

# PROMISING ADVANCES IN HIV CURE & HEALTHY AGING RESEARCH

**How close are we to finding the cure?  
How are you managing HIV and aging?**

Join HIV wellness advocate and author **Nelson Vergel** as he provides an update on HIV cure and aging research.

**Program for Wellness Restoration (PoWeR)  
PoWeRUSA.org**

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**These Slides Are Available at  
PoWeRUSA.org**

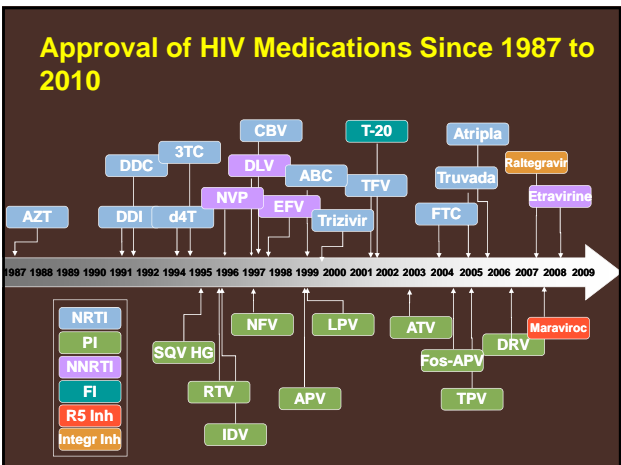
- ### AGENDA
- Update on stem cell approaches to cure HIV
  - Update on lipohypertrophy and lipoatrophy
  - How to prevent bone loss
  - Protecting yourself from anal cancer
  - Testosterone Tips
  - Questions?

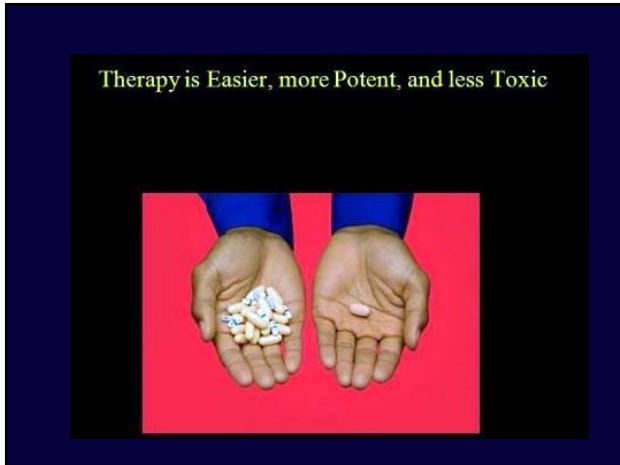
## HIV Epidemiology Facts

**33.4 MILLION PEOPLE LIVING WITH HIV**

<p>40% KNOW THEIR STATUS</p> <p>5 million on therapy</p> <p>10 million waiting for therapy</p>	<p>2 MILLION DEATHS THIS YEAR</p> <p>2.7 MILLION NEW INFECTIONS</p>
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UNAIDS Outlook Report | 2010





### Atripla's New Competitors: Once a Day Regimens in the Pipeline

- QUAD: Elvitegravir+Cobistat (booster)+ Truvada (tenofovir + emtriva)
- TMC278 (NNRTI-rilpivirine)+ Truvada
- GSK572 (integrase) + Epzicom

