THE
2016-17

Medical-Dental-Legal UPDATE

Medical Malpractice • Risk Management • Practice Management
Healthcare Law • Selected Clinical Topics

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COURSE OBJECTIVES

■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■

After completing ***The 2016-17 Medical-Dental-Legal Update*** you should have acquired the knowledge that will better enable you to:

- Advise patients of the anti-aging benefits of **exercise and cardiovascular fitness**.
- Understand the treatment implications of the **oral-systemic connection**.
- Be a more effective **expert or defendant physician witness**.
- Assess the appropriateness of the **concierge care** model for your practice.
- Determine the clinical implications of **the SPRINT trial**.
- Utilize a variety of clinically **relevant but relatively unknown treatments**.
- More judiciously recommend **vitamin D** supplementation.
- Better understand and insure against **practice business risks**.
- Identify and reduce **employment liability**.
- Better understand and comply with the **False Claims Act**.
- Better identify and guard against **cybersecurity** threats.
- Better prevent and treat **opioid overdose**.
- Better understand and help prevent **medical error**.
- Better understand and treat **common neurologic conditions**.
- Better recognize and respond to victims of **domestic violence**.
- Better diagnose and treat **HIV/AIDS**.
- Reduce stress by increasing **after tax income**.
- Evaluate and improve your practice's **revenue cycle**.
- More effectively screen for and treat **Hepatitis B and C**.

All learning objectives above address IOM/ACGME core competencies.

FACULTY DISCLOSURES

The individuals listed below have control over the content of ***The 2016-17 Medical-Dental-Legal Update***. None of them have a financial relationship with a commercial interest whose products or services are discussed in the presentation(s) over which they have control:

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Whitney D. Weiner, DDS, MS, is a speaker for Dentsply Friadent
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"Things I Wish I Knew Last Year"

Lateral Epicondylitis: Baseline Premises

"Tennis elbow, or lateral epicondylitis, is a common cause of chronic elbow pain….
No Rx is universally successful…current best practice…involves relative rest, forearm bracing, and a graduated stretching and strengthening exercise program."

Paoloni JA, et al Am J Sports Med 2003;31(6):915-920

Epicondylitis: Why Nitroglycerin? Implications of Animal Studies

Arginine —NO Synthase→ NO

Arginine —NO Synthase (crossed out)→ NO (crossed out)

- "...NO synthase inhibition resulted in a significant reduction in the cross-sectional area and load to failure of healing tendon, suggesting that nitric oxide stimulates collagen synthesis by wound fibroblasts."

Epicondylitis: What DOESN'T Work

- Ultrasound
- Laser
- Electrogalvanic Stimulation
- Corticosteroids Injections ± (improvement for 2-6 weeks, no improvement > 2months)

Paoloni JA, et al Am J Sports Med 2003;31(6):915-920

TD-NTG & Epicondylitis:

- Study: DBRPCT Chronic epicondylitis pts (n=86)
- Rx: Nitro-dur patch 5 mg/24 hr vs placebo patch
- Method: apply ¼ patch QD for 24 hrs X 6 months
- Outcomes:
  - Orthopedic Research Institute Tennis Elbow Testing System Score (ORI-TETS)
  - Pain with activity
  - Epicondylar Tenderness

Paoloni JA, et al Am J Sports Med 2003;31(6):915-920

TD-NTG & Epicondylitis: Adverse Effects & Dropouts

- D-C
  - severe persistent headache (2)
  - severe dermatitis (2)
  - transient facial flushing and angiodysplasia
  - no reason designated (2)

Paoloni JA, et al Am J Sports Med 2003;31(6):915-920

TD-NTG & Epicondylitis: Adverse Effects

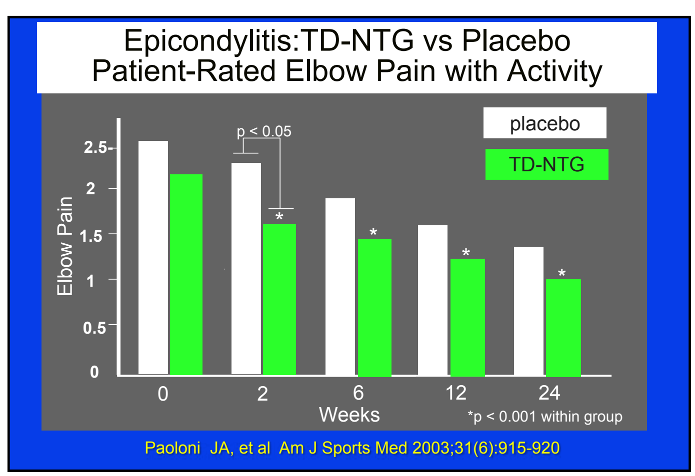
	TD-NTG	Placebo
Headache	63%	58%
Rash	21%	9%
Facial flushing/angiodysplasia	2%	-
Apprehension	2%	-
Axillary Sweating	2%	-

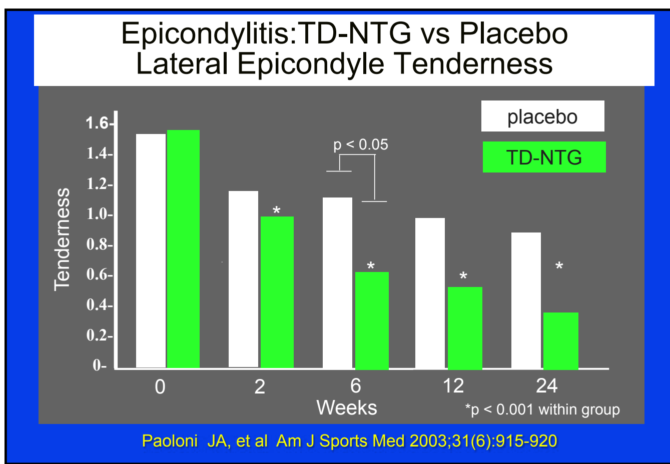
Paoloni JA, et al Am J Sports Med 2003;31(6):915-920

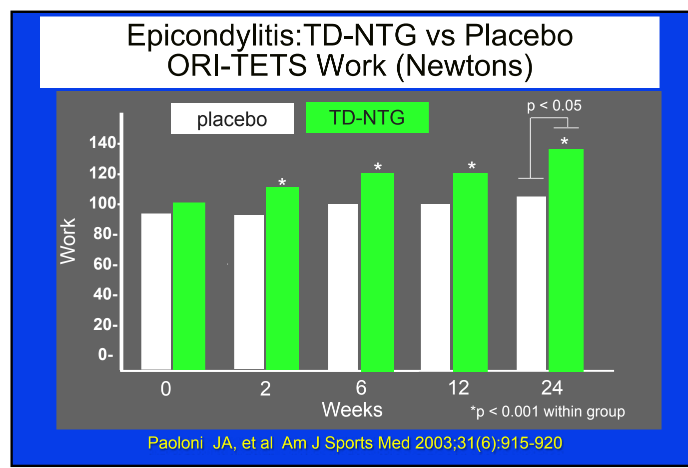
TD-NTG & Epicondylitis: Background Treatments (Both Groups)

- Tendon rehabilitation program
  - Rest from aggravating activities
  - Use of forearm counterforce brace
  - Stretching exercises
  - Graduated resistance exercises
- Rescue acetaminophen 500 mg tabs for headache

Paoloni JA, et al Am J Sports Med 2003;31(6):915-920







Epicondylitis:TD-NTG vs Placebo Patient-Reported Outcomes

	TD-NTG	Placebo
Excellent (aSx with ADL)	81%	60%
Unchanged (<10% better/worse)	16%	29%
Poor (worsening >10%)	2%	16%

Paoloni JA, et al Am J Sports Med 2003;31(6):915-920

Penicillin is BEST for Strep: Tradition or Science?

"In a recent meta-analysis, clinical Rx failures were found to occur 2X more frequently and bacterial failures 3 X more frequently after Rx for GABHS tonsillopharyngitis with penicillin than with oral cephalosporins."

Casey JR et al Clinical Pediatrics 2008;47(8):549-554

Penicillin vs Amoxicillin vs Cephalosporin for GABHS Throat

- Study: Retrospective analysis Peds practices
  - Rochester, NY (n= 1,947)
  - Houston, TX (n= 1,462)
  - Spokane, WA (n=587)
  - Los Angeles, CA (n=282)
- Subjects: Symptomatic return visit ≤30 days for GABHS (confirmed by RST or TC)

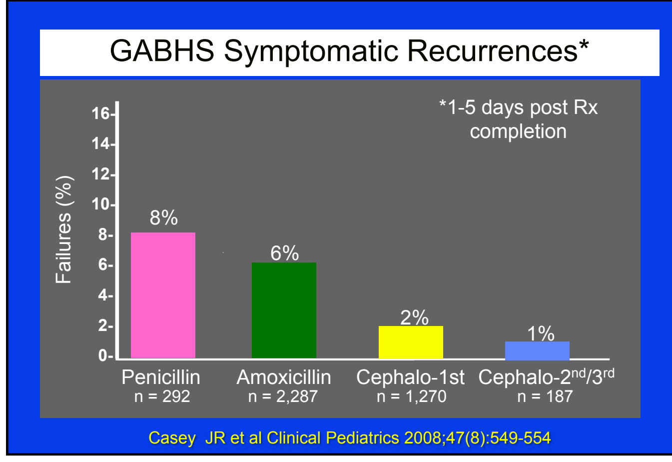
Casey JR et al Clinical Pediatrics 2008;47(8):549-554

