and insulin independent of food intake and total body fat. Endocrinology 2000;141:487-497. PMID: 10650927

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B. INVITED REVIEWS, BOOK CHAPTERS AND EDITORIALS

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D. MANUSCRIPTS SUBMITTED

1. Lee AP, Nya-Ngatchou J-J, Roth MY, Lin K, Walsh TJ, Page ST, **Matsumoto AM**, Bremner WJ, Amory JK, Anawalt BD. Testicular fine needle aspiration for the assessment of intratesticular hormone concentrations: a retrospective review of 404 procedures. Contraception, 2014.

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E. <u>PUBLISHED ABSTRACTS [# accepted for presentation]</u>

#1. Bremner WJ, Sussman A, **Matsumoto A,** Paulsen CA. Follicle stimulating hormone and human spermatogenesis. Clin Res 1980;28:69A. (Oral presentation, Western Society for Clinical Research, by **A Matsumoto)**

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#10. Karpas AE, **Matsumoto AM**, Paulsen CA, Bremner WJ. Normal sperm production and elevated follicle stimulating hormone (FSH) levels in man. Fertil Steril 1982;38:271 (Serono Award of the Pacific Coast Fertility Society).

#11. **Matsumoto AM,** Bremner WJ. Modulation of pulsatile gonadotropin secretion by testosterone in man. Clin Res 1983;31:84A. (Oral presentation, Western Society for Clinical Research, by **AM Matsumoto)**

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#13. Soules MR, Steiner RA, Clifton DK, **Matsumoto AM,** Bremner WJ. Modulation of the frequency of pulsatile luteinizing hormone (LH) secretion by progesterone in normal women. Clin Res 1983;31:27A.

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#189. Hirano LA, Page ST, **Matsumoto AM**. Dutasteride reduces prostate specific antigen (PSA) in hypogonadal men with benign prostatic hyperplasia undergoing testosterone (T) replacement therapy. J Invest Med 2010;58:121, Abstract No. 67 [AFMR Scholar Award to LA Hirano].

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#207. Shores MM, Arnold AM, Biggs ML, Longstreth WL, Smith NL, Hirsch CH, Cappola AR, **Matsumoto AM**. Sex steroid concentrations and incident ischemic stroke in older men without cardiovascular disease in the Cardiovascular Health Study. Endocr Rev 2013;334:SAT-582. The Endocrine Society 95th Annual Meeting, San Francisco, CA, June 15-18, 2013.

#208. **Matsumoto AM**, Getzenberg RH, Coss CC, Hancock M, Dalton JT, Steiner MS. The free hormone hypothesis: Correlation of decreases in PSA with free testosterone rather than total testosterone in men with advanced prostate cancer treated with GTx-758. Abstract e16015. American Society of Clinical Oncology Annual Meeting, Chicago, IL, May 31-June 4, 2013.

#209. Getzenberg R, **Matsumoto A**, Coss C, Hancock M, Dalton J, Steiner M. Confirmation of the free hormone hypothesis: descreases in PSA correlate with free testosterone rather than total testosterone in men with advanced prostate cancer treated with GTX-758. Society of Urologic Oncology 14th Annual Meeting, Bethesda, MD, December 4-6, 2013.

#210. Cooper LA, Page ST, Amory JK, Anawalt BD, **Matsumoto AM**. Body mass index has a greater influence than aging on serum SHBG and total testosterone in men: implications for the biochemical diagnosis of hypgonadism in older obese men. J Invest Med 62:249, 2014, Abstract No. 354.

#211. Mostaghel EA, Marck B, **Matsumoto AM**, Tamae D, Penning TM, Balk SP, Kantoff PW, Nelson P, Taplin ME, Montgomery RB. Association fo serum (SR) and tissue (TX) abiaterone (ABI) levels with intraprostatic steroids and pathologic outcomes in men with high-risk localized prostate cancer (PCa). American Association for Cancer Research (ASCO) Annual Meeting, San Diego, CA, April 5-9, 2014.

#212. Walsh T, **Matsumoto A**, Fox A, Moore K, Forsberg C, Heckbert S, Zeliadt S, Thompson M, Smith N, Shores M. Trends in testosterone replacement therapy among older men in a regional Veterans Affairs Health Care System. Abstract No. 14-5365. 2014 Annual Meeting, American Urological Association, Orlando, FL, May 16-21, 2014.

#213. Shores MM, Fox AE, Moore KP, **Matsumoto AM**, Forsberg CW, Smith NS, Heckbert SR, Thompson ML, Walsh TJ. Characteristics of treated and untreated middle-age and older men with low testosterone and testosterone use in a national Veterans Affairs (VA) cohort. Endocr Rev 2014; in press. Abstract No. SUN-0077. 16th International Congress of Endocrinology and The Endocrine Society 96th Annual Meeting ENDO 2014, Chicago, IL, June 21-24, 2014.

#214. Cunningham GR, Rosen RC, Wang C, Ellenberg SS, Stevens A, **Matsumoto AM**, Bhasin S, Molitch ME, Farrar JT, Cella D, Gill TM, Barrett-Connor E, Cauley JA, Cifelli D, Crandall JP, Ensrud KE, Fluharty L, Hadley E, Lewis CE, Pahor M, Resnick SM,

Romashkan S, Swerdloff RS, Snyder PJ. Free testosterone but not total testosterone or estradiol is associated with sexual function in symptomatic older hypogonadal men in The Sexual Function Trial of The Testosterone Trials. Endocr Rev 2014; in press. Abstract No. SUN-0084. 16th International Congress of Endocrinology and The Endocrine Society 96th Annual Meeting ENDO 2014, Chicago, IL, June 21-24, 2014.

#215. Cauley JA, Fluharty L, Ellenberg S, Gill TM, Ensrud KE, Barrett-Connor E, Cifelli D, Cunningham GR, **Matsumoto AM**, Bhasin S, Pahor M, Farrar JT, Cella D, Rosen RC, Resnick SM, Swerdloff RS, Lewis CE, Molitch ME, Crandall JP, Stephens AJ, Wang C, Romashkan S, Hadley E, Snyder PJ. Testosterone pharmacokinetics (PK) in older men in the Testosterone Trials (TTrials). Endocr Rev 2014; in press. Abstract No. SUN-0086. 16th International Congress of Endocrinology and The Endocrine Society 96th Annual Meeting ENDO 2014, Chicago, IL, June 21-24, 2014.

#216. Cauley JA, Fluharty L, Ellenberg S, Gill TM, Ensrud KE, Barrett-Connor E, Cifelli D, Cunningham GR, **Matsumoto AM**, Bhasin S, Pahor M, Farrar JT, Cella D, Rosen RC, Resnick SM, Swerdloff RS, Lewis CE, Molitch ME, Crandall JP, Stephens AJ, Wang C, Romashkan S, Hadley E, Snyder PJ. Screening and recruitment for the Testosterone Trials (TTrials). Endocr Rev 2014; in press. Abstract No. SUN-0096. 16th International Congress of Endocrinology and The Endocrine Society 96th Annual Meeting ENDO 2014, Chicago, IL, June 21-24, 2014.

#217. Muram D, **Matsumoto AM**, Zhang X, Cui Z. Application of the Endocrine Society clinical guidelines on testosterone therapy in men with androgen deficiency syndromes in clinical practice. Endocr Rev 2014; in press. Abstract No. MON-0021. 16th International Congress of Endocrinology and The Endocrine Society 96th Annual Meeting ENDO 2014, Chicago, IL, June 21-24, 2014.

16. INVITED LECTURESHIPS AND CONSULTANT

April 2015 Invited Speaker, Meet-the-Professor Session, “Assessing and managing tesotosterone abnormalities in all your patients”, American College of Physicians Annual Meeting Internal Medicine 2015, Boston, MA, April 30, 2015

Mar 2015 Invited Speaker, Controversies in the Diagnosis and Treatment of Male Hypogonadism Symposium, “Testosterone measurements to confirm the diagnosis of male hypogonadism”, The Endocrine Society 97th Annual Meeting, San Diego, CA, March 7, 2015

Mar 2015 Invited Speaker, Meet-the-Professor Session, “Evaluation of men with hypogonadotropic hypogonadism: clinical, laboratory and imaging”, The Endocrine Society 97th Annual Meeting, San Diego, CA, March 6, 2015

Nov 2014 Invited Speaker, Endocrine Essentials Live Pro, The Endocrine Society, “Diagnosis and management of hypogonadism”, Manhattan Beach, CA, November 15, 2014

Nov 2014 Invited Speaker, Endocrine Essentials Live for Primary Care, The Endocrine Society, “Low testosterone: when to treat”, Manhattan Beach,

CA, November 15, 2014

Oct 2014 Invited Participant, 13th Annual United States Anti-Doping Agency (USADA) Symposium on Anti-Doping Science, Phoenix, AZ, October 3-6, 2014

Sept 2014 Invited Speaker, Clinical Endocrinology Update 2014, The Endocrine Society, "Androgen Deficiency Maintenance Of Certification (MOC) Live Learning Session", San Francisco, CA, September 3, 2014

August 2014 Invited Speaker, American Association of Clinical Endocrinologists, Heartland Chapter, 5th Annual Meeting, "Testosterone and cardiovascular disease: what do I do now?", Omaha, NE, August 24, 2014

July 2014 Invited Speaker and Consultant, Men's Health Scientific Advisory Board Meeting, "The Endocrine Society Guidelines and the Bendfits of Testosterone Replacement Therapy", AbbVie, Chicago, IL, July 25, 2014

June 2014 Invited Speaker, "Testosterone and aging", Skyline at First Hill, Seattle, WA, June 26, 2014

June 2014 Invited Chair and Consultant, Scientific Advisory Board Meeting, Clarus Therapeutics, Chicago, IL, June 25, 2014

June 2014 Invited Consultant, Testosterone Undecanoate R&D Scientific Advisory Board Meeting, Endo Pharmaceuticals, Chicago, IL, June 19, 2014

May 2014 Invited Speaker, American Society for Men's Health, American Urological Association, Annual Meeting, "Testosterone replacement: a balanced clinical perspective", Orlando, FL, May 19, 2014

May 2014 Invited Speaker, Northwest Geriatric Education Center (NWGEC), Geriatric Health Series, "Thyroid disorders in older adults", University of Washington, Seattle, WA, May 13, 2014

Mar 2014 Consultant, New Geriatric Research, Education and Clinical Center Review Committee, Office of Geriatrics and Extended Care, Department of Veterans Affairs, Washington, DC, March 13-14, 2014.