THE NEW ENGLAND JOURNAL OF MEDICINE

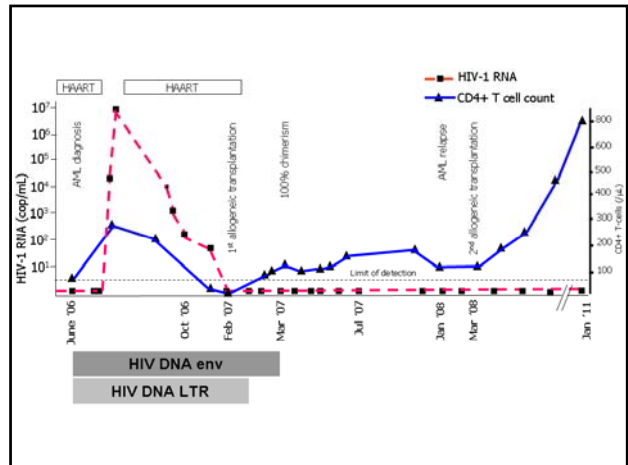
BRIEF REPORT

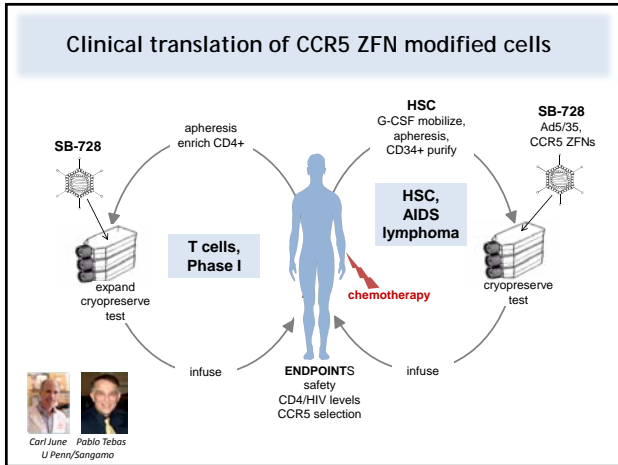
#### Long-Term Control of HIV by CCR5 Delta32/ Delta32 Stem-Cell Transplantation

Caro Hütter, M.D., Daniel Nowak, M.D., Maximilian Moosner, B.S., Susanne Ganapola, M.D., Anne Müllig, M.D., Britta Allers, Ph.D., Thomas Schindler, M.D., Jörg Hoffmann, Ph.D., Claudia Kuchler, M.D., Olga Blau, M.D., Ina W. Blau, M.D., Wolf K. Hübner, M.D., and Eckhard Thiel, M.D.

CCR5 $\Delta$ 32 donor

"Berlin patient"

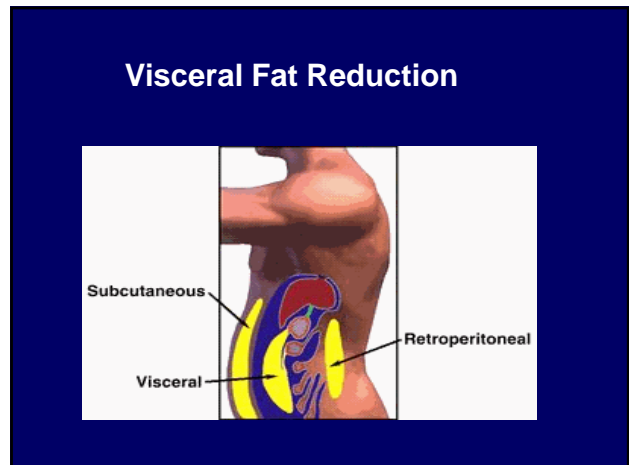
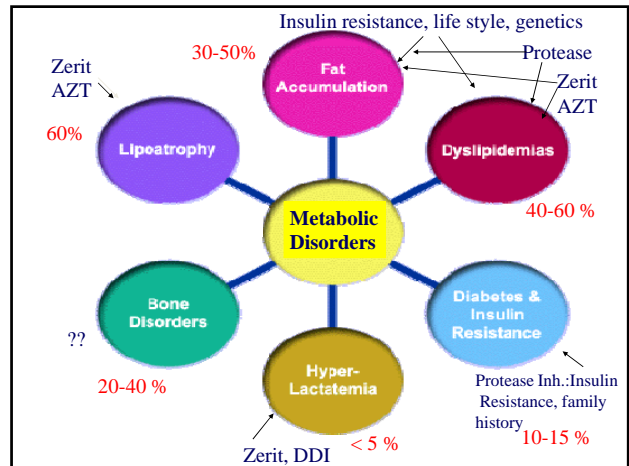
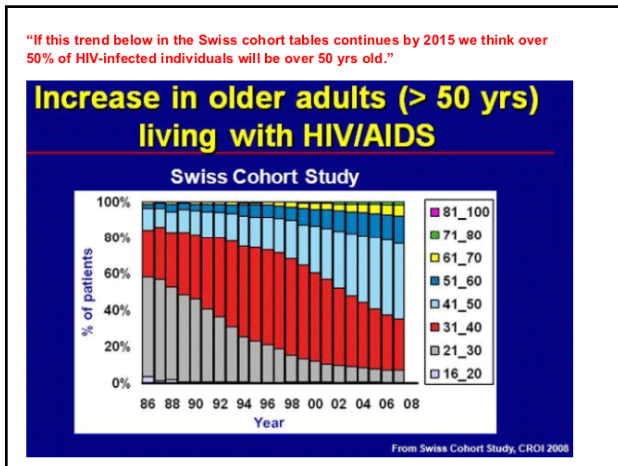