GABHS Throat Recurrences

- Antibiotic Group Categorization
  - Penicillin (pen VK or benzathine pen)
  - Amoxicillin (various)
  - 1st generation cephalosporin (e.g., cephalexin, cefadroxil)
  - 2nd/3rd generation cephalosporin (e.g., cefprozil, cefdinir, cefpodoxime)

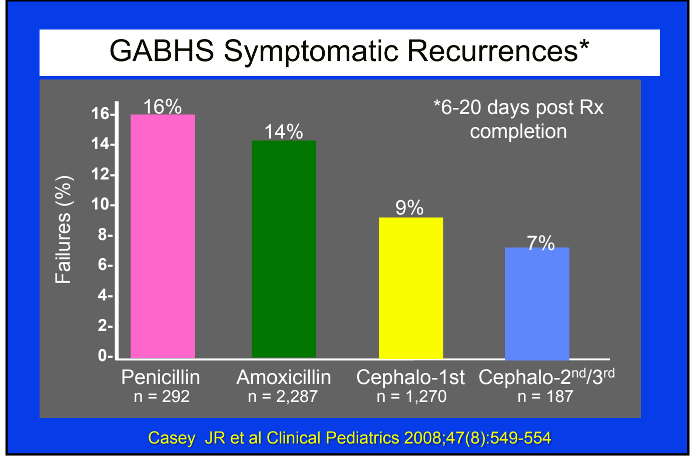
Casey JR et al Clinical Pediatrics 2008;47(8):549-554

GABHS Symptomatic Recurrences*



Casey JR et al Clinical Pediatrics 2008;47(8):549-554

GABHS Symptomatic Recurrences*



Casey JR et al Clinical Pediatrics 2008;47(8):549-554

Ampicillin + Mono Rash: How Common?

Patient Group	Dermatologic Eruption
Ampicillin (all indications)	2.5-7.5%
Ampicillin + Mono	70%-100%

Leung AKC, Rafaat M Int J Dermatology 2003;42:553-555

What's the Take Home?

- It *looked like* Strep
- It *turned out to be* Mono
- It could always be Mono + Strep (4%)
- Other antibiotics present less uncertainty when rash appears than amoxicillin

Alzheimer's Apathy

"Apathy in Alzheimer's disease is described as loss of interest and motivation in daily activities *in the absence of depression* or other mood changes."

emphasis added

Rosenberg PB et al J Clin Psychiatry 2013;74(8):810-816

Alzheimer's Apathy: How Common?

"Apathy is one of the most common syndromes [in Alzheimer's], with a 5-year prevalence estimate of 71%."

Rosenberg PB et al J Clin Psychiatry 2013;74(8):810-816

Methylphenidate for Alzheimer's Apathy Premises

- Alzheimer's observations:
  - ↓ dopaminergic neurotransmission
  - blunted dextroamphetamine response
  - modafinil: no effect
  - Pilot methylphenidate trial (enhances dopamine) positive

Rosenberg PB et al J Clin Psychiatry 2013;74(8):810-816

Methylphenidate for Alzheimer's Apathy

- Study: DBRPCT Alzheimer's apathy pts (n-60)
- Rx: methylphenidate 20 mg/d vs placebo X 6 wks
- Outcomes (at 6 weeks)
  - Apathy Evaluation Scale score
  - Modified ADCS-CGI-C score
  - NPI apathy score
  - Mini-Mental State Examination score

Rosenberg PB et al J Clin Psychiatry 2013;74(8):810-816

Methylphenidate for Alzheimer's Apathy Outcomes

	MTP	Pbo	p
Apathy Evaluation Scale	↓1.90	↑6.0	0.23
NPI Apathy score Improvement	4.4 pts	2.6 pts	0.02
Alzheimer's CGI Change Moderate-Marked Improvement	21%	3%	0.02

AEs not statistically different between groups*

Rosenberg PB et al J Clin Psychiatry 2013;74(8):810-816

Methylphenidate for Alzheimer's Apathy Discussion

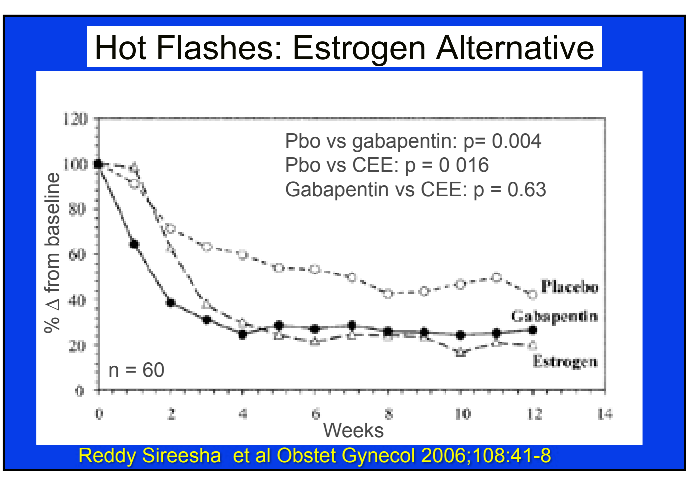
"The results…suggest that methylphenidate may be a safe and effective Rx for apathy in Alzheimer's disease and is possibly associated with cognitive improvements as well."

Rosenberg PB et al J Clin Psychiatry 2013;74(8):810-816

Hot Flashes: When Estrogen is Not an Option

- Study: RDBPCT PMP women (n=60)
- Inclusion:
  - age 35-60 yrs
  - Surgical or medical menopause
  - 50 hot flashes/wk X >2 months
- Rx: titrated gabapentin 2400 mg/d (t.i.d) vs 0.625 CEE vs placebo X 12 weeks

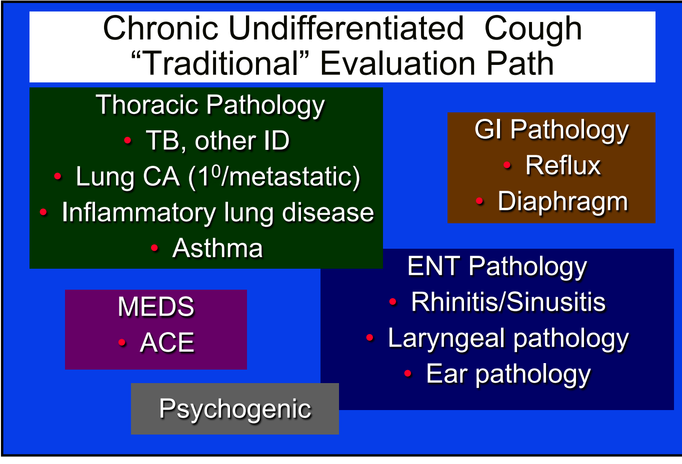
Reddy Sireesha et al Obstet Gynecol 2006;108:41-8

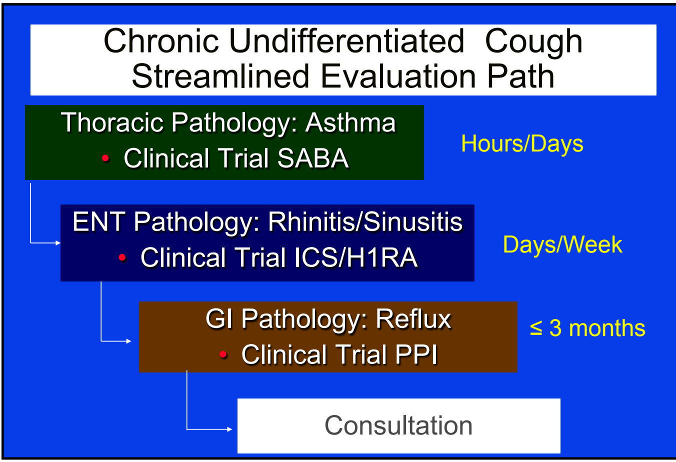


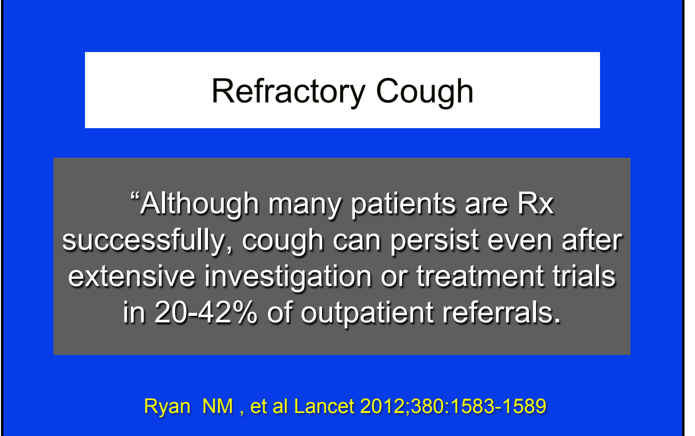
Hot Flashes: Gabapentin?

"Despite the small scale of this study, gabapentin appears to be as effective as estrogen in the Rx of PMP hot flashes."