Feb 2014 Invited Speaker, SPORE Clinical Studies Seminar, Fred Hutchinson Cancer Research Center, "Important issues and state of knowledge in male hormone hormone replacement therapy: whoa T for low T", February 27, 2014

Dec 2013 Invited Participant, Testosterone Replacement Therapy Advisory Board Meeting, Arlington, VA, December 8, 2013

Aug 2013 Invited Speaker, "Osteoporosis in men: not just a problem in postmenopausal women", Geriatric Grand Rounds, University of Washington, Harborview Medical Center, August 30, 2013

Jun 2013 Invited Speaker, “Maintaining the pace in androgen deficiency: improving the diagnosis and management of hypogonadism”, Endocrine Society CMES program, The Endocrine Society Annual Meeting ENDO 2013, San Francisco, CA, June 15, 2013 and June 17, 2013

Jun 2013 Invited Speaker, “Androgen deficiency syndromes in men: maintenance of certification (MOC), Live Learning Session”, The Endocrine Society Annual Meeting ENDO 2013, San Francisco, CA, June 16, 2013

May 2013 Invited Speaker, “Diagnosis, evaluation and management of hypogonadism”, University of Washington Department of Medicine Grand Rounds, Seattle, WA, May 9, 2013

Apr 2013 Invited Speaker, “Testosterone replacement therapy and mortality”, Innovations in Men’s Health, ASA Special Symposium, San Antonio, TX, April 13, 2013

Apr 2013 Invited Speaker, “Diagnosis, evaluation and treatment of hypogonadism in older men: in search of a patient-centered hole in one”, Medicine Grand Rounds, Boise VA Medical Center, Boise, ID, April 4, 2013

Apr 2013 Invited Speaker, “Osteoporois: not just a problem in older women”, Internal Medicine Residents Teaching Conference, Boise VA Medical Center, Boise, ID, April 4, 2013

Feb 2013 Invited Participant, Program for Accurate Testing of Hormones (PATH) Steering Committee Strategic Planning Meeting, Reston, VA, February 12-13, 2013

Feb 2013 Invited Speaker, “ Why is measuring free testosterone better than total?”, GTx Roundtable on Free Testosterone and Prostate Cancer Treatment, Memphis, TN, February 2, 2013

Dec 2012 Invited Participant, Lilly Consultants Meeting on Diabetes and Hypogonadism, Indianapolis, IN, December 14, 2012

July 2012 Invited Speaker, “Diagnosis & Management of Hypogonadism in Older Men”, Geriatrics Grand Rounds, University of Washington, Harboview Medical Center, July 20, 2012

June 2012 Invited Speaker, “Diagnosis & management of male hypogonadism in the older man”, Case Management Forum, The Endocrine Society 94th Annual Meeting ENDO 2012, Houston, TX, June 23, 2012

Dec 2011 Invited Participant, Partnership for Clean Competition 2011 Conference on The Doping Decision: Deterring Doping in Sport, New York, NY, December 1, 2011

Nov 2011 Invited Speaker, Sexual Medicine Society of North America Annual Meeting, “The evolving role of testosterone in bone health”, Las Vegas, NV, November 11, 2011

Jul 2011 Invited Participant, Oral testosterone treatment of male hypogonadism meeting, Abbott Pharmaceuticals, Chicago, IL, July 21, 2011

Jun 2011 Invited Speaker, Controversies in the Guidelines for the Diagnosis and Management of Hypogonadism Symposium, The Endocrine Society 93rd Annual Meeting ENDO 2011, "Management of male hypogonadism: who, when, what and how", Boston, MA, June 5, 2011

May 2011 Invited Speaker, Endocrine Grand Rounds, University of Pittsburgh, "Use and abuse of androgens", Pittsburgh, PA, May 20, 2011

May 2011 Invited Participant, Selective Androgen Receptor Modulator Advisory Board, Ligand Pharmaceuticals, Chicago, IL, May 5, 2011

Apr 2011 Invited Speaker, "Testosterone and bone health in men", Washington Osteoporosis Coalition Meeting, Fred Hutchinson Cancer Research Center, Seattle, WA, April 13, 2011

Apr 2011 Invited Speaker, CME Symposium, American College of Medicine Internal Medicine 2011, "Male Hypogonadism: Diagnostic and Therapeutic Strategies", San Diego, CA, April 7, 2011

Mar 2011 Invited Speaker, Biology of Aging Lecture, Huffington Center of Aging, Baylor College of Medicine, "Testosterone and the aging male: clinical practice and research challenges", Houston, TX, March 16, 2011

Feb 2011 Invited Participant, Hypogonadism Advisory Board, Abbott Pharmaceuticals, Dallas, TX, February 12, 2011

Dec 2010 Invited Participant, Testosterone Replacement Therapy Advisory Board, Endo Pharmaceuticals, Philadelphia, PA, December 11, 2010

Oct 2010 Invited Participant, 9th Annual USADA Symposium on Anti-Doping Science, "Emerging Technologies in Anti-Doping", Washington, DC, October 1-4, 2010

Apr 2010 Invited Speaker, ASA 2010, 35th Annual Meeting, American Society of Andrology, Houston, TX, April 10-13, "Testosterone and the aging male", April 13, 2010

Mar 2010 Invited Participant, Partnership for Clean Competition 2010 Conference on The Science Behind Anti-Doping, New York, NY, March 4, 2010

Feb 2010 Invited Participant, Center for Disease Control Testosterone Measurement Consensus Conference, Atlanta, GA, February 11-12, 2010

Jan 2010 Invited Speaker, Update in Internal Medicine, 33rd Annual Winter Conference, Idaho ACP, "Challenges in the diagnosis and treatment of male hypogonadism", McCall, ID, January 16, 2010

Oct 2009 Invited Consultant, Merck & Company, "SARMs and HDL Cholesterol Scientific Meeting, "The Testosterone Trial and cardiovascular outcomes", New Brunswick, NJ, October 29-30, 2009

Oct 2009 Invited Participant, 8th Annual USADA Symposium on Anti-Doping Science, "Detection of enhancement of oxygen transport: 7 years of progress", Vancouver, BC, Canada, October 2-5, 2009

Jun 2009 Invited Speaker, Merck Research Laboratories, "The Testosterone Trial" and "Importance of active metabolism of testosterone and selective androgen receptor modulators", Rahway, NJ, June 29, 2009

June 2009 Invited Participant, Endo Pharmaceuticals Regional Advisory Board Meeting, Marina Del Rey, CA, June 26-27, 20009

Jun 2009 Invited Speaker, The Endocrine Society 91st Annual Meeting, ENDO 2009 Meet-the-Professor session, "Erectile dysfunction: who, when, what treatment", Washington, DC, June 10, 2009

May 2009 Invited Participant, Merck Global Therapeutic Experts Forum (GTEF), "Bone anabolic agents, SARMs, sarcopenia and frailty", Newark, NJ, May 8-9, 2009

Mar 2009 Invited Reviewer, Merck Bone, Respiratory, Immunology, Endocrine (BRIE) Research Strategy Review Committee (RSRC), Upper Gwynedd, PA, March 11, 2009

Oct 2008 Invited Participant, 7th Annual USADA Symposium on Anti-Doping Science, "Proteins to Mitochondria: New Challenges for Anti -Doping Science", Colorado Springs, CO, October 17-20, 2008

Aug 2008 Invited Participant, "AndroGel DEMAND trial and PRO development", Dallas, TX, August 20-21, 2008

Jun 2008 Invited Speaker, "Considerations for the diagnosis and treatment of hypogonadism", TesosteroneUpdate ENDO Disease State Theater, The Endocrine Society 90th Annual Meeting, San Francisco, CA, June 17, 2008.

Jun 2008 Invited Speaker, "Testosterone and cognitive function", ENDO 2008 CMES Program, The Endocrine Society 90th Annual Meeting, San Francisco, CA, June 16, 2008.