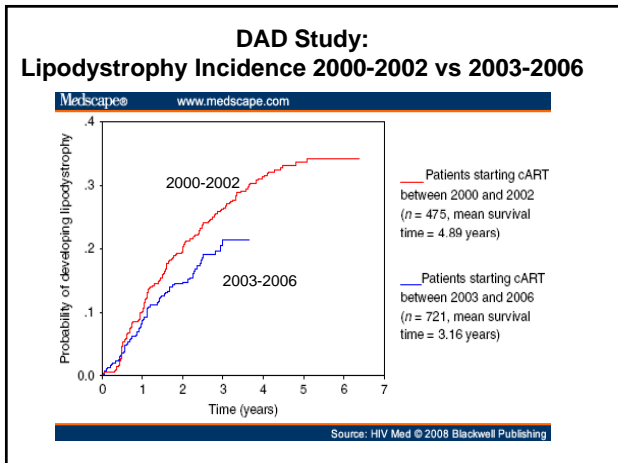


### Cure-Related Clinical Trials Recruiting Patients

Principal Investigators	Sponsors	Intervention
Christine Katlama and Eramune O1 team	ORVACS, Cytheris, Merck, Pfizer	IL-7 + HIV vaccine + intensification
Robert Murphy and Eramune O2 team	Northwestern University, ORVACS, NIAID, Pfizer, Merck	HIV vaccine + intensification
Steve Deeks, Adriana Andrade	UCSF, Johns Hopkins Univ.	Disulfiram
David Margolis	University of North Carolina, NIH, Merck	SAHA
Sharon Lewin	Merck, Alfred Hospital in Melbourne, Australia	SAHA
Joseph Alvarnas, Richard Ambinder	NHLBI	Cytoablative therapy for lymphoma
John Mellors	University of Pittsburgh, NCI	Chemotherapy for lymphoma
Joseph Lalezari, Ronald Mitsuyasu, Isabela Sierra, Ana Sizemore, Winson Tang	Quest Clin. Res., UCLA, Kinder Med. Grp., Orlando Imm. Ctr., Sangamo Biosciences	Autologous CD4s w/CCR5- gene
Pablo Tebas, David Stein, Carl June	University of Pennsylvania, Sangamo	Autologous CD4s w/CCR5- gene
Amrita Krishnan	Beckman Res. Inst., City of Hope (Duarle, CA), NCI	Autologous stem cells w/CCR5- and anti-HIV genes
Frank Maldarelli	NIAID, NCI	Interferon α2B

NIH, NCI, NIAID, NHLBI = U.S. National Institutes of Health and branches  
ORVACS = Objectif Recherche Vaccin SIDA





### HIV Medications and Lipodystrophy (Fat Wasting)

**Higher Risk**

Stavudine-D4T

AZT

Didanosine-DDI?

**Lipodystrophy**

Fat Wasting

**Low Risk**

Nevirapine- Viramune

Atripla

Tenofovir- Viread/Truvada

Abacavir- Ziagen

Lamivudine- 3TC

Emtricitabine- Emtriva

Fuzeon

Isentress

Selzentry

All protease inhibitors

### Effect of HIV Drugs on Lipids

**Higher Risk**

Stavudine- D4T

AZT

Didanosine-DDI

Lopinavir/r-Kaletra

Amprenavir-Lexiva

Duranavir-Prezista

Sustiva (Atripla)