Reddy Sireesha et al Obstet Gynecol 2006;108:41-8







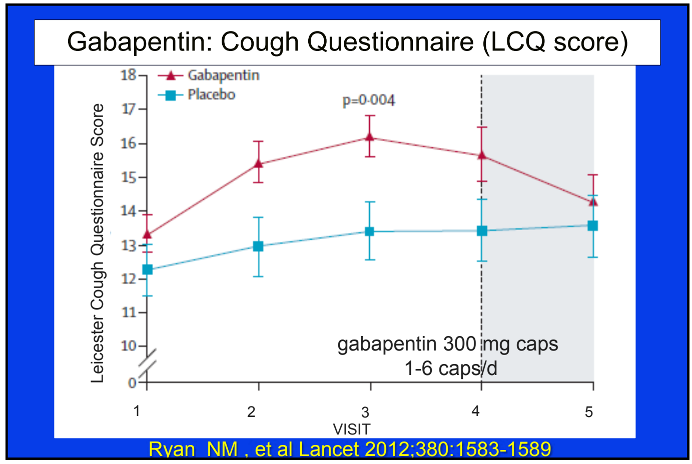
Study: Gabapentin for Undifferentiated Cough

Inclusions

- Etiology unknown after investigation
- Failed Rx for asthma
- Failed Rx for GERD (PPI)
- Failed Rx for rhinitis (nasal steroids, antihistamines)

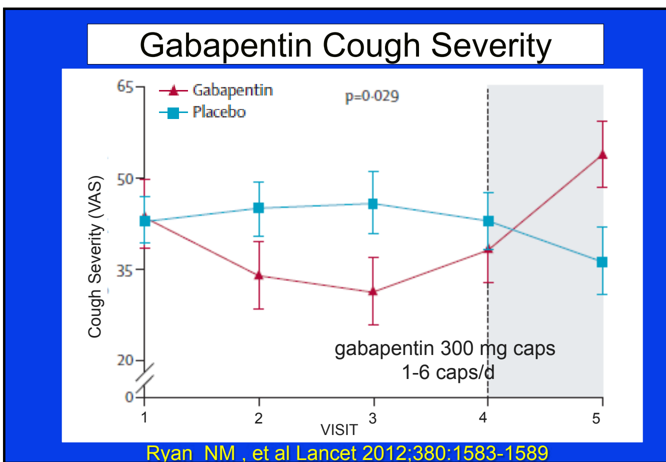
Ryan NM , et al Lancet 2012;380:1583-1589

Gabapentin: Cough Questionnaire (LCQ score)



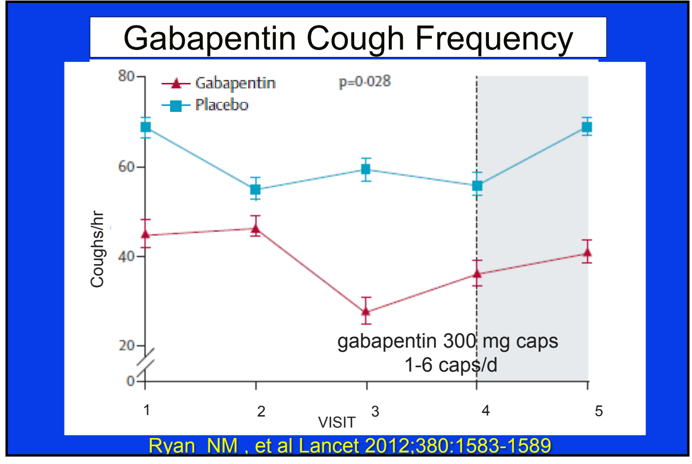
Ryan NM , et al Lancet 2012;380:1583-1589

Gabapentin Cough Severity



Ryan NM , et al Lancet 2012;380:1583-1589

Gabapentin Cough Frequency



Ryan NM , et al Lancet 2012;380:1583-1589

Venous Ulcers: Simvastatin?

"Simvastatin has shown potential wound-healing properties; however, no studies have investigated its use in venous ulcers."

Evangelista MTP et al Brit J Dermatol 2014;170:1151-1157

Venous Ulcers: Simvastatin?

- Study: RDBPCT venous insufficiency ulcers (n=66)
- Rx: ≤10 wks simvastatin 40 mg/d vs pbo
  - All pts: elevation, compression, etc.
- Outcome: Ulcer healing

Evangelista MTP et al Brit J Dermatol 2014;170:1151-1157

Venous Ulcers & Simvastatin: Outcomes

	Placebo	Simvastatin	p
All Ulcers			
Healed Time to Heal	34% 8.55 weeks	90% 7.53 weeks	*
Ulcer ≤ 5 cm			
% Healed Time to Heal	50% 6.89 weeks	100% 8.40 weeks	* *
Ulcer > 5 cm			
% Healed Time to heal	0%	67% 9.17 weeks	*

Evangelista MTP et al Brit J Dermatol 2014;170:1151-1157

Venous Ulcers & Simvastatin: Outcomes

"…simvastatin 40 mg daily, in addition to standard wound care and compression, is associated with a significant improvement in healing rate and time, as well as improved patient quality of life when compared with placebo…."

Evangelista MTP et al Brit J Dermatol 2014;170:1151-1157

Venous Insufficiency Ulcers: Physical Therapy

"Leg elevation…is also considered standard of care. Leg elevation requires raising lower extremities above the level of the heart…"

Collins L, Seraj S "Dx and Rx of Venous Ulcers" Amer Fam Phys 2010;81(8):989-996

Fibromyalgia: Why Memantine?

"A growing body of evidence suggests that glutamate…may play a part in the pathophysiology of fibromyalgia, given that its concentration is elevated in the insula, hippocampus, and posterior cingulate cortex."

↓

"…..some authors have suggested that glutamate-blocking drugs such as memantine may be useful in the Rx of fibromyalgia…."

Olivan-Blazquez B, et al Pain 2014;155:2517-2525

Fibromyalgia: MORE Why Memantine?

- Used in various conditions successfully: Parkinson's, spasticity, convulsions, vascular dementia, Alzheimer's, complex regional pain syndrome, phantom limb
- Excellent safety record > 20 yrs
- Clinical trials: well tolerated
- Long-term use: well tolerated

Olivan-Blazquez B, et al Pain 2014;155:2517-2525

Fibromyalgia: Memantine

- Study: DBRPCT (n=63)
- Location: Zaragoza, Spain
- Independent Study (No Industry Sponsorship)
- Rx: memantine vs placebo
  - 5 mg/d X 1 week
  - 10 mg/d x 1 week
  - 15 mg/d x 1 week
  - 20 mg/d x 21 weeks
- Outcomes (at 6 months): pain, anxiety

Olivan-Blazquez B, et al Pain 2014;155:2517-2525

Memantine for Fibromyalgia: Favorable Outcomes

- Pain
- Pain threshold
- Cognitive function
- Depression
- Adverse Effects: "mild and infrequent… memantine is considered one of the safest and most well-tolerated drugs for the elderly."

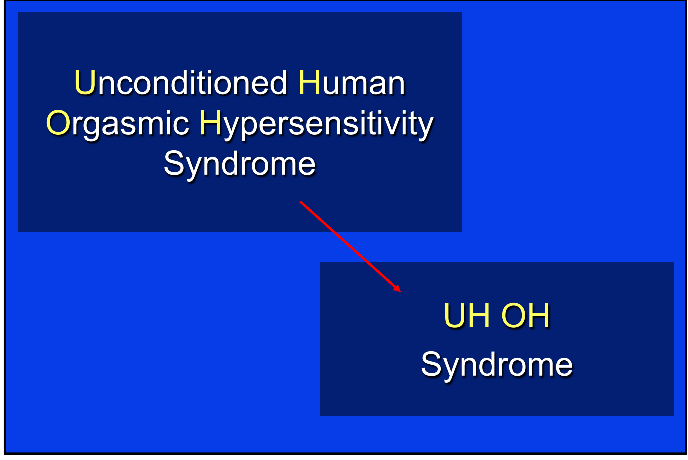
Olivan-Blazquez B, et al Pain 2014;155:2517-2525

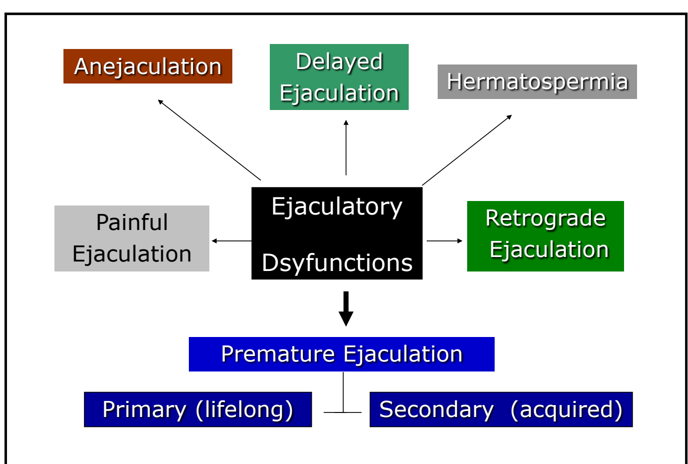
Premature Ejaculation Does it Need a 'Makeover'?