Mar 2008 Invited Speaker, "Evaluation and treatment of male hypogonadism in primary care. Do we need a Men's Health Initiative?" Department of Internal Medicine Grand Rounds, University of Kansas School of Medicine, Kansas City, KA, March 19, 2008

Mar 2008 Invited Speaker, "Diagnosis and evaluation of male hypogonadism for the endocrinologist", University of Kansas School of Medicine, CME,

Kansas City, KA, May 19, 2008

Mar 2008 Invited Participant, CDC Workshop on Improving Steroid Hormone Measurements in Patient Care and Research Translation, Centers for Disease Control and Prevention, National Center for Environmental Health, Division of Laboratory Sciences, CDC Chamblee Campus, Atlanta, GA, March 17-18, 2008

Mar 2008 Invited Participant, 1st Annual Conference on Improving Clinical Outcomes in Hypogonadism, Western Region, Los Angeles, CA, March 15, 2008

Feb 2008 Invited Speaker, "Androgen deficiency, its effects", 6th World Congress on the Aging Male, February 21-24, 2008, Tampa, FL, February 24, 2008

Feb 2008 Invited Speaker, "Will selective androgen receptor modulators work for older men?", 6th World Congress on the Aging Male, February 21-24, 2008, Tampa, FL, February 21, 2008

Jan 2008 Invited Participant, Amgen AMG 475 Geriatric Sarcopenia Advisory Board, Los Angeles, CA, January 25, 2008

Nov 2007 Invited Participant, 1st Annual Conference on Improving Clinical Outcomes in Hypogonadism, Eastern Region, American Conference Center, New York, NY, November 3, 2007

Sept 2007 Invited Speaker, "Hypogonadism in men", 35th Annual Advances in Family Medicine and Primary Care, UW CME, Seattle, WA, September 11, 2007

Aug 2007 Invited Speaker, "Androgen deficiency: syndromes and challenges", Solvay Men's Health Advanced Clinical Training, Bell Harbor Conference Center, Seattle, WA, August 21, 2007.

May 2007 Invited Speaker, "The role of androgens in aging men", Geriatrics Research Conference, VAPSHCS, American Lake, May 22, 2007.

Apr 2007 Invited Speaker, "Measurement of insulin resistance in SARM treatment trials", GTx Ostarine Advisory Board, Houston, TX, April 28, 2007.

Apr 2007 Invited Speaker, "Menopause/Menopause" Panel, The American College of Physicians Internal Medicine 2007, April 19-21, 2007, San Diego, CA, April 20, 2007.

Mar 2007 Invited Speaker, "The role of testosterone in aging, cognitive function and contraception: implications for SARM development", Acadia Pharmaceuticals, San Diego, CA, March 26, 2007.

Feb 2007 Invited Speaker, "The role of androgens in the ageing male", Society for Endocrinology, British Endocrine Society 2007 Meeting,

March 5-8, 2007, Birmingham, United Kingdom, March 6, 2007.

Jan 2007 Invited Consultant, SARMs in cancer cachexia and sarcopenia, GTx SARM Advisory Board, Memphis, TN, January 26-27, 2007.

Sept 2006 Invited Speaker, Androgens: Problem or Solution? Issues with Testosterone Supplementation and Deprivation in the Risk and Treatment of Prostate Cancer, University of Washington CME, Fred Hutchinson Cancer Research Center, "Androgen replacement in older hypogonadal men", September 30, 2006.

Sept 2006 Invited Speaker, "Testosterone deficiency in men: evidence-based protocols for effective therapy", University of Wisconsin Regional CME San Francisco, CA, September 27, 2006.

Sept 2006 Invited Speaker, "Testosterone deficiency in men: evidence-based protocols for effective therapy", University of Wisconsin Regional CME Seattle, WA, September 26, 2006.

July 2006 Invited Consultant, Use of Peptibody to Myostatin for Muscle Wasting in Geriatric Rehabilitation, Amgen, Thousand Oaks, CA, July 19-20, 2006.

July 2006 Invited Speaker, Primary Care Conference, VA Puget Sound Health Care System, American Lake, "Clinical evaluation and treatment of male Hypogonadism in primary care", Tacoma, WA, July 18, 2006.

Jun 2006 Invited Speaker, Meet-The-Professor, The Endocrine Society, Annual Meeting, ENDO 2006, Boston, MA, June 24-27, "Replacement strategies for male hypogonadism", June 24, 2006.

Apr 2006 Invited Speaker, Endocrine Issues in Male Reproductive Failure Symposium, American Society of Andrology, 31st Annual Meeting, Chicago, IL, April 8-11, 2006, "Strategies for stimulating androgen production in aging men and men with secondary hypogonadism", April 10, 2006.

Feb 2006 Invited Speaker, From Frail to Fit after Fifty Conference, International Conference on Aging, Disability and Independence, University of Florida, St. Petersburg, FL, ""How can we avoid the adverse effects of androgens?", February 1, 2006

Jan 2006 Invited Speaker, University of Washington Endocrine Days, "Androgen deficiency in the aging male". Seattle, WA, January 27, 2006. Chair, Endocrinology and Aging Half-Day Session, Seattle, WA, January 27, 2006

Jan 2006 Invited Speaker, Diabetes & Endocrinology in 2006, Colorado Society of Endocrinology and Metabolism, Snowmass, Aspen, CO, "Male infertility: It takes two to tango", January 23, 2006; "Male hypogonadism: sometimes a hard nut to crack";, January 24, 2006.

Jan 2006 Invited Consultant, Quatrx Fispemifene External Experts Meeting, Seattle, WA, January 19, 2006

Oct 2005 Visiting Professor, Oregon Health Sciences University, Bone and Mineral Unit and Division of Endocrinology/Diabetes and Clinical Nutrition, "Testosterone and the aging male: what's so new and challenging?"; Invited Speaker, Portland Bone Club, "Androgens, body composition and bone: are non-steroidal selective androgen receptor modulators (SARMs) necessary?", October 10, 2005.

Oct 2005 Invited Consultant, GTx Renal Failure Advisory Board, Chicago, IL, October 8, 2005

Sept 2005 Invited Consultant, AndroGel Advisory Board, Solvay Pharmaceuticals, Chicago, IL, September 25-26, 2005.

Sept 2005 Invited Speaker, 33rd Annual Advances in Family Practice & Primary Care, Continuing Medical Education, University of Washington School of Medicine, "Hypogonadism in men", Seattle, WA, September 14, 2005.

Aug 2005 Invited Consultant, GTx SARM Phase 1 Clinical Trial Data Evaluation, Seattle, WA, August 24, 2005.

June 2005 Invited Speaker, The Endocrine Society 2005 Annual Meeting, Endocrinology of Aging Symposium, "Testosterone (T) Levels in the Aging Male: Challenges in the Diagnosis of Androgen Deficiency and Actions of T on Target Tissues in Older Men", June 4, 2005.

May 2005 Invited Speaker, Medicine Grand Rounds, Boise VA Medical Center, "Clinical evaluation of androgen deficiency", May 5, 2005.

April 2005 Invited Consultant, GTx SARM Advisory Board, Memphis, TN, April 30-May 1, 2005.

Jan 2005 Invited Consultant, Medical Treatment of Benign Prostatic Hyperplasia Meeting, Threshold Pharmaceuticals, San Francisco, CA, January 13-14, 2005.

Jan 2005 Invited Consultant and Participant, SARMs: Novel Approaches to Frailty, Osteoporosis and Sexual Dysfunction Meeting, TAP and Ligand Pharmaceuticals, Chicago, IL, January 3-4, 2005.

Dec 2004 Invited Participant, Evidence-Based Guidelines for the Management of Androgen Deficiency Syndrome in Men Task Force, Endocrine Society, Philadelphia, PA, December 7, 2004

Nov 2004 Invited Speaker, Seattle Surgical Society Meeting, "Highlights of potential
future uses of androgens", Ranier Club, Seattle, WA, November 22, 2004

Nov 2004 Invited Speaker, PriMed Mid-Atlantic 2004 Conference, “Challenges in the Clinical and Biochemical Diagnosis of Hypogonadism in Men”, Washington, DC, November 18, 2004

Oct 2004 Invited Consultant, New England Research Institutes, Massachusetts Male Aging Study, Boston, MA, October 29, 2004

Oct 2004 Invited Speaker, PriMed East 2004 Conference, “Challenges in the Clinical and Biochemical Diagnosis of Hypogonadism in Men”, Boston, MA, October 29, 2004

Sept 2004 Invited Participant, Evidence-Based Guidelines for Management of Androgen Deficiency Syndrome in Men Task Force, Endocrine Society, Chicago, IL, September 17, 2004

July 2004 Invited Consultant, Johnson & Johnson PRD SARM Expert Meeting, New York, NY, July 23, 2004

July 2004 Invited Consultant, ICOS Selective Androgen Receptor Modulator, Seattle, WA, July 1, 2004

June 2004 Invited Speaker, Endocrine Society CMES, “Screening and Diagnosis of Hypogonadism in Men, Including Selection of Appropriate Patients for Therapy and Benefits of Therapy”, New Orleans, LA, June 19, 2004

June 2004 Invited Speaker, Medicine Grand Rounds, Boise VA Medical Center, “Androgen Replacement in Older Men”, Boise, ID, June 10, 2004

May 2004 Invited Speaker and Discussion Leader, VA Special Fellowship Program in Advanced Geriatrics Annual Meeting, “How Prepare and Write a Grant”, Las Vegas, NV, May 17, 2004

May 2004 Invited Speaker, PriMed West 2004 Conference, “Challenges in the Clinical and Biochemical Diagnosis of Hypogonadism in Men”, Anaheim, CA, May 13, 2004

Apr 2004 Invited Consultant, GlaxoSmithKline SARM Advisory Board Meeting, Baltimore, MD, April 17, 2004

Mar 2004 Invited Speaker, Auxilium National Advisory Board Meeting, “Current Research Topics in Androgen Therapy”, Phoenix, AZ, March 20, 2004

Mar 2004 Invited Speaker, Division of Gerontology & Geriatric Medicine, Geriatric Grand Rounds, “Erectile dysfunction in the elderly: diagnosis and treatment”, March 19, 2004

Nov 2003 Invited Speaker, Portland Diabetes & Endocrinology Center, “Diagnosis and Treatment of Male Hypogonadism”, Portland, OR, November 12, 2003.

Oct 2003 Invited Consultant, Solvay AndroGel Lifecycle Advisory Panel, San

Antonio, TX, October 29-30, 2003.