**Cholesterol/ Triglycerides**

**Lower Risk**

Nevirapine- Viramune

Tenofovir- Viread

Abacavir- Ziagen

Lamivudine- 3TC

Emtricitabine- Emtriva

Enfuvirtide-Fuzeon

Saquinavir- Invirase

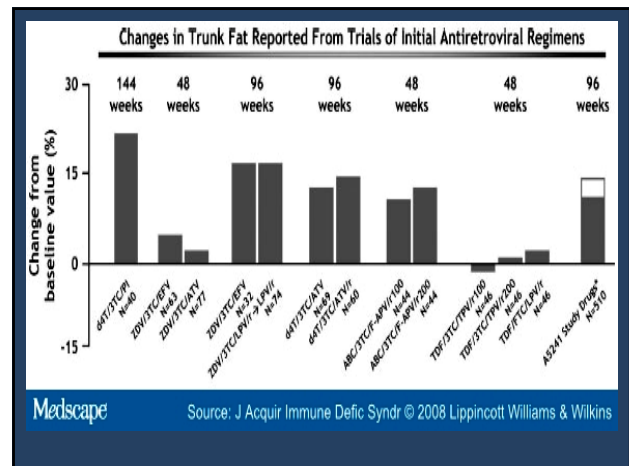
Atazanavir- Reyataz

Raltegravir- Isentress

Maraviroc- Selzentry

Etravirine-Intence

DHSP



- ### Potential Interventions for Decreasing Abdominal Fat (visceral adipose tissue-VAT)
- Diet- **Lower carb?**- No data available in HIV
  - Exercise- cardiovascular and resistance training- *Some pilot data with good results*
  - Weight reduction- *non HIV data*
  - Anti-diabetic drugs: **Metformin (Glucophage)**- *conflicting and inconclusive data*
  - Testosterone gel- *subcutaneous fat loss only*
  - Anabolic steroids- Oxandrin, nandrolone?- *limited VAT data*
  - Human Growth Hormone (Serostim)- *highly effective. FDA declined approval due to side effects*
  - Human Growth Hormone Releasing Hormone- **Tesamorelin**- *Not approved yet- Pending issues. Slow action*
  - Modification or cessation of HAART?- *Not effective*
  - Surgery- *Liposuction of visceral fat very difficult and risky*

### DIET Study (Dietary Intervention: Effects on Tryglicerides in HIV Lipodystrophy)

Using food records that began from 6 to 24 months before development of fat deposition the following factors were identified.

When compared to people with HIV who developed fat deposition, **patients without fat deposition had:**

- greater overall energy intakes from their diet (p = 0.03)
- greater intakes of total protein (p = 0.01)
- more total dietary fiber (p = 0.01)
- more soluble dietary fiber (p = 0.01)
- insoluble dietary fiber (p = 0.03)
- pectin (P = 0.02)

Those without fat deposition also were currently doing more resistance training exercise and were less likely to be smoking - (only borderline statistical significance (p = 0.05))

Hendricks et al, Am J Clin Nutr, 2003 Oct;78(4):790-5

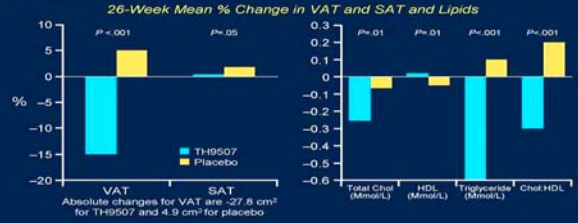
**Newly FDA Approved Product to Decrease Visceral Fat in HIV+ Patients**



- 2 mg injections under the skin every day. Effect disappears when stopped
- A patient assistance program for those without insurance and incomes under \$60K
- More information on Egrifita.com

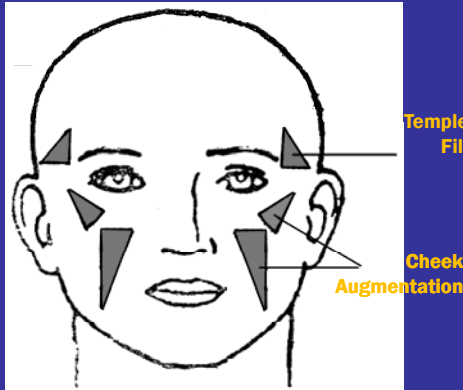
**Egrifita (Tesamorelin) -FDA Approved for Belly Fat Reduction**

**Growth Hormone Releasing Hormone (TH9507) vs Placebo**



Falutz J et al. 14<sup>th</sup> CROI; 2007; Los Angeles. Abstract 45LB.

**Lipoatrophy Deficits Requiring Correction**



**Carruthers Lipoatrophy Severity Scale**



James J et al. *Dermatol Surg.* 2002;28:979-986.