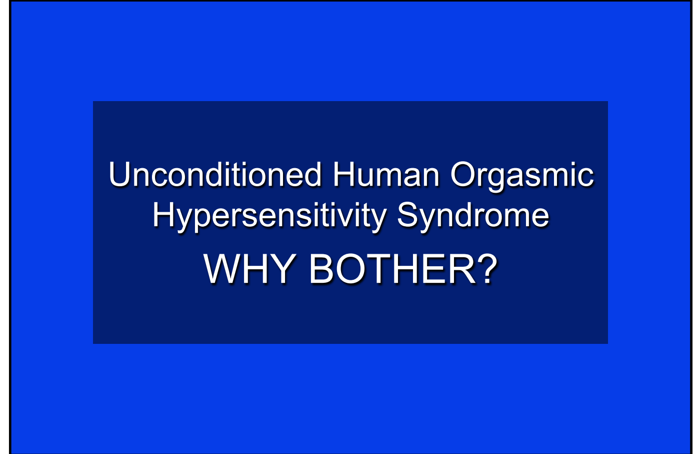
- Too Complicated
  - Detrusor Hyperactivity → Overactive Bladder
- Pejorative
  - Impotence → ED
- Ill-defined
- Unwieldy for clinicians to elicit
- No Acronym: CHF, ARB, ALS, SCUBA

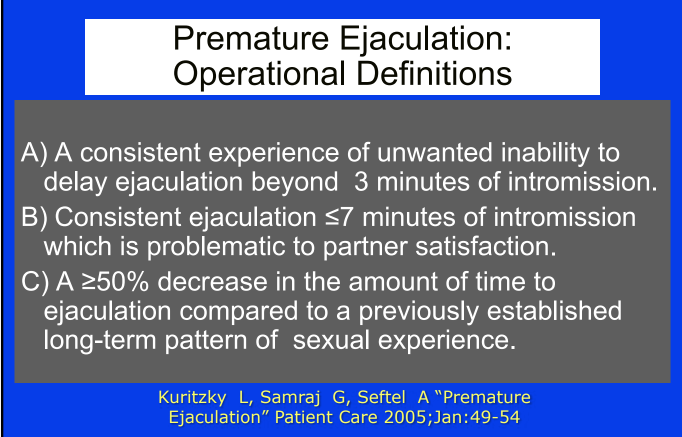
Olivan-Blazquez B, et al Pain 2014;155:2517-2525

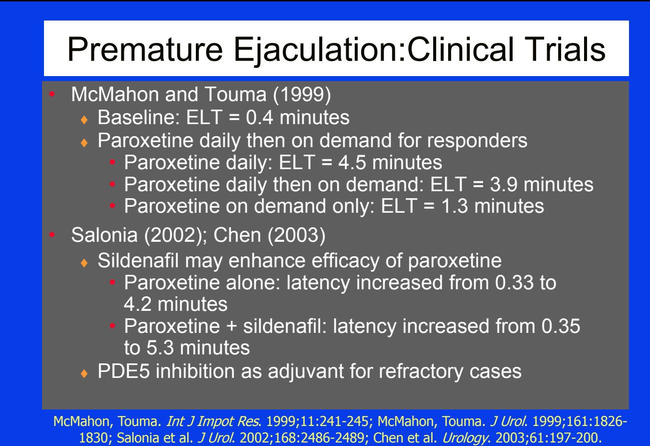
Unconditioned Human Orgasmic Hypersensitivity Syndrome

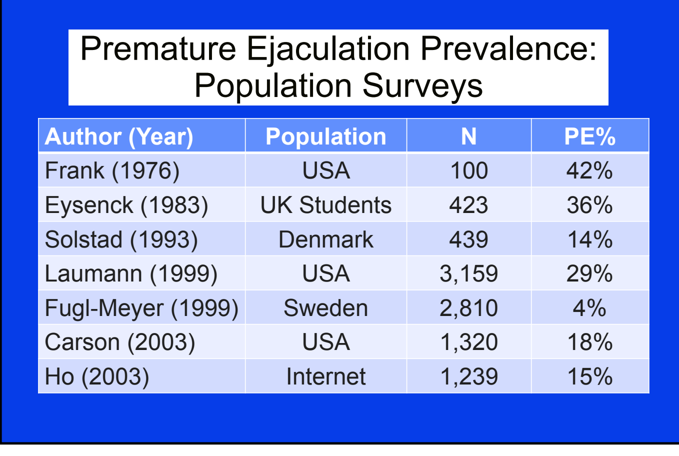




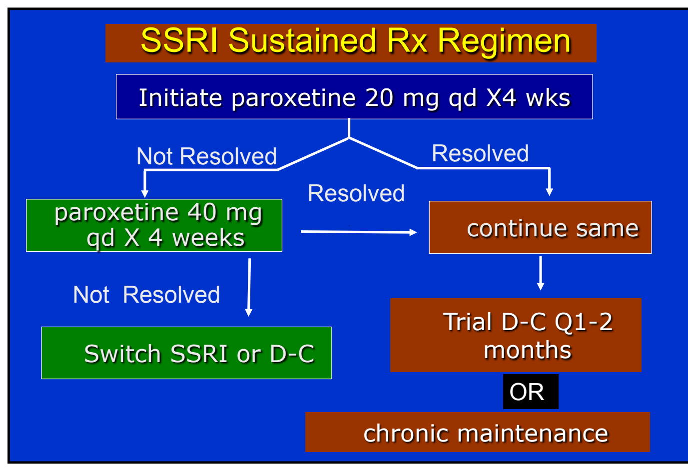


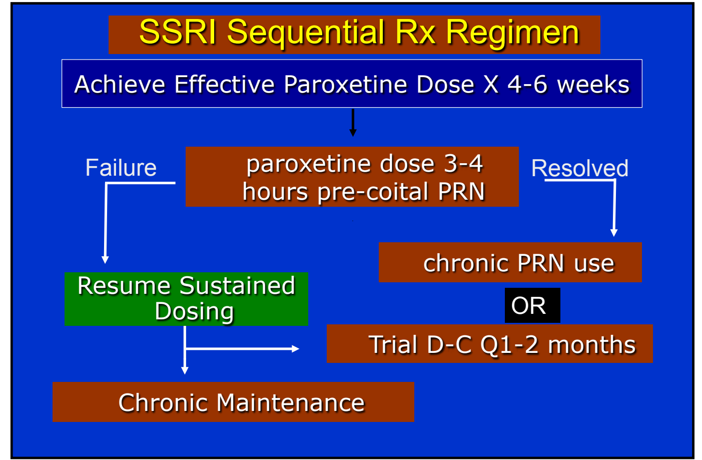





Premature Ejaculation Prevalence: Population Surveys

Author (Year)	Population	N	PE%
Frank (1976)	USA	100	42%
Eysenck (1983)	UK Students	423	36%
Solstad (1993)	Denmark	439	14%
Laumann (1999)	USA	3,159	29%
Fugl-Meyer (1999)	Sweden	2,810	4%
Carson (2003)	USA	1,320	18%
Ho (2003)	Internet	1,239	15%





Equipotent SSRI Target Doses

Paroxetine (Paxil) 40 mg qd

Sertraline (Zoloft) 100 mg qd

Fluoxetine (Prozac) 40 mg qd

Clomipramine (Anafranil) 50 mg qd

Premature Ejaculation: Tramadol

- "Over the past 10 years, a number of studies have evaluated the efficacy of tramadol for the Rx of PE. Although the dosage and timing of use varied across studies, there was universal improvement in PE Sx….regardless of dose…."
- Easy dose: tramadol 25 mg 1-2 hrs pre-coital

Olivan-Blazquez B, et al Pain 2014;155:2517-2525

Any REAL Hope for Chocolate?

A chronologically mature physician (D.O.B. 10/9/1946) has ingested for breakfast every morning of his life, since he was 18 years, a Mountain Dew and a Chunky candy bar. Nutrition for other meals is 'traditional'. He is ostensibly of sound mind and body, though obviously of dubious judgement. Numerous well intended advisors have failed to dissuade him from this habit. Scientifically, you might say

A) You *seem* fine, but better nutrition would probably have made you even healthier

B) Perhaps the chocolate helps your brain

C) Diet Mountain Dew would be more sensible

D) The sodium benzoate ingredient in Mt. Dew says "Preserves Freshness"; you are already fresh enough

The NEW ENGLAND JOURNAL of MEDICINE

OCCASIONAL NOTES

Chocolate Consumption, Cognitive Function, and Nobel Laureates

Franz H. Messerli, M.D.

2012;367(16):1562-1564

Dietary flavonoids, abundant in plant-based foods, have been shown to improve cognitive function. Specifically, a reduction in the risk of dementia, enhanced performance on some cognitive tests,

cause the population of a country is substantially higher than its number of Nobel laureates, the numbers had to be multiplied by 10 million. Thus, the numbers must be read as the number

Chocolate & Cognitive Function

"A subclass of flavonoids called flavanols, which are widely present in cocoa, green tea, red wine, and some fruits, seems to be effective in slowing down or even reversing the reductions in cognitive performance that occur with aging."

Messerli RH Chocolate Consumption, Cognitive Function, and Nobel Laureates" NEJM 2012;367(16):1562-1564

SELF EVALUATION

"Things I Wish I Knew Last Year"

1. Which intervention has been shown to improve lateral epicondylitis Sx in a long-term trial?

a. Systemic vitamin D
b. Topical Vitamin E
c. Topical nitroglycerin
d. Injectable botulinum toxin

2. Which Rx for streptococcal tonsillitis in children has demonstrated the lowest risk of post-Rx recurrence?

a. Penicillin
b. Amoxicillin
c. Tetracycline
d. Cephalosporin

3. A patient with exudative tonsillitis received treatment with amoxicillin for presumptive GABHS, but subsequently was determined to have acute mononucleosis. What is the likelihood he will develop a rash?

a. <10%
b. 30-50%
c. 70-100%
d. I don't have a crystal ball. How am I supposed to know?