Oct 2003 Invited Consultant, GSK Talnetant Clinical Advisory Board Meeting, Chicago, IL, October 20, 2003.

June 2003 Invited Consultant and Speaker, "Potential Role of Androgens in the Treatment of Frailty", Ligand Metabolic Diseases, Selective Androgen Receptor Modulator, Oncology and Glucocorticoid Receptor Inflammation Programs Advisory Board Meeting, San Diego, CA, June 25, 2003.

June 2003 Invited Consultant, BMS Selective Androgen Receptor Modulator Advisory Committee, Philadelphia, PA, June 22, 2003.

Apr 2003 Invited Speaker, Columbia Laboratories Consultant's Meeting, American Urological Association, "Pharmacokinetics, Safety and Efficacy of Buccal Testosterone in Hypogonadal Men", Chicago, IL, April 28, 2003.

Apr 2003 Invited Consultant, GlaxoSmithKline, "Testosterone Replacement with and without Dustasteride in Older Men", Research Triangle Park, NC, April 21, 2003.

Apr 2003 Invited Speaker, GlaxoSmithKline Research Seminar, "Regulation of Food Intake, Body Weight and Body Composition in Developing and Aging Rat Models", Research Triangle Park, NC, April 21, 2003.

Apr 2003 Invited Consultant, GlaxoSmithKline Selective Androgen Receptor Modulator Program, Research Triangle Park, NC, April 21, 2003

Mar 2003 Invited Speaker and Consultant, Institute of Medicine Workshop on Clinical Trials of Testosterone Replacement Therapy in Older Men, "Issues in Measuring and Monitoring Prostate-Related Outcomes in Clinical Trials", Phoenix, AZ, March 31, 2003

Mar 2003 Invited Consultant, GlaxoSmithKline Dutasteride and Spermatogenesis Advisory Board, Phoenix, AZ, March 30, 2003

Mar 2003 Invited Consultant, GlaxoSmithKline Talnetant and Reproductive Function Advisory Board, Phoenix, AZ, March 28, 2003

Mar 2003 Invited Speaker and Consultant, AndroGel Clinical Investigators Meeting, "A Long-Term Study of the Safety and Effectiveness of Testosterone Gel for Hormonal Replacement in Hypogonadal Men", San Juan, Puerto Rico, March 14, 2003

Feb 2003 Invited Speaker and Consultant, Content Development & Prostatic Disease and Testosterone Replacement Consensus Conference, "Testosterone Replacement Therapy and Treatment Options in the Aging Male", Vail, CO, February 18, 2003

Dec 2002 Invited Speaker, 22nd Annual St. Louis Geriatric Research, Education and Clinical Center Conference on Health Promotion and Disease

Prevention in Older Persons, and 14th Annual St. Louis University Symposium for Medical Directors on Nursing Home Issues,"Clinical Implications of Andropause", December 7, 2002

Dec 2002 Invited Consultant, Investigators/Speakers Bureau Development Meeting, Auxilium Pharmaceuticals, Chicago, IL, December 2, 2002

Nov 2002 Invited Speaker, Special Fellowship Program in Advanced Geriatrics 2nd Annual Meeting, "Career Pathways in Academic Geriatrics", Boston, MA, November 22, 2002

Oct 2002 Invited Speaker, Primed Regional Conference, Hypogonadism: From Prevalence to Treatment, "Hypogonadism and Andropause: Overview and Prevalence", Tampa, FL, October 26, 2002

Aug 2002 Invited Consultant, Expert Meeting on Org 538 Andriol® Testocaps™, Salt Lake City, UT, August 24-25, 2002

Aug 2002 Invited Consultant, Postgraduate Institute for Medicine Roundtable Meeting on the "Role of DHT in Prostate Health", Dallas, TX, August 3, 2002

July 2002 Invited Consultant, GlaxoSmithKline Selective Androgen Receptor Modulator Advisory Meeting, Seattle, WA, July 27, 2002

July 2002 Invited Speaker, "The Aging Male" Opinion Leader Roundtable, "Fundamental Aspects of Hypogonadism in the Aging Male", Seattle, WA, July 20, 2002

July 2002 Invited Speaker, Expert Panel on the Development of a Case Finding Instrument for Androgen Deficiency in Men "Clinical Manifestations of Androgen Deficiency", Chicago, IL, July 1, 2002

June 2002 Invited Speaker, Endocrine Society Annual Meeting Symposium, "Physiology of Andropause", San Francisco, CA, June 19, 2002

June 2002 Invited Speaker, Solvay Pharmaceuticals Seminar "New Developments In Androgen Replacement Therapy", Seattle, WA, June 11, 2002

May 2002 Invited Speaker, International Longevity Center-USA, Kronos Longevity Research Institute, and NIA, Masculine Vitality Conference, "Biochemistry and Physiology of Male Hormones", Canyon Ranch, AZ, May 16-19, 2002

May 2002 Invited Consultant, The Endocrine Society, 3rd Andropause Task Force, Los Angeles, CA, May 3-5, 2002

May 2002 Invited Speaker, American Association of Clinical Endocrinologists Satellite Symposium, "Effects of Testosterone on Mood and Cognitive Function", Chicago, IL, May 2, 2002

Apr 2002 Invited Consultant, Selective Androgen Receptor Modulators, Bristol Myers Squibb, Princeton, NJ, April 29, 2002

Apr 2002 Invited Consultant, AndroGel Advisory Board, Solvay Pharmaceuticals, Dallas, TX, April 16-17, 2002

Apr 2002 Invited Speaker, Department of Medicine Grand Rounds, University of Washington School of Medicine, “Andropause: Clinical Implications of the Age-Related Decline in Serum Testosterone Levels in Men”, Seattle, WA, April 4, 2002

Mar 2002 Invited Speaker, Geriatrics Grand Rounds, University of Washington School of Medicine, “Androgens and the Aging Male”, Seattle, WA, March15, 2002

Mar 2002 Invited Speaker, Uniform Services Urology Research Group Annual Meeting, “Androgen Decline in the Aging Male, Las Vegas, NV, March 9, 2002

Jan 2002 Invited Speaker, University of Washington Endocrine Days, "Sex Hormone-Secreting Tumors in the Male: Clinical Presentations and Evaluation”. Seattle, WA, January 18, 2002. Chair, Endocrinology and Aging Half-Day Session, Seattle, WA, January 18, 2002

Dec 2001 Invited Speaker, Endocrine Society CMES Ancillary Symposium on Aging Men and Women: Does Sex Steroid Therapy Improve Quality of Life, "Health Benefits and Risks of Testosterone Therapy", Roslyn, Long Island, NY, December 1, 2001.

Nov 2001 Invited Consultant, GTx Medical Advisory Board for GTx-007 and SARMs, GTx Innovative Therapies, Memphis, TN, November 8-9, 2001.

July 2001 Invited Speaker, Primary Care for the Disabled Seminar Series, "Testosterone Replacement in the Elderly and a Rehabilitation Setting", Department of Physical Medicine and Rehabilitation, University of Washington, Seattle, WA, July 30, 2001.

May 2001 Invited Consultant, Dutasteride Spermatogenesis Study (ARIA 1009) and Gonadal Effects of SB223412, GlaxoSmithKline, Seattle, WA, May 26, 2001.

Apr 2001 Invited Speaker, Research Seminar, "Androgen Replacement Treatment: New Indications, Formulations and Animal Models", R.W. Johnson Pharmaceutical Research Institute, Raritan, NJ, April 23, 2001.

Apr 2001 Invited Consultant, The Endocrine Society, 2nd Annual Andropause Consensus Meeting, "Andropause 2001", Beverly Hills, CA, April 20-22, 2001.

Apr 2001 Invited Speaker, Endocrinology & Metabolism Grand Rounds, "Androgen Replacement Therapy: New Indications and Delivery Systems",

Vanderbilt University, April 10, 2001.

Feb 2001 Invited Consultant, "Andropause: Quality of Life and Frailty", Organon, Inc., San Francisco, CA, February 10-11, 2001.

Oct 2000 Invited Speaker and Participant, First United States Anti-Doping Agency Research Summit, "Androgenic Anabolic Steroid Abuse: Lessons from Clinical Trials" and Research Priorities Group Leader, Denver, CO, October 20-21, 2000.

July 2000 Invited Speaker, Fifth International Symposium on Neurobiology and Neuroendocrinology of Aging, "Aging and the Neuroendocrine Regulation of Reproduction and Body Weight", Bregenz, Vorarlberg, Austria, July 28, 2000.

May 2000 Invited Speaker, Evergreen Hospital Medical Center Grand Rounds, "New Developments in Androgen Treatment", Kirkland, WA, May 5, 2000.

Apr 2000 Invited Speaker, Andropause Consensus 2000: Advances in Testosterone Replacement Therapy, "The Aging Male: Demographics, Physical and Endocrine Changes and the "Andropause", Beverly Hills, CA, April 28, 2000.

Jan 2000 Invited Speaker, Endocrine Basis of Reproductive Function Symposium, "Physical, metabolic and endocrine correlates of male aging", Tampa, FL, January 22, 2000.

Dec 1999 Invited Speaker, Department of Medicine Grand Rounds, "Androgens and Aging", Emory University School of Medicine, Atlanta, GA, December 7, 1999.

Nov 1999 Invited Speaker, GRECC Symposium, "The Brown Norway (BN) rat as a model to study age-related alterations in the neuroendocrine regulation of food intake (FI) and body weight (BW) and body composition", The Gerontological Society or America, 52nd. Annual Meeting, San Francisco, CA, November 21, 1999.