**FDA Approved Facial Lipoatrophy Products**



Off Label Use: Silicone Microdroplet, Artefill

**Commonly Used Options for HIV-related Facial Lipoatrophy (From FacialWasting.org)**

Product	Type/Sessions	Approved?	Cost
Sculptra (New Fill-PolyLactic Acid)	Non- permanent 3-7 sessions needed	FDA approved	Patient Assistance for Product only (under \$40,000 a year income) <a href="http://www.sculptra.com/patientassistance.pdf">http://www.sculptra.com/patientassistance.pdf</a> Labor cost avg. \$400 per session. Full Price: \$1,100 per session for product.
Radiesse Calcium hydroxylapatite (CaHA) microspheres	Non- permanent 2-3 sessions needed	FDA approved	Patient Assistance Available <a href="http://www.radiesse.com/Physician_Support/PatientAssistanceForm.pdf">http://www.radiesse.com/Physician_Support/PatientAssistanceForm.pdf</a> Full Price: \$1,200 per session.
Silikon 1000 Microdroplets	Permanent 4-6 sessions needed	Off label use- FDA approved for intracocular injections to treat CMV-related retinal detachment	No Patient Assistance- \$600-800 per session
PMMA polymethylmethacrylate	Permanent 1-2 sessions needed	Not FDA approved- Mexico, Brazil, US version: Artefill but too expensive for volume required	\$2,000 avg. total cost for total reconstruction. Patient assistance in Tijuana: <a href="http://www.MedicalPMMA.com">www.MedicalPMMA.com</a>

**CMS** Centers for **Medicare & Medicaid** Services

**Proposed Decision Memo for Dermal injections for the treatment of facial lipodystrophy syndrome (FLS) (Jan 2010)**

“Dermal injections for facial lipodystrophy syndrome are only reasonable and necessary using dermal fillers approved by FDA for this purpose, and then only in HIV infected beneficiaries who manifest depression secondary to the physical stigmata of HIV treatment. All other indications are noncovered.”

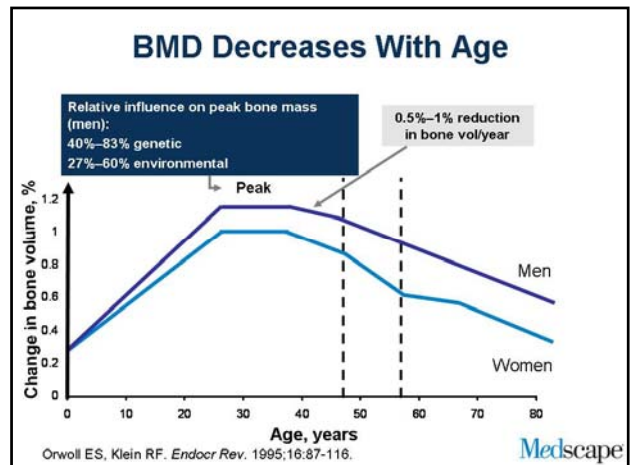
**Pre- and Post-Silikon 1000**  
14 treatments over 2 years, 24 cc total



**Buttock Augmentation with PMMA**  
Not Approved in the U.S.

Courtesy of Dr Luis Casavantes- Tijuana

**Protecting Your Bones**



## Osteoporosis and AIDS

Publication	Number of Patients		Overall Prevalence of Reduced BMD, %	
	HIV+	HIV-	HIV+	HIV-
Amiel et al, 2004	148	81	82.5	35.8
Brown et al, 2004	51	22	63	32
Bruera et al, 2003	111	31	64.8	13
Dolan et al, 2004	84	63	63	35
Huang et al, 2002	15	9	66.6	11
Knobel et al, 2001	80	100	87.5	30
Loiseau-Peres et al, 2002	47	47	68	34
Madeddu et al, 2004	172	64	59.3	7.8
Tebas et al, 2000	95	17	40	29
Teichman et al, 2003	50	50	76	4
Yin et al, 2005	31	186	77.4	56

Adapted from Brown TT, Qaish RB. AIDS. 2008;20:2165-2174.

Medscape



DEXA BONE SCAN

## Bone Disorders in HIV

### Treatments for bone loss

- Resistance exercise, preventing wasting syndrome, and avoiding tobacco
- Calcium (1000- 1500 mg/day) and Vitamin D (400-1000 IU/day ). Get 20 minutes of sun daily
- Biophosphonates (Alendronate- Fosamax)
- Calcitonin (Intranasal and oral)
- Teriparatide (Forteo)
- Testosterone and/or thyroid replacement therapy