4. An 83 y.o. women with Alzheimer dementia has exhibited apathy for 2 months. What might help?

a. Droxidopa (Northera)
b. Methylphenidate (Ritalin)
c. Tea Tree Oil
d. High dose vitamin D

5. A 43 y.o. man has undergone extensive evaluation for cough, without finding a cause. Other than cough, he is essentially healthy. What symptomatic Rx might help?

a. Tiotropium (Spiriva)
b. Fluticasone MDI (Flovent)
c. Gabapentin (Neurontin)
d. Azelastine Nasal Spray (Astelin)

6. A patient with a venous insufficiency ulcer has failed traditional Rx. What might help?

a. Simvastatin (Zocor)
b. Ramipril (Altace)
c. Doxycycline
d. Carbamazepine

7. A 33 y.o. woman with fibromyalgia has followed advice for exercise, counseling, and medications, but has substantial residual symptom burden. What might help?

a. Oxycodone 10 mg t.i.d.
b. Tramadol 50 mg q.i.d.
c. 10 mg t.i.d.
d. Memantine 20 mg qd

Answer Key: 1. C, 2. D, 3. C, 4. B, 5. C, 6. A, 7. D

Barry A. Franklin, PhD

Barry A. Franklin, PhD, of Royal Oak, Michigan, is director of Preventive Cardiology and Cardiac Rehabilitation at William Beaumont Hospital which, during his tenure, has achieved national recognition in the diagnosis and treatment of coronary artery disease. He served as president of the American Association of Cardiovascular and Pulmonary Rehabilitation (1989-1990) and of the American College of Sports Medicine (1999-2000).

Dr. Franklin is a past editor in chief of the *Journal of Cardiopulmonary Rehabilitation* and currently holds formal editorial board appointments with 15 other scientific and clinical journals. He has written or edited nearly 600 scientific and clinical publications, including 27 books and, since 1976, he has given over 1000 invited presentations to state, national and international audiences.

You may contact Dr. Franklin at Barry.Franklin@beaumont.org.

The Anti-aging Benefits of Exercise and Cardiorespiratory Fitness

Turning 50

According to the Census Bureau, 64,054 centenarians are in the U.S., and there will be *1.1 million centenarians by 2050*. Currently, the 'fastest growing' subset of the population are those over 85 years of age. These data highlight the escalating importance of geriatrics in the future.

The Census Bureau projects that **41%** of the women and **18%** of the men who turn **50** this year will live to **celebrate their 100th birthday.**

Regular Exercise Prevents Cellular Senescence

Twins who exercise regularly are biologically younger – by ~ 10 years – than those who don't.

cell

This striking finding may explain why exercise reduces the risk of heart attacks, diabetes, cancer, and other degenerative diseases. It actually suggests that active twins have cells that are measurably "younger" than those of inactive ones.

Cherkas LF et al. Arch Intern Med 2008;168:154

Exercise Physiology

Physical Exercise Prevents Cellular Senescence in Circulating Leukocytes and in the Vessel Wall

Christian Werner, MD; Tobias Fürster, MD; Thomas Widmann, MD; Janine Pöss, MD; Cristiana Roggia, MD; Milad Hanhoun, MD; Jürgen Scharhag, MD; Nicole Büchner, DBBSc; Tim Meyer, MD; Wilfried Kindermann, MD; Judith Haendeler, PhD; Michael Böhm, MD; Ulrich Laufs, MD

Background—The underlying molecular mechanisms of the vasculoprotective effects of physical exercise are incompletely understood. Telomere erosion is a central component of aging, and telomere-associated proteins regulate cellular senescence and survival. This study examines the effects of exercising on vascular telomere biology and endothelial apoptosis in mice and the effects of long-term endurance training on telomere biology in humans.

Methods and Results—C57/Bl6 mice were randomized to voluntary running or no running wheel conditions for 3 weeks. Exercise upregulated telomerase activity in the thoracic aorta and in circulating mononuclear cells compared with sedentary controls, increased vascular expression of telomere repeat-binding factor 2 and Ku70, and reduced the expression of vascular apoptosis regulators such as cell-cycle–checkpoint kinase 2, p16, and p53. Mice preconditioned by voluntary running exhibited a marked reduction in lipopolysaccharide-induced aortic endothelial apoptosis. Transgenic mouse studies showed that endothelial nitric oxide synthase and telomerase reverse transcriptase synergize to confer endothelial stress resistance after physical activity. To test the significance of these data in humans, telomere biology in circulating leukocytes of young and middle-aged track and field athletes was analyzed. Peripheral blood leukocytes isolated from endurance athletes showed increased telomerase activity, expression of telomere-stabilizing proteins, and downregulation of cell-cycle inhibitors compared with untrained individuals. Long-term endurance training was associated with reduced leukocyte telomere erosion compared with untrained controls.

Conclusions—Physical activity regulates telomere-stabilizing proteins in mice and in humans and thereby protects from stress-induced vascular apoptosis. (*Circulation*. 2009;120:2438-2447.)

Key Words: aging ■ exercise ■ nitric oxide synthase ■ prevention ■ telomeres

Circulation 2009;129:2438-2447

Regular Aerobic Exercise Prevents Cellular Senescence

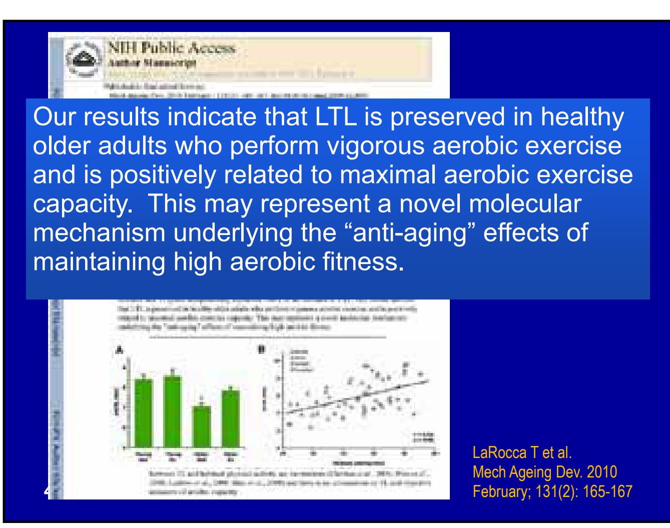
- Telomere erosion is a central component of aging, and telomere – associated proteins regulate cellular senescence and survival.
- Regulation of telomere stabilizing proteins by exercise reduces telomere shortening and thus protects from cellular deterioration and programmed cell death.

Dividing cell

Telomere: Series of links at the end of each chromosome

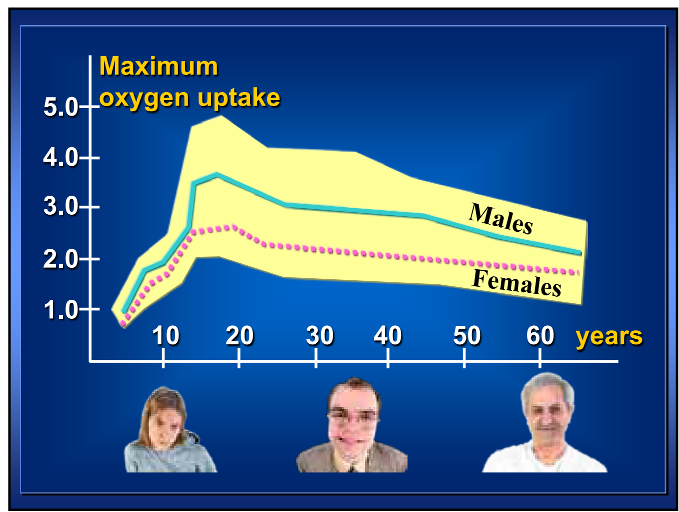
Chromosome

Werner CW et al. Circulation 2009;120:2438



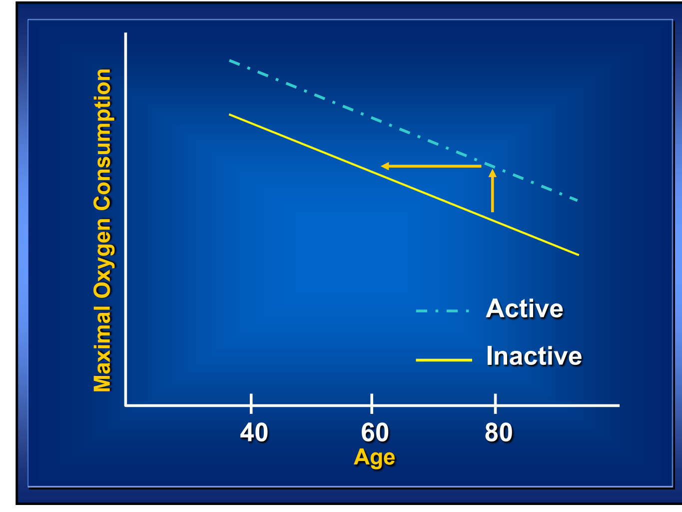
Outline

- Aerobic Capacity and Muscular Strength/Endurance
- Walking Metrics, Fitness, Fatness, Mortality, and Surgical Outcomes
- Cognitive & Sexual Function
- Aging and Disability
- Exercise Prescription: High Risk Activities



A 20-Year Functional Rejuvenation

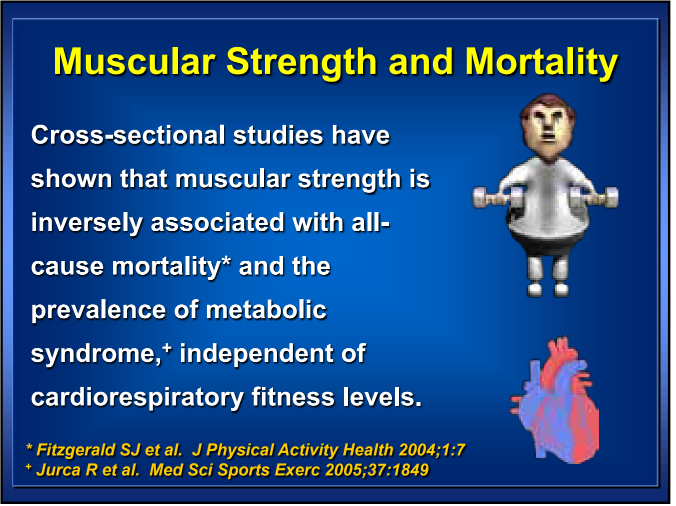
After the age of 20, VO_2 max typically declines by ~1% per year. An aerobic exercise program can lead to a 20% increase in aerobic capacity, which translates to a 20-year functional rejuvenation. In other words, a physically trained 80-year-old can achieve the same fitness level as an inactive 60-year-old.