Oct 1999 Invited Expert, Expert Meeting on Androgenic Steroids and Steroid Precursors, Drug Enforcement Administration, U.S. Department of Justice, Washington, D.C., October 19-20, 1999.

Sept 1999 Invited Expert, U.S. Expert Meeting on Improved Andriol®, Organon, Toronto, Canada, September 25, 1999.

Apr 1999 Invited Speaker, Geriatrics Grand Rounds, Division of Gerontology and Geriatric Medicine, University of Washington, "Testosterone Treatment in the Elderly", Seattle, WA, April 16, 1999.

Feb 1999 Invited Speaker, Seminars in Reproductive Medicine, Department of Obstetrics and Gynecology, Division of Reproductive Endocrinology,

University of Washington, "Androgen Replacement: Pharmacology and Dosing", Seattle, WA, February 19, 1999.

Feb 1999 Invited Speaker, Endocrinology Grand Rounds, Baylor College of Medicine, "Hormone Replacement in the Elderly", Houston, TX, February 18, 1999.

Feb 1999 Invited Speaker, Medicine Grand Rounds, Madigan Army Medical Center, "Hormone Replacement Therapy in Elderly Women and Men", Tacoma, WA, February 12, 1999.

Nov 1998 Invited Speaker, Straub Foundation, Health in Paradise: A Symposium on Prevention and Screening, Public Program, "Male Menopause", Honolulu, HI, November 21, 1998.

Nov 1998 Invited Speaker, Straub Foundation, Health in Paradise: A Symposium on Prevention and Screening, "Male Menopause"; "Osteoporosis"; and "Geriatrics in the 21st Century", Honolulu, HI, November 19 and 20, 1998.

Oct 1998 Invited Speaker, Male Reproduction Symposium, 16th World Congress on Fertility and Sterility (IFFS '98) and 54th Annual Meeting of the American Society for Reproductive Medicine, "Androgens and the Aging Male", San Francisco, CA, October 7, 1998.

Aug 1998 Invited Speaker, Drew University of Medicine, Endocrinology, Metabolism and Molecular Medicine Division Seminar, "Rat Models of Age-Related Sarcopenia", Los Angeles, CA, August 28,1998

Jun 1998 Invited Speaker, 2nd. Summit Meeting on Hormonal Male Contraception, "Male Contraceptive Development Studies Using Testosterone Enanthate Plus Levonorgestrel", New Orleans, LA, June 28, 1998

Apr 1998 Invited Speaker, Contraceptive Research and Development (CONRAD) Male Methods Program and CICCR Evaluation Meeting, "Strategies in Male Hormonal Contraception: A Review of CONRAD-Sponsored Studies and Future Perspectives", Arlington, VA, April 7, 1998

Mar 1998 Invited Speaker, Serono Male Infertility Task Force, "Endocrine Control of Human Spermatogenesis", Geneva, Switzerland, March 6, 1998

Feb 1998 Invited Speaker, Puget Sound Forums on Aging, "Hormone Replacement Therapy in Men and Women", Seattle, WA, February 3, 1998

Oct 1997 Invited Speaker, University of Washington Endocrine Days, "Gonadotropins in the diagnosis and treatment of pituitary disease", Seattle, WA, October 24, 1997

June 1997 Invited Speaker, Endocrine Society Annual Meeting Symposium on Androgen Use in Men, "Androgen replacement in hypogonadal men",

Minneapolis, MN, June 11, 1997

May 1997 Invited Speaker, 25th. Annual Spring Update, Advances in Internal Medicine, University of Michigan Medical School, Department of Internal Medicine, "Benefits and Risks of Hormone Replacement Therapy for Older Adults", Ann Arbor, MI, April 30, 1997.

May 1997 Invited Speaker, Division of Geriatric Medicine Research Conference, University of Michigan Medical School, "Alteration in Food Intake and Body Weight Regulation with Aging in a Rat Model", Ann Arbor, MI, April 29, 1997.

May 1997 Invited Speaker, Geriatrics Section, Ann Arbor V.A. Medical Center, "Geriatrics and Extended Care at the V.A. Puget Sound Health Care System", Geriatrics Research, Education and Clinical Center, Ann Arbor, MI, April 29, 1997.

Sep 1996 Invited Speaker and Session Chairman, North American Menopause Society, 7th. Annual Meeting, "Age-related changes in physiology and function in women and men", Chicago, IL, September 28, 1996

Sep 1996 Invited Roundtable Discussant, Meet-the-Professor Sessions, North American Menopause Society, 7th. Annual Meeting, "Evaluation and Treatment of Impotence", Chicago, IL, September 26 and 27, 1996

July 1996 Invited Speaker, NICHD Conference on Androgen Receptors: Exploiting Differences in Hormone Action, ""Androgens and Aging", Bethesda, MD, July 23, 1996

Mar 1995 Invited Speaker, International Conference on Androgenic Hormones, Prostate Cancer and Benign Prostatic Hyperplasia, "Androgens and Aging", New Orleans, LA, March 13, 1995

Feb 1995 Invited Speaker, Second International Androgen Workshop, "Hormonal Male Contraceptive Development: Combined Administration of Androgens and Progestogens", Long Beach, CA, February 20, 1995

Jan 1994 Invited Speaker, University of Washington Endocrine Days, "Is There a Role for Treatment of Elderly with Anabolic Hormones", Seattle, WA, January 28, 1994

Jan 1994 Invited Speaker, University of Washington Population Center for Research in Reproduction Research Seminar Series, "New Strategies in Hormonal Contraception for Men, Seattle, WA, January 10, 1994

June 1993 Invited Speaker, Contraceptive Research and Development (CONRAD) Program Male Systemic Methods of Contraception Meeting, "Levonorgestrel-Testosterone Combinations in Male Contraception", Alexandria, VA, June 16, 1993

May 1993 Invited Speaker, Vth International Congress of Andrology, Symposium on

Male Sexual Behavior, "Behavioral Effects of High Dose Androgens", Tokyo, Japan, May 6, 1993

June 1992 Invited Speaker, Endocrine Society Symposium on Hormonal Control of Spermatogenesis, "Hormonal Regulation of Spermatogenesis in Humans", San Antonio, TX, June 25, 1992

Mar 1992 Invited Speaker, Wyeth-Ayerst Research, "The Use of Progestin-Androgen Combinations in Male Contraception", Radnor, PA, March 26, 1992

Nov 1990 Invited Speaker, NICHHD Conference on Reproductive Issues and the Aging Male "Aging and Human Male Reproductive Function," NIH, Bethesda, MD, November 26, 1990

Feb 1990 Invited Speaker, International Conference on Perspectives in Primate Reproductive Biology, "The Hormonal Regulation of Spermatogenesis in Man," Indian Institute of Science, Bangalore, India, February 6, 1990

Jan 1990 Invited Speaker, Invitational Symposium: Pulsatile GnRH in Clinical Medicine, "Abnormalities of the GnRH Pulse Generator in Men and Their Management," Fort Myers, FL, January 20, 1990

Apr 1989 Invited Speaker, Clinical Research Symposium: Physiology of Male Hypogonadism, American Society of Andrology, "Regulation of Germ Cell Maturation in Man," New Orleans, LA, April 16, 1989

Apr 1988 Invited Speaker, International Symposium on Gonadotropins: Structure, Control, Action, and Clinical Applications, "Endocrine control of human spermatogenesis," Paris, France, April 21, 1988

Jun 1987 Participant, Office of Technology Assessment Workshop on Prevention of Infertility, Seattle, WA, June 25, 1987

May 1986 Invited Speaker, Recent Advances in Neuroendocrinology Symposium, "Clinical Studies Using LHRH", University of British Columbia, Vancouver, B.C., Canada, May 4, 1986

Mar 1985 Invited Speaker, Abbott Conference on Episodic Hormone Secretion: Methods of Analysis and Normative Data, "Pulsatile gonadotropin secretion in hypergonadotropic hypogonadal men", Chicago, IL, March 13, 1985

May 1984 Invited Speaker, Basic Science Foundations in Endocrinology Lecture Series, "Gonadotropin control of spermatogenesis in man," Harbor-UCLA Medical Center, Los Angeles, CA, May 4, 1984

May 1983 Invited Speaker, NICHHD Reproductive Endocrinology Lecture Series, "Hormonal control of human spermatogenesis", NIH, Bethesda, MD, May 23, 1983

17. MILITARY

1979-80	United States Public Health Service, Commissioned Officer, Inactive Reserve
1976-79	United States Public Health Service, Commissioned Officer, Active Grade 0-4 (Lieutenant Commander)

Testosterone Testing

Teresa L. Rogstad, MPH,
Project Leader, Hayes, Inc.
March 20, 2015

Presentation overview

- Policy Context and Clinical Background
- Scope, Methods, and Search Results
- Inferences Based on Indirect Evidence
- Summary: Indirect Evidence, Practice Guidelines, and Payer Policies
- Final Comments

Policy Context and Clinical Background

Policy context

- Controversy
  - Diagnostic criteria for hypogonadism
  - Benefits and harms of treatment
  - New, easier-to-use formulations; direct-to-consumer advertising
- Analysis of claims data, 2000-2010 (Layton et al., 2014)
  - ↑ new testing (from 39.6 -170.0/10,000 person-years)
    - But constant prevalence
  - Diagnosis prior to testing
    - Erectile dysfunction (10.4%); diabetes (15.1%)
    - Hypertension (28.7%); fatigue (19.8%)
  - Substantially different patterns in UK
- National policies
  - No CMS policy or USPSTF recommendation
  - FDA approval of T products: primary/secondary "organic" hypogonadism