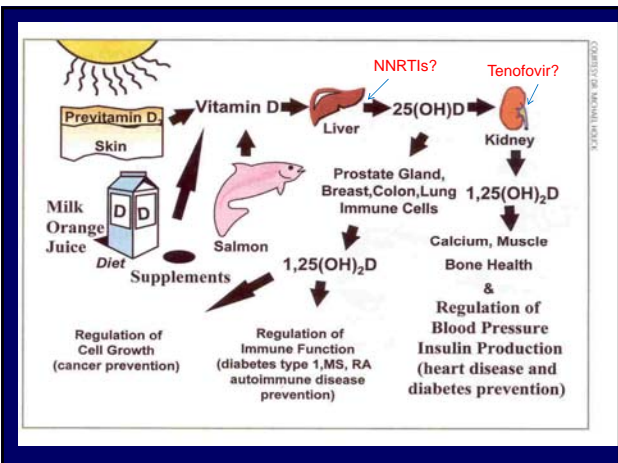
## Bone Drugs

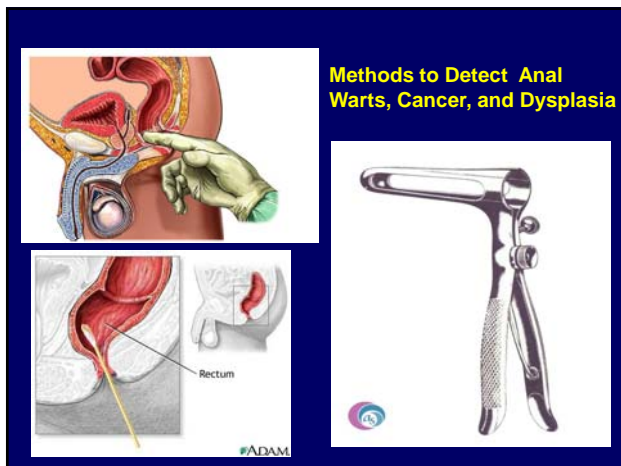
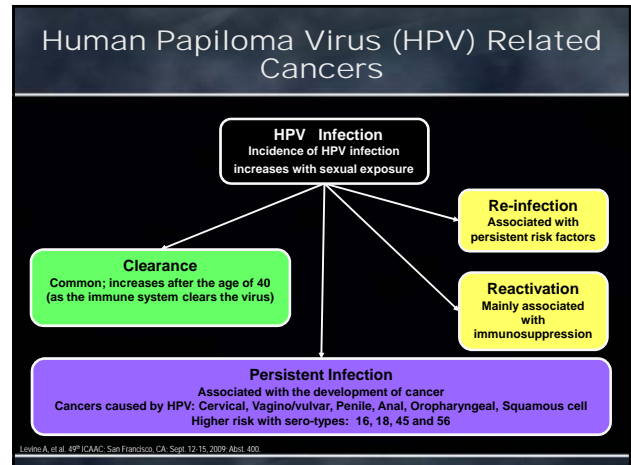
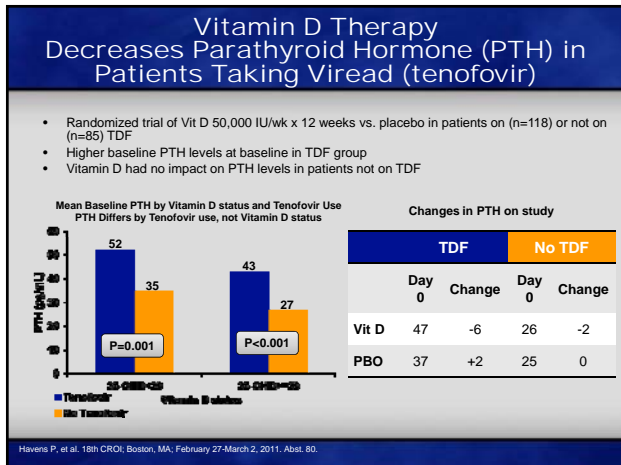