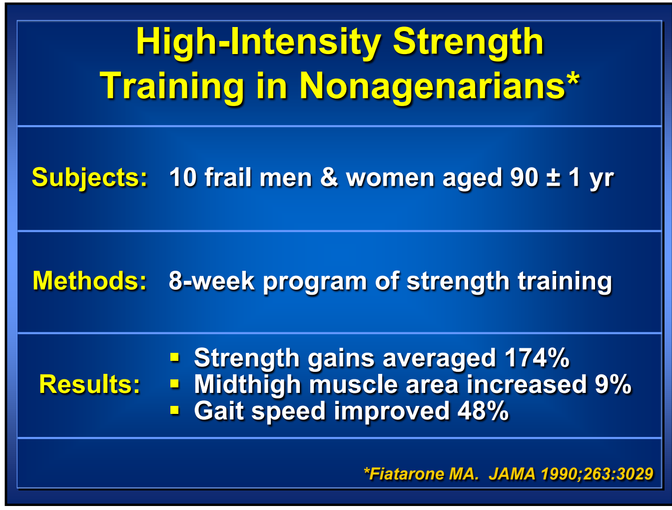


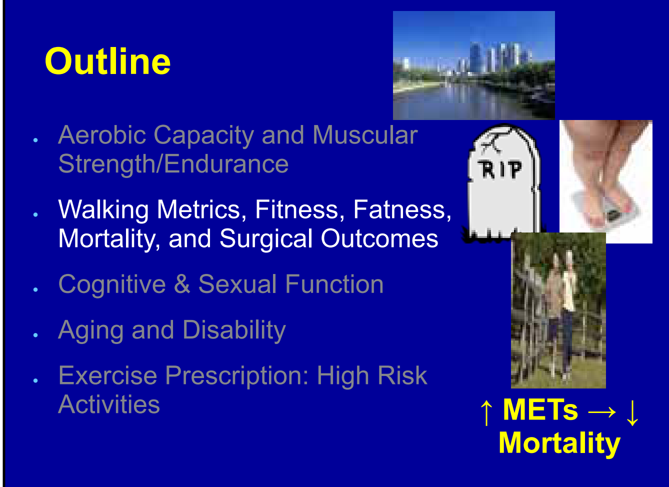
The Framingham Heart Study found that about half of women over age 65 cannot lift 10 pounds.

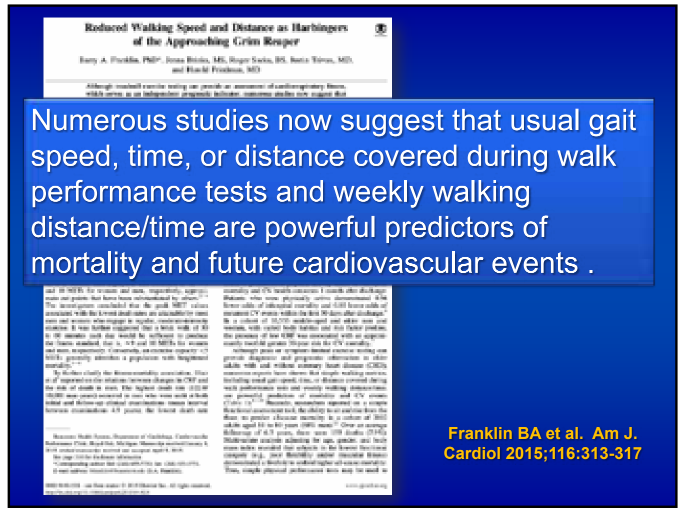
Muscle Mass and Strength: Key Points

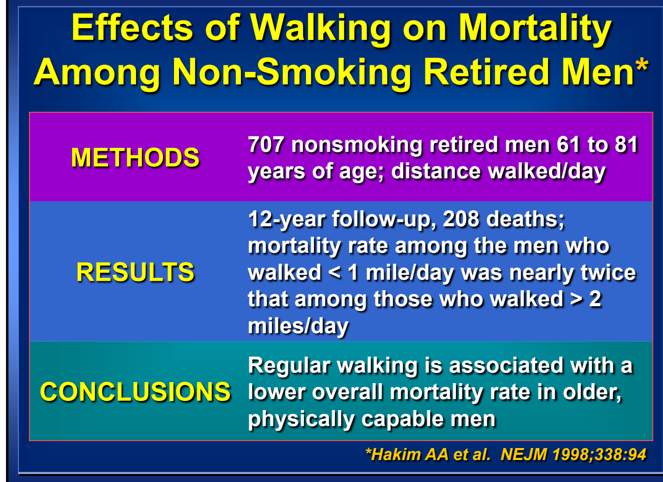
- Between ages 20 and 70, people lose about 30 ± 10% of their lean body tissue (muscle mass)
- This process (sarcopenia) is associated with marked declines in muscular strength
- Resistance training can improve muscle strength and endurance in men and women of all ages by 25% to 100%, or more!

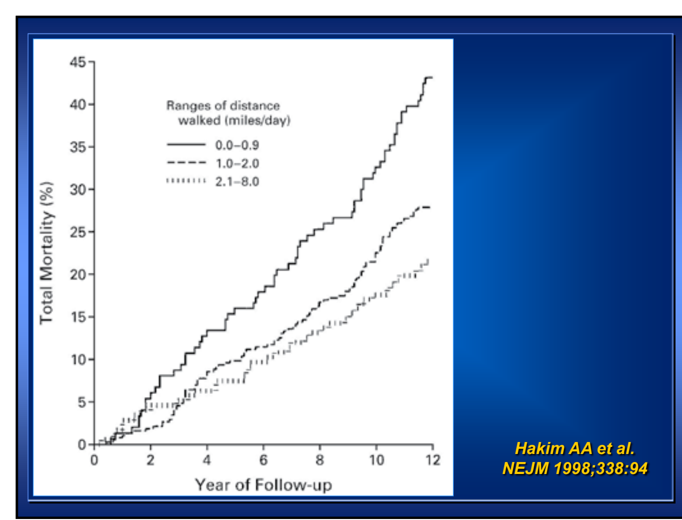

Muscular Strength and Mortality
Cross-sectional studies have shown that muscular strength is inversely associated with all-cause mortality* and the prevalence of metabolic syndrome,+ independent of cardiorespiratory fitness levels.
* Fitzgerald SJ et al. J Physical Activity Health 2004;1:7
+ Jurca R et al. Med Sci Sports Exerc 2005;37:1849

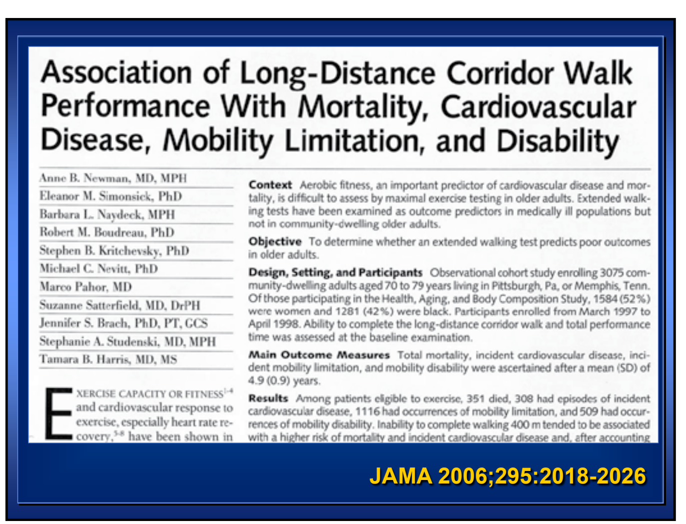

High-Intensity Strength Training in Nonagenarians*
Subjects: 10 frail men & women aged 90 ± 1 yr
Methods: 8-week program of strength training
Results:
Strength gains averaged 174%
Midthigh muscle area increased 9%
Gait speed improved 48%
*Fiatarone MA. JAMA 1990;263:3029


Outline
Aerobic Capacity and Muscular Strength/Endurance
Walking Metrics, Fitness, Fatness, Mortality, and Surgical Outcomes
Cognitive & Sexual Function
Aging and Disability
Exercise Prescription: High Risk Activities
RIP
↑ METs → ↓ Mortality