Rationale for this report

- Nonspecific indicators for testing
- Threats to analytic validity
- Clinical validity: link with some medical conditions
  - But no definitive cutoff values for predicting risk based on T levels
- Uncertain benefits, long-term safety of T therapy
- Evidence needed
  - Clinical utility studies

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Low testosterone/hypogonadism

- Prevalence, **low testosterone (T)** levels, American men
  - Age 45–54 years, **9.0%**; 55–64 years, **16.5%**; 65–74 years, **18.3%**
- Hypogonadism
  - Primary (abnormalities at testicular level)
  - Secondary (defects in testes and pituitary)
  - **Age-related hypogonadism (androgen deficiency)**
    - Low serum T levels + characteristic symptoms
    - "Male menopause", "andropause", "late-onset hypogonadism (LOH)", "androgen decline in the aging male (ADAM)"
    - Prevalence, age > 40 years: **2%–6%**
- How low is low?
  - Reference ranges for healthy young men
  - Typical cutoff values: **280–300 ng/dL (9.7–10.4 nmol/L)**

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Characteristic signs/symptoms (The Endocrine Society)

More specific (classic)	Less specific
Incomplete or delayed sexual development	Decreased energy, motivation, initiative, and self-confidence
Reduced libido	Depressed mood
Decreased spontaneous erections	Poor concentration/memory
Breast discomfort/enlargement	Sleep problems
Loss of body hair	Mild anemia
Very small/shrinking testes	Reduced muscle bulk and strength
Inability to father children	Increased body fat or body mass index
Low or zero sperm count	Diminished physical or work performance
Osteoporosis	
Hot flushes, sweats	

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Low T levels and patient complaints

Background evidence (observational studies)	Endocrine Society recommendations (2010)
Symptoms of sexual dysfunction ◦ Association (*2 studies*) ◦ OR of 3 simultaneous symptoms (low vs high T level): 1.64–2.24	*Test* in patients with *more-specific* symptoms
Health status, physical performance, psychological symptoms ◦ Inclusive evidence (4 *studies*)	*Consider testing*, patients with *less-specific* symptoms
	Weak recommendations, very-low-quality evidence

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Low T levels and poor health

Background evidence (observational data)

- Prevalence data
  - Chronic kidney disease, COPD, HIV
- Meta-analyses (risk estimates)
  - Osteoporosis, metabolic syndrome (MetS), type 2 DM, cardiovascular disease (CVD) and mortality, all-cause mortality
- Individual studies (risk estimates)
  - Obesity, poorer lifestyle or life situation
- Direction of causality uncertain

Endocrine Society: consider testing if

- No symptoms but
  - Pathology/radiation, sellar region
  - Medications (glucorticoids, anabolic steroids, opioids)
  - HIV-related weight loss
  - Osteoporosis
- Symptoms and
  - Type 2 DM
  - End-stage renal disease (ESRD)
  - Moderate-severe COPD

Weak recommendations, very-low-quality evidence

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Medical treatment

- Address reversible conditions first
- Indications used in practice*
  - Improve sexual function
  - Promote well-being
  - Correct effects of HIV treatment, glucocorticoids, opioids
- Positive evidence of efficacy (meta-analyses)
  - Sexual dysfunction, especially in hypogonadism
  - Diabetes-related outcomes, depending on outcome measure
- Safety in older men
  - Erythrocytosis
  - Prostate events?
  - Conflicting evidence: obstructive sleep apnea, cardiovascular events, mortality
  - FDA is reassessing

*All supported by *strong* Endocrine Society recommendations; *low* quality evidence.

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Testing T levels: technical issues

- Total, free, bioavailable testosterone
- Threats to analytic validity
  - Diurnal/day-to-day/age-related variation
  - Variation across labs (different populations)
  - Variation across commercial assays
  - Precision poor at lower limit of reference ranges
- Best practice
  - Measure total testosterone (TT) 8:00–10:00 a.m.
  - Measure ≥ 2 times, different days
  - TT near lower limit of normal range → measure free/bioavailable T levels
- Voluntary quality control programs

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Testing T levels: other considerations

- Clinical validity
  - Decline starts approximately at age 30
  - To evaluate symptomatic men, regardless of age
    - Compare levels with normal range for young men
  - No cutoff for assessing health risk
- Monitoring
  - No definitive schedule
  - During therapy, assess need for adjustments

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Scope, Methods, and Search Results

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PICO

- **Population:** Adult men
- **Interventions:** Measurement of circulating total, free, or bioavailable testosterone as an initial assessment of possible hypogonadism
- **Comparisons**: Investigation and clinical management of symptoms or health problems without the use of testosterone testing
- **Outcomes:** Outcomes such as symptom improvement; general health outcomes (e.g., osteoporosis, chronic disease, mortality); clinical management decisions; potential harms; potential harms resulting from testosterone treatment decisions; cost and cost-effectiveness

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Key Questions

- 1. Is there evidence that testosterone **testing improves outcomes**?
- 1a. **Does the impact on outcomes vary** according to age, race/ethnicity, baseline testosterone levels, treatment status, or clinical history?
- 1b. What is the **minimum interval** required to assess a change in testosterone status in untreated and treated individuals?
- 2. What are the **potential harms** of testosterone testing, including potential subsequent harms resulting from treatment decisions?
- 3. What are the **costs and cost-effectiveness** of testosterone testing?

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Methods for selecting key question (KQ) evidence

- Searched for direct evidence
  - Consistent with PICO
  - KQ #1, #1a, #2 (effectiveness and safety of testing)
    - Any study comparing groups tested and not tested
    - Published 1990 or later
  - KQ #1b (monitoring intervals)
    - Longitudinal studies
    - Published 1990 or later
  - KQ #3 (cost implications)
    - Published 2003 or later
- **No eligible studies identified**

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Post hoc analysis: indirect evidence

- 2 subpopulations selected based on systematic reviews (SRs) and large population studies
  - Type 2 DM or metabolic syndrome (MetS)
    - 3 SRs: association with low T levels
    - 1 SR: efficacy of T therapy*
  - Sexual dysfunction
    - 2 large population studies: association with low T levels
    - 1 SR: efficacy of T therapy

**A second review published after Draft Report cast doubt on conclusions regarding treatment efficacy.*

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Post hoc analysis: indirect evidence (cont.)

- Systematic search for <u>new</u> publications published since recent SRs and population studies

Association with MetS or type 2 DM	15 studies*
Efficacy of T therapy, men with type 2 DM	5 studies*
Low T levels and sexual symptoms	4 population studies
Efficacy of T therapy, men with sexual dysfunction	No studies

**Studies potentially matching inclusion criteria of systematic reviews.*

- **Post hoc search did not suggest change in conclusions**

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Inferences Based on Indirect Evidence

Indirect evidence, KQs #1, #1a: Effectiveness of testing in men with type 2 DM

Indirect Evidence	Findings from Indirect Evidence	Inferences re: KQs
2 fair or good MAs (≥32 studies)	MetS vs TT level: • RR, 0.38; CI, 0.25–0.50) • Significant differences	Unclear implications for effectiveness of testing
1 fair MA (33 studies)	Type 2 DM vs TT level: • Significant differences • Especially in younger men or higher BMI	
2 fair or good MAs (9 RCTs)	Effect of T therapy on diabetes-related outcomes • Varies by outcome measure and study selection • Baseline T levels low/low-normal in most participants • Confounding by medications changes?	

Detail: T therapy in men with type 2 DM (Cai et al., 2014)

MA Description	Findings
5 RCTs 351 men w/ LOH and type 2 DM Mean age, 44–64 yrs F/u, 3–12 mos 2 RCTs compared w/ no treatment rather than placebo Fair quality	**Mean difference, control minus T therapy** FPG (nmol/L): –1.10 (CI, –1.88 to –0.31) (5 RCTs) FSI (mIU): –2.73 (CI, –3.62 to –1.84) (4 RCTs) HbA1c (%): –0.87 (CI, –1.32 to –0.42) (3 RCTs) Triglycerides (mmol/L): –0.35 (CI, –0.62 to –0.07) (4 RCTs) Generally low heterogeneity. SR-assigned study quality, 5–7 on a 0–8 scale. Some inconsistency in study results, FSI and HbA1c. No effect, body fat or blood pressure (3 RCTs each).