Subcutaneous, once daily

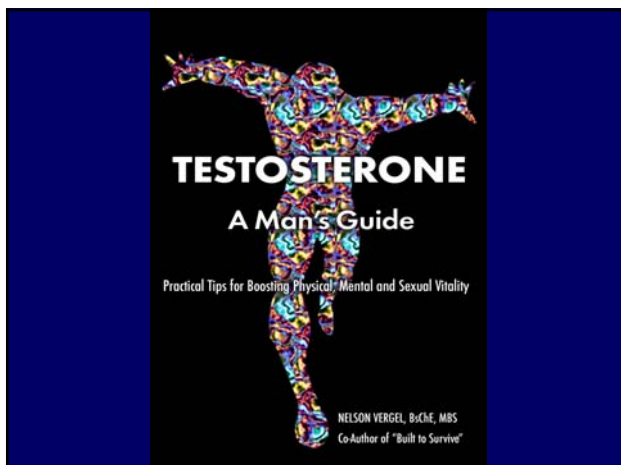


IV Once a year

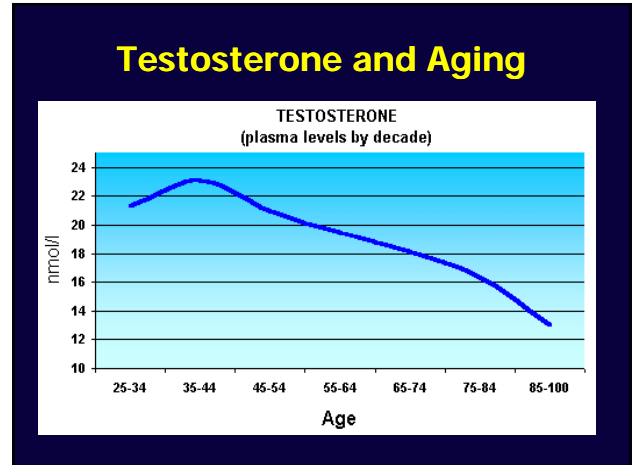
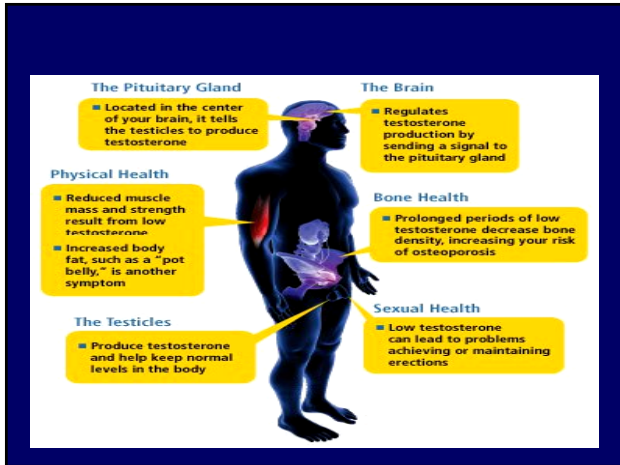




- ### Anal Cancer in HIV+ Men and Women Diagnosis and Treatment
- Pap-smears and simple anoscopy done in the office. Cytology obtained from pap smears.
  - Outpatient under anesthesia: after **high resolution anoscopy (HRA)** with vinegar, any lesions are treated with **infrared coagulation (IRC)**, which involves inserting a light probe into the anal canal under direct visualization, touching the tip of this light probe to the lesion, and delivering a pre-specified amount of energy.
  - Trained Physicians by UCSF's anal neoplasia and research group web site : <http://www.analcancerinfo.ucsf.edu/>



- ### Signs and Symptoms of Low Testosterone
- Loss of muscle mass and strength
  - Loss of libido and erectile dysfunction
  - Depression
  - Lethargy (fatigue, lack of focus)
  - Bone loss
  - Some regression of secondary sexual characteristics (body hair loss, etc)
  - Low or no sperm count
- Tanover JL. Endocrinol Metab Clin North Am. 1998;27:969-987  
Poisk SM, et al. AAACE Clinical Practice Guidelines. Available at: <http://www.aace.com/clin/guides/hypogonadism.html>