Reduced Walking Speed and Distance as Harbingers of the Approaching Grim Reaper
Numerous studies now suggest that usual gait speed, time, or distance covered during walk performance tests and weekly walking distance/time are powerful predictors of mortality and future cardiovascular events .
Franklin BA et al. Am J. Cardiol 2015;116:313-317


Effects of Walking on Mortality Among Non-Smoking Retired Men*
METHODS
707 nonsmoking retired men 61 to 81 years of age; distance walked/day
RESULTS
12-year follow-up, 208 deaths; mortality rate among the men who walked < 1 mile/day was nearly twice that among those who walked > 2 miles/day
CONCLUSIONS
Regular walking is associated with a lower overall mortality rate in older, physically capable men
*Hakim AA et al. NEJM 1998;338:94


Total Mortality (%)
Year of Follow-up
Ranges of distance walked (miles/day)
0.0–0.9
1.0–2.0
2.1–8.0
Hakim AA et al. NEJM 1998;338:94


Association of Long-Distance Corridor Walk Performance With Mortality, Cardiovascular Disease, Mobility Limitation, and Disability

Anne B. Newman, MD, MPH
Eleanor M. Simonsick, PhD
Barbara L. Naydeck, MPH
Robert M. Boudreau, PhD
Stephen B. Kritchevsky, PhD
Michael C. Nevitt, PhD
Marco Pahor, MD
Suzanne Satterfield, MD, DrPH
Jennifer S. Brach, PhD, PT, GCS
Stephanie A. Studenski, MD, MPH
Tamara B. Harris, MD, MS

Context Aerobic fitness, an important predictor of cardiovascular disease and mortality, is difficult to assess by maximal exercise testing in older adults. Extended walking tests have been examined as outcome predictors in medically ill populations but not in community-dwelling older adults.

Objective To determine whether an extended walking test predicts poor outcomes in older adults.

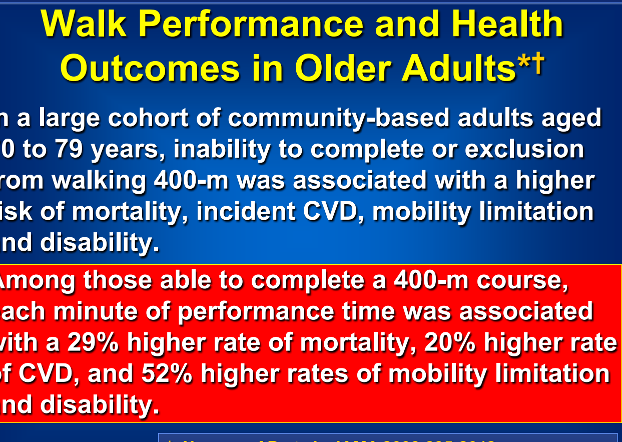
Design, Setting, and Participants Observational cohort study enrolling 3075 community-dwelling adults aged 70 to 79 years living in Pittsburgh, Pa, or Memphis, Tenn. Of those participating in the Health, Aging, and Body Composition Study, 1584 (52%) were women and 1281 (42%) were black. Participants enrolled from March 1997 to April 1998. Ability to complete the long-distance corridor walk and total performance time was assessed at the baseline examination.

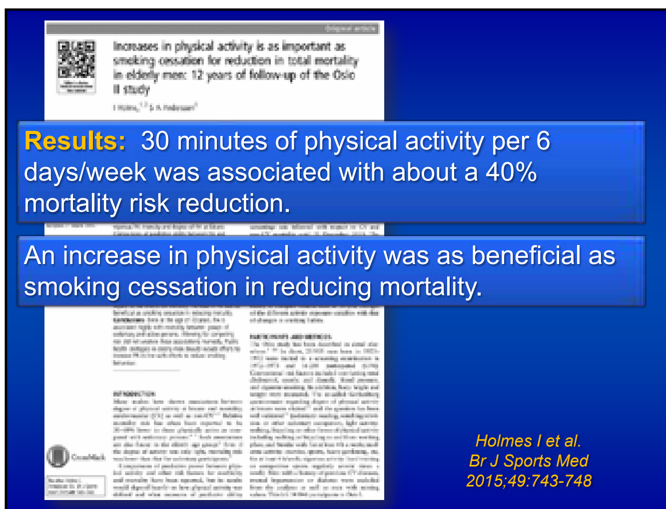
Main Outcome Measures Total mortality, incident cardiovascular disease, incident mobility limitation, and mobility disability were ascertained after a mean (SD) of 4.9 (0.9) years.

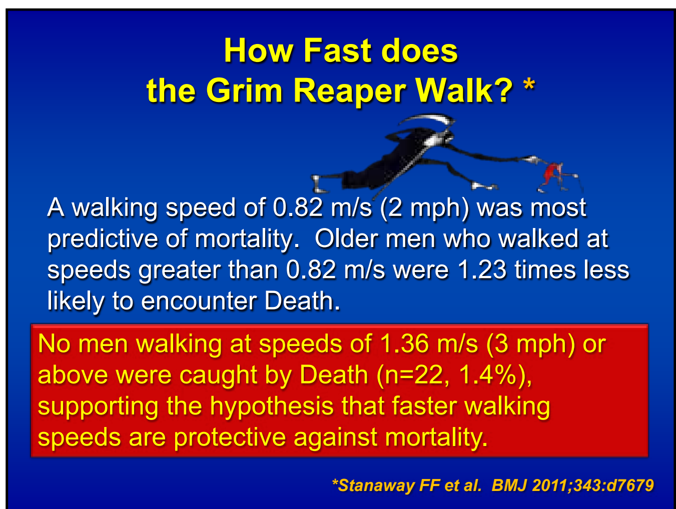
Results Among patients eligible to exercise, 351 died, 308 had episodes of incident cardiovascular disease, 1116 had occurrences of mobility limitation, and 509 had occurrences of mobility disability. Inability to complete walking 400 m tended to be associated with a higher risk of mortality and incident cardiovascular disease and, after accounting

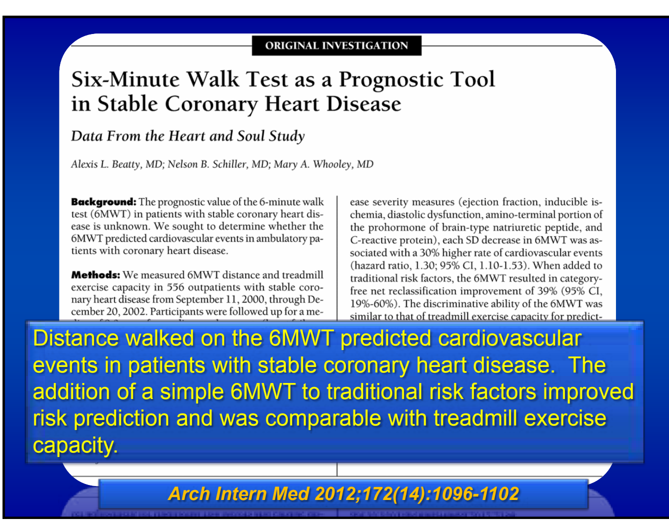
EXERCISE CAPACITY OR FITNESS[1-4] and cardiovascular response to exercise, especially heart rate recovery,[5-8] have been shown in

JAMA 2006;295:2018-2026








ORIGINAL INVESTIGATION

Six-Minute Walk Test as a Prognostic Tool in Stable Coronary Heart Disease

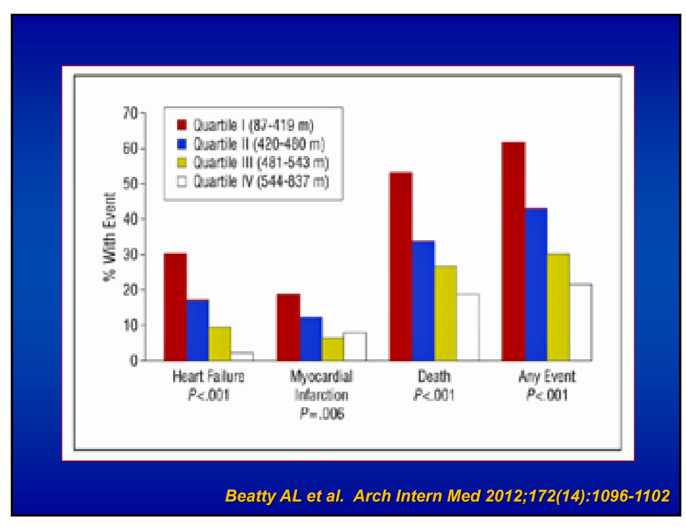
Data From the Heart and Soul Study

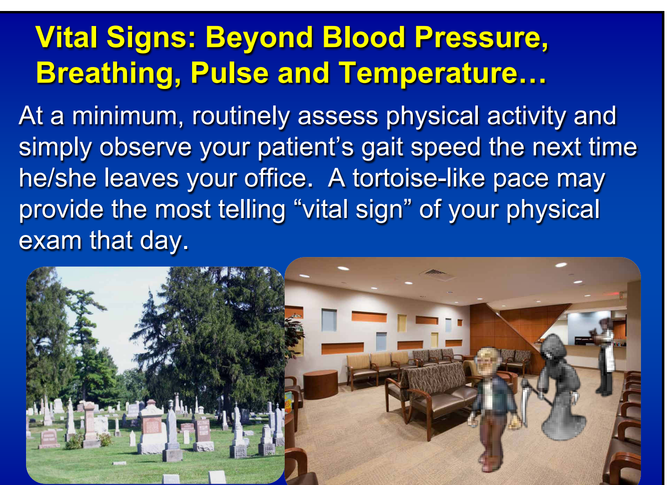
Alexis L. Beatty, MD; Nelson B. Schiller, MD; Mary A. Whooley, MD