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Detail: T therapy in men with MetS/type 2 DM (Grossman et al., 2014)

MA Description	Findings
7 RCTs (double-blind, placebo-controlled) 833 men w/ MetS (1 RCT) or type 2 DM (6 RCTs) Mean age, 44–64 yrs Mean TT, 8.6–10.1 nmol/L F/u, 3–12 mos Good quality	Mean difference, control minus T therapy: HOMA-IR: –0.26 (CI, –1.09 to 0.57) (7 RCTs [3 included by Cai et al.]) Trials using more conventional, less rigorous technique: SMD–0.34 (CI, –0.51 to –0.16) HbA1c (%): –0.15 (CI, –0.39 to 0.10) (6 RCTs [3 included by Cai et al.]) Larger trials: no difference High heterogeneity; SR-assigned study quality 14–24 on 0–25 scale. Modest effect, lipids; no effect, triglycerides and blood pressure. *HOMA-IR=Homeostasis Model Assessment for Insulin Resistance*

Indirect evidence, KQs #1, #1a: Effectiveness of testing in men with sexual dysfunction

Indirect Evidence	Findings	Inferences re: KQs
2 population studies 414 men (fair); 3369 men (good)	Low T levels associated w/ ED (1 small study) Low T levels vs simultaneous multiple symptoms (1 large study): ORs, 1.64–2.24	Positive but weak inference of clinical utility of testing
1 MA (17–24 RCTs per symptom) Men with erectile dysfunction (ED) Fair quality	T therapy improves sexual symptoms • Significant standardized mean differences (SMDs): 0.68–0.82 • More so in men with low T levels (SMDs 1.00–1.23) • More so in men with type 2 DM • No evidence of superiority to conventional medication or effectiveness as add-on	

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KQ #1b: Minimum interval to assess change in T status

Evidence	Potentially Policy-Relevant Information	Inferences re: KQ

No direct evidence	• 1 study (282 men, age 60–82 yrs after 5 yrs f/u)
	  • TT and bioavailable T had declined
	  • 9 of 10 symptoms remained constant
	• Check T levels at 3–6 mos following initiation of therapy
	  • Weak recommendation, very-low-quality evidence (Endocrine Society)
		• Frequent testing in untreated men may not be necessary
		• Since no evidence of benefit of T therapy at above-normal levels
		  • Monitoring men receiving T therapy might avoid adverse treatment effects

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KQ #2: Harms of testing and consequent treatment

No significant procedure harms

Safety of T therapy (typical follow-up 2-3 years)

Composite prostate outcome	Relative risk (RR), 1.41 (CI, 0.93-2.14; low heterogeneity) 1 MA (15 studies)
Erythrocytosis	RR, 3.15 (CI, 1.56-6.35; low heterogeneity) 1 MA (11 studies)
Obstructive sleep apnea	Inconsistent findings Small case series
Cardiovascular events	No clear overall effect Conflicting evidence for subpopulations 2 population studies 1 MA (31 studies)
All-cause mortality	Hazard ratio (HR), 0.61 (CI, 0.42-0.88) (protective) 1 observational study (follow-up, 41 mos)

Inference, KQ: Testing → unknown risk from long-term T therapy

KQ #2: RCT evidence of no overall cardiovascular risk (Corona et al., 2014)

- MA
- 5464 men; mean age 60 years
  - Mean duration of treatment 34 weeks
- OR (T therapy vs placebo)
  - Any cardiovascular event: 1.07 (CI, 0.69-1.65) (31 studies)
  - MACE, overall: 1.01 (CI, 0.57-1.77) (26 studies)
  - Considerable inconsistency, direction of results
- Metaregression: no differential risk of MACE established for
  - Age/frailty
  - TT < 12 nmol/L
  - Diabetes

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KQ #2: Cardiovascular risk, Xu vs Corona MA

Xu et al. (2013) (not cited in report)	Corona et al. (2014) (cited in report)
Any CV event: OR, 1.54 (CI, 1.09–2.18) (27 RCTs) Pharma funding: OR, 0.89 (CI, 0.5–1.6) No pharma funding: OR, 2.06 (CI, 1.34–3.1)	Any CV event: OR, 1.07 (CI, 0.69–1.65) (31 RCTs)
No calculation of MACE	MACE: OR, 1.01 (CI, 0.57–1.77) (26 studies)
PubMed and WHO trial registry End of 2012	MEDLINE, Embase, Cochrane, ClinicalTrials.gov January 2014
2 RCTs not in Corona review	5 RCTs not in Xu review
1 RCT, significant elevated risk (Baseria et al., 2010)	1 RCT, significant elevated risk (Baseria et al., 2010)

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KQ #2: Observational studies, T therapy and cardiovascular risk, FDA concern

Vigen et al. (2013)	Finkle et al. (2014)
Retrospective cohort 8709 men, prior coronary angiography, low T levels Follow-up, 2 yrs	Retrospective cohort 55,593 men Follow-up, 90 days
Cumulative incidence, death/MI/stroke (T therapy vs no T therapy) 25.7% vs 19.9% Risk difference 5.8% (CI, -1.4% to 13.1%) HR adjusted for CAD: 1.29 (CI, 1.04–1.58) No treatment–CAD interaction	RR of MI in 90 days after initial T prescription vs 1 yr prior to prescription Age ≥65 yrs 2.19 (CI, 1.27–3.77) Age <65 yrs and prior history of heart disease 2.90 (CI, 1.49–5.62) Age <65 yrs and no history of heart disease No effect

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KQ #2: Recent observational study, T therapy and reduced mortality (Shores et al., 2012)

- Retrospective cohort study
  - 1031 men
  - Age >40 years; mean, 63 treated, 61 untreated
  - TT <250 ng/dL (8.7 nmol/L)
  - No history of prostate cancer
  - Mean follow-up 41 months
- Mortality (treated vs untreated)
  - 10.3% vs 20.7% (*P*<0.0001)
- Cumulative mortality (treated vs untreated)
  - 3.4 vs 5.7 deaths/100 person-years
- Adjusted HR, 0.61 (CI, 0.42-0.88)

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KQ #3: Costs, cost-effectiveness

- No direct or indirect evidence

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Summary of Indirect Evidence, Practice Guidelines, and Payer Policies

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Organizations with no relevant policy

- CMS
- USPSTF
- GroupHealth
- OR Health Evidence Review Commission (HERC)
- Regence

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Primary hypogonadism

Guideline Indications	Relevant Policies	Evidence
---	FDA-approved indications for T therapy Aetna covers anabolic steroids for constitutional delay in growth, delayed male puberty, Klinefelter's syndrome w/ hypogonadism, microphallus	---
Examples: chromosomal or genetic disorders, toxin exposure or chemotherapy, orchitis due to mumps or an autoimmune disorder, trauma, hemochromatosis, medications that inhibit androgen biosynthesis, damage due to varicocele		

Secondary hypogonadism: conditions that might prompt testing

Guideline Indications	Relevant Policies	Evidence Cited in Background Section (SRs cited where possible)
Endocrine Society • Pathology, **sellar regions** • **Medications** • **HIV**, weight loss • **Osteo-porosis** (T therapy also recom-mended)	FDA-approved general indication Aetna covers anabolic steroids for AIDS wasting syndrome	**Opioid dose vs TT:** Inverse association in 3 of 4 studies (1 SR) **HIV** • High prevalence of low T level • T therapy: Small positive effect only when T levels are normal (1 good SR) **Osteoporosis** • High vs low T level: OR, 1.76-2.77) (1 large observational study) • T therapy: Possible benefit; no evidence regarding fracture (2 good SRs)

Secondary hypogonadism: conditions in which *characteristic signs/symptoms* might prompt testing

Guideline Indications	Relevant Policies	Evidence Cited in Background Section (SRs cited where possible)
Endocrine Society • **Type 2 DM** • **ESRD** • **COPD** American Urological Association (AUA) • **Infertility**	FDA-approved general indication	***MetS/Type 2 DM** MetS vs TT: RR, 0.38 (CI, 0.25-0.50) (1 good SR) Type 2 DM vs TT: Sig differences (1 fair SR) Type 2 DM outcomes, T therapy: • Some positive effects, 1 fair SR (3 RCTs) • No sig overall effects, 1 good SR (7 RCTs) **Chronic kidney disease:** Some evidence of association **COPD:** Prevalence data **Infertility:** None cited in sources used
*Evidence subjected to post hoc analysis.		

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Symptoms of sexual dysfunction are relatively specific symptoms that might prompt testing

Guideline Indications	Relevant Policies	Evidence Cited in Background Section (SRs cited where possible)

Endocrine Society
• Consider testing
• T therapy an option for low libido or ED, after established therapies tried
AUA
• Impaired sexual function
• Clinical findings (not specified)
	None	Symptoms vs low T levels:
		• OR 2.24 (n=3369)
		  • 3 simultaneous symptoms
		  • Both TT and free T considered
		  • Otherwise, smaller or nonsignificant ORs
		• ED but not sex drive (n=414)
		T therapy:
		• Positive effect in men with ED
		• Especially if hypogonadal or type 2 DM at baseline
		• 1 fair SR
		NOTE: Evidence subjected to post hoc analysis.

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Other possible indications for T testing

Guideline Indications	Relevant Policies	Evidence Cited in Background Section (SRs cited where possible)
Endocrine Society: TEST • **Classic symptoms*** of androgen deficiency CONSIDER testing • **Less specific symptoms** DO **NOT** test • On basis of **age alone** • During **acute or subacute illness**	Aetna covers anabolic steroids • Symptomatic androgen deficiency • Weight loss from cancer	**Classic symptoms:** See previous **Less specific symptoms:** Physical symptoms: • Associated with low T levels, but no OR or RR (2 observational studies) • No T therapy evidence Psychological symptoms: • Mixed findings of association (2 large observational studies) • T therapy: positive effect on depression, regardless of hypogonadal status (1 good SR) **Age alone:** None

**E.g., sexual symptoms, loss of body hair, osteoporosis, hot flashes.*

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Final Comments

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General observations

- No direct empirical evidence that testing for low testosterone in any subpopulation leads to better health outcomes
- Endocrine Society guidelines
  - Evidence for testing and treatment recommendations is “low” or “very low”
- Concerns regarding analytic validity

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General conclusions (cont.)

- Subpopulations most likely to benefit
  - Type 2 DM and symptomatic hypogonadism
  - Sexual dysfunction and low T levels
- Caveats
  - Latest systematic review of T therapy for improvement of type 2 DM showed uncertain benefit
  - T testing in men with diabetes:
    - Intended to address symptomatic hypogonadism, not diabetes (Endocrine Society)
  - Clinical relevance of gains in sexual function uncertain
  - Insufficient evidence
    - T therapy instead of/in addition to ED medication

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Evidence gaps

- Cutoff points associated with health risk
- Clinical trials designed to compare health outcomes, testing versus no testing
- Large, long-term studies of T therapy
  - Durability of benefits
  - Risks
- Cost and cost-effectiveness of testing in specific subpopulations

Limitations of this report

- Post hoc process for identification of subpopulations with best indirect evidence
- Unknown efficacy of T treatment in subpopulations for which no systematic reviews have been published
- No detailed review or critical appraisal of studies published more recently than systematic reviews

HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are evidence-based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards[2]:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms[3]:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

[1] Based on Legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of Evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the Evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

3. Factors for Consideration - Importance

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document:

What are the key factors and health outcomes and what evidence is there?