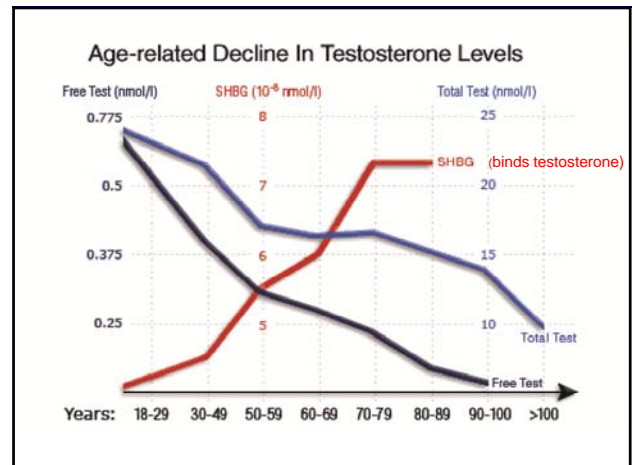
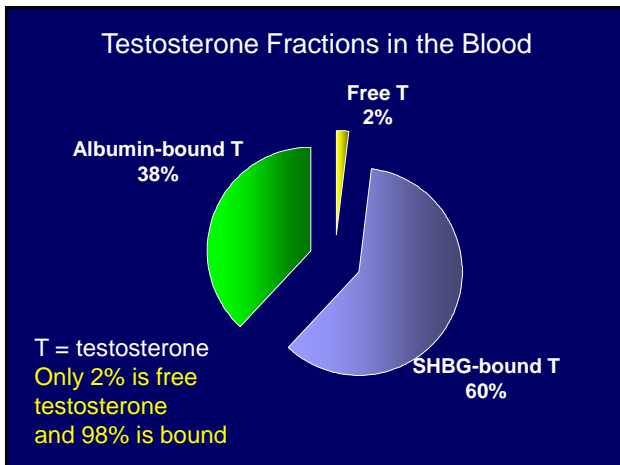


### Testosterone Deficiency (Hypogonadism)

- Normal levels in blood:
  - Men... Total test. 300-1100 ng/dL, Free test. 5 - 21 ng/dL
  - Women... Total test. 10-50 ng/dL, Free test. 0.10-0.85 ng/dL
- Symptoms of testosterone deficiency:
  - Fatigue, low or lack of sex drive, poor appetite, loss of muscle mass & strength, depression

### Testosterone Replacement Benefits

- Sexual function
- Mental focus
- Stamina and Bone Strength
- Lean Body Mass



### Testosterone Options

**Injections**

**Buccal**  
StriantSR

**Gels**  
AndroGel patches  
Andropac  
AndroGel pump for higher doses

**Pellets**

**Patch**

### Potentially Approved in the Next 12-24 Months

**NEBIDO**  
2000 mg/ml solution for injection  
Testosterone undecanoate  
For intramuscular injection only

**LibGel**  
Testosterone  
Testosterone Phosphate  
Undecanoate, 4.5000g

### Side Effect: Gynecomastia (breast enlargement in men)

**Normal male breast tissue**  
Fat  
Muscle

**Gynecomastia**  
Fat  
Muscle  
Glandular Tissue

Treatment: Estrogen Blocker Medications or surgery (in worst cases)

**Arimidex**  
Arimidex  
Arimidex  
Arimidex  
Arimidex  
Arimidex

**Tamoxifen Tablets BP**  
20 mg  
30 Tablets in blister of 10

### Side Effect: Increased number of red blood cells (polycythemia)

Watch out for hematocrit over 52 !

**Solution: Donate blood or therapeutic phlebotomy (4-5 units every 3-4 months)**

### Side Effect: Testicular Shrinkage (atrophy)

**Testes**  
Spermatic cord  
Scrotum  
Testes

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Treatment: Human Chorionic Gonadotropin (hCG)

**Chorionic Gonadotrophin Injection 5000 I.U.**  
Human Chorionic Gonadotrophin (hCG)  
polymer  
**HUCOG** 5000 I.U.  
5000 I.U./ml  
For intramuscular injection only

### Side Effect : Increased prostate size (benign prostatic hypertrophy)

**Normal prostate**

**Benign prostatic hypertrophy (BPH)**

Prevention: Digital Rectal Exam (DRE) Prostatic Specific Antigen (PSA) blood test

Bladder  
Rectum  
Prostate



**Testosterone: A Man's Guide**

For More Information:  
[TestosteroneWisdom.com](http://TestosteroneWisdom.com)

**For More Information**

- More details in "Built To Survive" and "Testosterone- A Man's Guide" ([amazon.com](http://amazon.com) or [testosteronewisdom.com](http://testosteronewisdom.com))
- Email:  
Nelson Vergel – [Nelsonvergel@yahoo.com](mailto:Nelsonvergel@yahoo.com)
- Websites:  
[www.powerusa.com](http://www.powerusa.com)  
[www.facialwasting.org](http://www.facialwasting.org)  
[www.tpan.com](http://www.tpan.com)  
[www.TheBody.com](http://www.TheBody.com)
- Join my Internet discussion group by sending a blank email to [Pozhealth-subscribe@yahoogroups.com](mailto:Pozhealth-subscribe@yahoogroups.com)

**Questions?**