Outcomes	Evidence
Safety	**Safety**
Overtreatment	
Treatment related harms	
Efficacy – Effectiveness	**Efficacy / Effectiveness**
Test characteristics	
Improved health outcomes	
Clinical management	
Symptom improvement	
Special Population / Considerations	**Special Populations/ Considerations**
Age	
Race/ethnicity	
Baseline testosterone levels	
Treatment status	
Clinical history	
Cost	**Cost**
Cost	
Cost-effectiveness	
Cost-utility	

Medicare Coverage and Guidelines

[From Page 28 of evidence report]

CMS: No CMS National Coverage Determination (NCD) was identified for testosterone testing.

Guidelines: From Final Evidence Report Pages 111-115

Sponsor, Title	Relevant Recommendations (*Strength of Recommendation; Quality of Evidence According to Authors*)				Quality*/Main Limitations
	Screening/Testing	**Diagnosis**	**Testosterone Therapy**	**Monitoring T Levels During Treatment**	
American College of Physicians (ACP) (Qaseem et al., 2009) *Hormonal Testing and Pharmacologic Treatment of Erectile Dysfunction*	No recommendation for or against routine hormonal blood tests (testosterone or prolactin) for management of ED. *Insufficient evidence.*	---	No recommendation for or against hormonal treatment for management of ED. *Insufficient evidence.*	---	6 – Good
American Diabetes Association (ADA) (2014) *Standards of Medical Care in Diabetes—2014* (VII. Assessment of Common Comorbid Conditions)	No specific recommendation, but document states that "obesity is a major confounder" (p. S49) and cites Endocrine Society guidelines and their recommendations to test only in the presence of symptoms.		No specific recommendation, but document states that "evidence for effects of testosterone replacement on outcomes is mixed" (p. S49) and cites Endocrine Society guidelines regarding treatment.		
American Urological Association (AUA) (2010b) *The Optimal Evaluation of the Infertile Male: AUA Best Practice Statement*	Endocrine evaluation if (1) abnormal semen analysis, (2) impaired sexual function, *or* (3) other clinical findings (not specified) suggestive of a specific endocrinopathy. Minimum initial hormonal evaluation should include T and FSH. All recommendations based on expert opinion due to *insufficient evidence*.	---	---	---	6 – Good NOTE: A best practice statement based on expert opinion was issued because the literature search did not identify sufficient evidence.
American Urological Association (AUA) (2010a) *The Evaluation of the Azoospermic Male: AUA Best*	Minimum initial hormonal evaluation should include T and FSH. All recommendations based on expert opinion due to	---	---	---	6 – Good NOTE: A best practice statement based on expert opinion was

Sponsor, Title	Relevant Recommendations (*Strength of Recommendation; Quality of Evidence According to Authors*)				Quality*/Main Limitations
	Screening/Testing	**Diagnosis**	**Testosterone Therapy**	**Monitoring T Levels During Treatment**	
Practice Statement	*insufficient evidence*.				issued because the literature search did not identify sufficient evidence.
The Endocrine Society (Bhasin et al., 2010) *Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes*	<u>Screening</u> Do not screen in general population. *Strong; very low.* Consider case detection by total T measurement in conditions in which there is a high prevalence of low T levels.[5] *Weak; very low.* <u>Testing to diagnose</u> Test patients w/ more specific signs and symptoms suggestive of AD.[6] Consider testing patients w/ less specific signs and symptoms.[7]	Diagnose AD only w/ consistent symptoms and signs and unequivocally low serum T levels. *Strong; very low.* Do not diagnose AD during acute or subacute illness. *Weak; low.*	<u>Recommended for</u> Symptomatic men w/ classical AD syndromes[8] for purposes of including and maintaining secondary sex characteristics and improving sexual function, sense of well-being, and BMD. *Strong; low.* <u>Suggested as an option for</u> Low T levels and low libido. *Weak; very low.* Low T levels and ED after evaluation of underlying causes of ED and consideration of established	3-6 mos after initiation of T therapy to assess whether T levels have reached the normal range. *Weak recommendation; very low.*	5 (fair) (search details and study selection criteria not provided).

[5] According to Table 3 in the guidelines: Conditions in which T measurement should be based on characteristic symptoms include type 2 diabetes, end-stage renal disease, and moderate to severe COPD; symptoms such as sexual dysfunction, unexplained weight loss, weakness, or mobility limitation may indicate the need for testing. These symptoms were identified on the basis of panelists' experience rather than population surveys. Conditions in which measurement of T levels may be indicated regardless of symptoms include mass in, radiation of, or disease of sellar region (a depression in the upper surface of the sphenoid bone in which the pituitary gland sits); medications that affect T production or metabolism (e.g., glucocorticoids and opioids); HIV-associated weight loss; or osteoporosis or low-trauma fracture (especially in a young man).

[6] According to Table 1 in the guidelines: <u>A. More specific signs and symptoms</u> (incomplete or delayed sexual development; eunuchoidism; reduced sexual desire (libido) and activity; decreased spontaneous erections; breast discomfort, gynecomastia; loss of body [axillary and pubic] hair, reduced shaving; very small [especially <5 mL] or shrinking testes; inability to father children, low or zero sperm count; height loss, low-trauma fracture, low BMD; hot flushes, sweats.

[7] According to Table 1 in the guidelines: <u>B. Other less specific signs and symptoms</u> (decreased energy, motivation, initiative, and self-confidence; feeling sad or blue, depressed mood, dysthymia; poor concentration and memory; sleep disturbance, increased sleepiness; mild anemia (normochromic, normocytic, in the female range); reduced muscle bulk and strength; increased body fat, BMI; diminished physical or work performance).

Sponsor, Title	Relevant Recommendations (*Strength of Recommendation; Quality of Evidence According to Authors*)				Quality*/Main Limitations
	Screening/Testing	**Diagnosis**	**Testosterone Therapy**	**Monitoring T Levels During Treatment**	
	Test morning total T. All testing recommendations: *Weak; very low.* <u>Exclude reversible illness, drugs that can deplete T levels, nutritional deficiency</u> (not rated) <u>Confirmatory testing to establish androgen deficiency</u> Repeat measurement of total T. *Strong; low quality.* Measure free or bioavailable serum T in some men w/ total serum T near lower limit of normal and in whom alterations of SHBG are suspected. *Weak; low.* <u>Additional testing to establish etiology</u> LH+FSH		therapies for ED. *Weak; very low.* Case-by-case for older men w/ low T levels on >1 occasion and clinically significant symptoms of AD after discussion of uncertainty about risks and benefits. *Weak; very low.* HIV-infected men w/ low T levels and weight loss to promote weight maintenance and gains in lean body mass and muscle strength. *Weak; low.* Low T levels and high doses of glucocorticoids to promote preservation of lean body mass and BMD. *Weak; very low.* <u>Not recommended</u> As a general policy for all older men w/ low T levels. *Strong; very low.* <u>Contraindicated</u> Men w/ history of breast cancer (*weak; very low) or* prostate cancer *(weak; low*). In presence of palpable prostate nodule or induration or PSA 4 ng/mL, or PSA 3 ng/mL and high risk of		

8 See More specific signs and symptoms in Footnote 2.

Sponsor, Title	Relevant Recommendations (*Strength of Recommendation; Quality of Evidence According to Authors*)				Quality*/Main Limitations
	Screening/Testing	**Diagnosis**	**Testosterone Therapy**	**Monitoring T Levels During Treatment**	
			prostate cancer. *Strong; very low.* Hematocrit >50%, untreated severe OSA, severe lower urinary tract symptoms, uncontrolled/poorly controlled HF. *Strong; very low.* To improve fertility. *Strong; very low.*		
The Endocrine Society (Watts et al., 2012) *Osteoporosis in Men*	Test for TT in men being evaluated for OP or considered for pharmacological treatment w/ bone-active agents. *Weak; low.* In men w/ a history or physical examination suggesting a specific cause of OP, conduct further testing, e.g., calculated FT or BT. *Weak; low.*		Offer in lieu of "bone drug" for men at borderline high risk for fracture who have serum T levels <200 ng/dL (6.9 nmol/L) on >1 determination, if accompanied by signs or symptoms of AD or "organic" hypogonadism (e.g., due to hypothalamic, pituitary, or specific testicular disorder). *Weak; low.* Consider for men at high risk for fracture w/ T levels <200 ng/dL (6.9 nmol/L) who lack standard indications for T therapy but who have contraindications to approved pharmacological agents for OP. *Weak; low.*		5 (fair) (search details and study selection criteria not provided).

Clinical Committee Findings and Decisions

Efficacy Considerations

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next Step: Cover or No Cover

If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions

If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?

- Refer to evidence identification document and discussion.
- Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
- Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:

- What are the known conditions/criteria and evidence state
- What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Clinical Committee Evidence Votes

First Voting Question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Is there sufficient evidence under some or all situations that the technology is:

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective				
Safe				
Cost-effective				

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not Covered _____ Covered Unconditionally _____Covered Under Certain Conditions

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Next Step: Proposed Findings and Decision and Public Comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?

2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next Step: Final Determination

Following review of the proposed findings and decision document and public comments:

Final Vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie) outcome Chair will lead discussion to determine next steps.