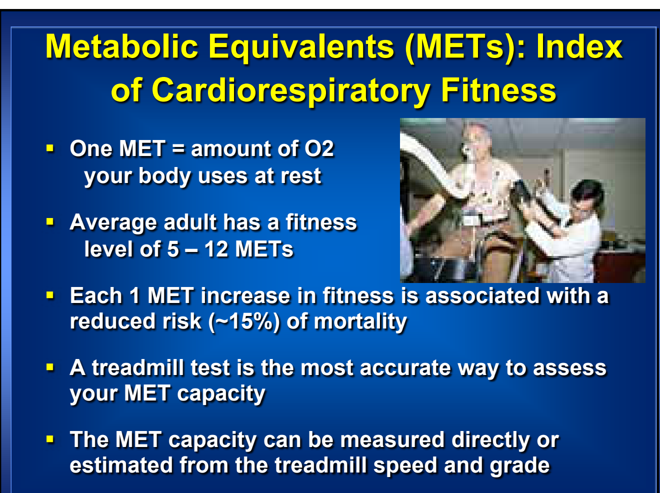
Background: The prognostic value of the 6-minute walk test (6MWT) in patients with stable coronary heart disease is unknown. We sought to determine whether the 6MWT predicted cardiovascular events in ambulatory patients with coronary heart disease.

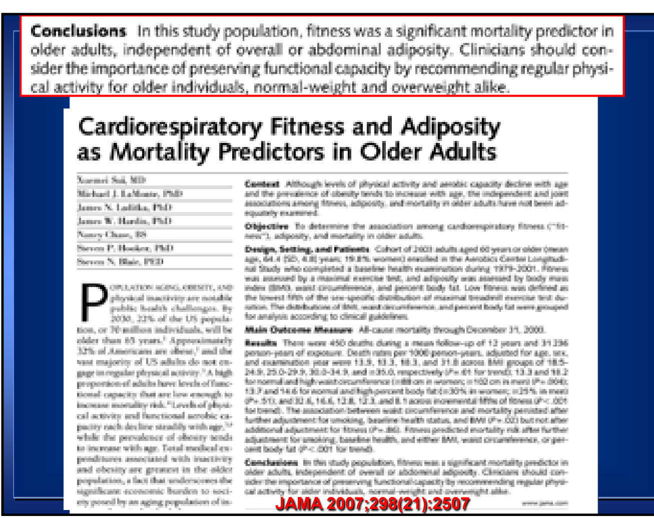
Methods: We measured 6MWT distance and treadmill exercise capacity in 556 outpatients with stable coronary heart disease from September 11, 2000, through December 20, 2002. Participants were followed up for a me-

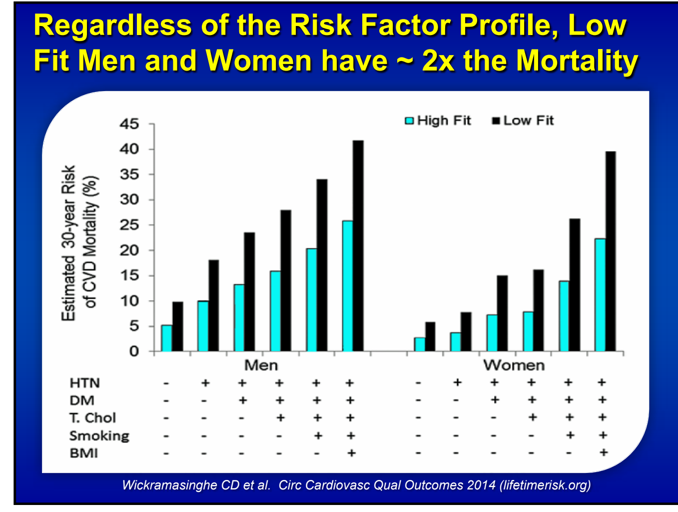
ease severity measures (ejection fraction, inducible ischemia, diastolic dysfunction, amino-terminal portion of the prohormone of brain-type natriuretic peptide, and C-reactive protein), each SD decrease in 6MWT was associated with a 30% higher rate of cardiovascular events (hazard ratio, 1.30; 95% CI, 1.10-1.53). When added to traditional risk factors, the 6MWT resulted in category-free net reclassification improvement of 39% (95% CI, 19%-60%). The discriminative ability of the 6MWT was similar to that of treadmill exercise capacity for predict-

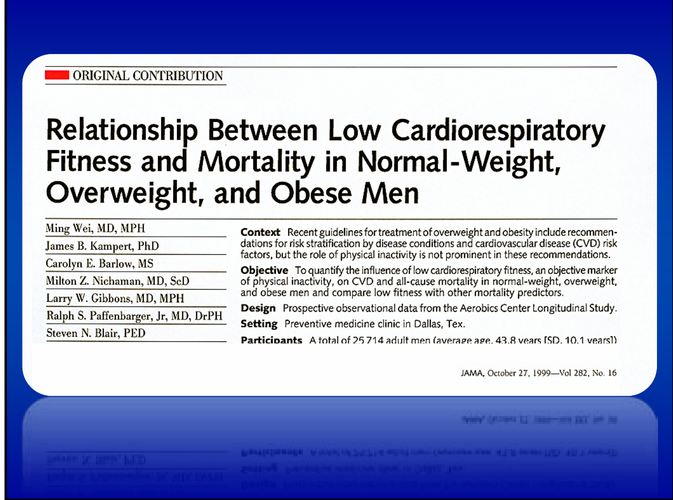


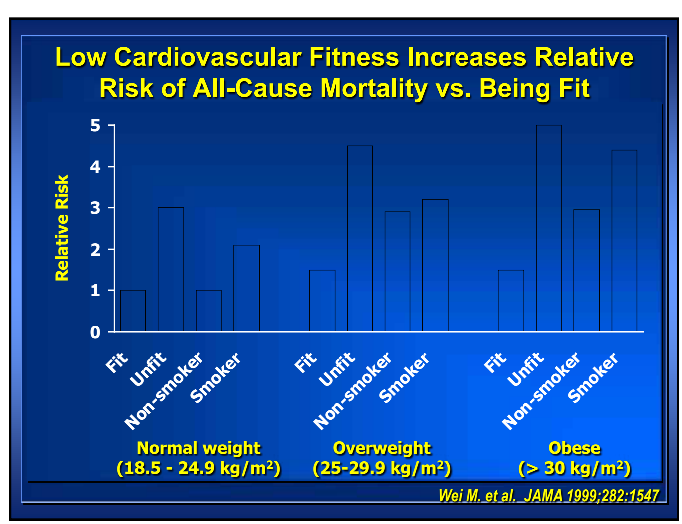

Vital Signs: Beyond Blood Pressure, Breathing, Pulse and Temperature…
At a minimum, routinely assess physical activity and simply observe your patient's gait speed the next time he/she leaves your office. A tortoise-like pace may provide the most telling "vital sign" of your physical exam that day.


Metabolic Equivalents (METs): Index of Cardiorespiratory Fitness
One MET = amount of O2 your body uses at rest
Average adult has a fitness level of 5 – 12 METs
Each 1 MET increase in fitness is associated with a reduced risk (~15%) of mortality
A treadmill test is the most accurate way to assess your MET capacity
The MET capacity can be measured directly or estimated from the treadmill speed and grade


Conclusions In this study population, fitness was a significant mortality predictor in older adults, independent of overall or abdominal adiposity. Clinicians should consider the importance of preserving functional capacity by recommending regular physical activity for older individuals, normal-weight and overweight alike.
Cardiorespiratory Fitness and Adiposity as Mortality Predictors in Older Adults
JAMA 2007;298(21):2507


Regardless of the Risk Factor Profile, Low Fit Men and Women have ~ 2x the Mortality
High Fit
Low Fit
Estimated 30-year Risk of CVD Mortality (%)
0
5
10
15
20
25
30
35
40
45
Men
Women
HTN
DM
T. Chol
Smoking
BMI
Wickramasinghe CD et al. Circ Cardiovasc Qual Outcomes 2014 (lifetimerisk.org)


ORIGINAL CONTRIBUTION
Relationship Between Low Cardiorespiratory Fitness and Mortality in Normal-Weight, Overweight, and Obese Men
Ming Wei, MD, MPH
James B. Kampert, PhD
Carolyn E. Barlow, MS
Milton Z. Nichaman, MD, ScD
Larry W. Gibbons, MD, MPH
Ralph S. Paffenbarger, Jr, MD, DrPH
Steven N. Blair, PED
Context Recent guidelines for treatment of overweight and obesity include recommendations for risk stratification by disease conditions and cardiovascular disease (CVD) risk factors, but the role of physical inactivity is not prominent in these recommendations.
Objective To quantify the influence of low cardiorespiratory fitness, an objective marker of physical inactivity, on CVD and all-cause mortality in normal-weight, overweight, and obese men and compare low fitness with other mortality predictors.
Design Prospective observational data from the Aerobics Center Longitudinal Study.
Setting Preventive medicine clinic in Dallas, Tex.
JAMA, October 27, 1999—Vol 282, No. 16


Low Cardiovascular Fitness Increases Relative Risk of All-Cause Mortality vs. Being Fit
Relative Risk
0
1
2
3
4
5
Fit
Unfit
Non-smoker
Smoker
Normal weight (18.5 - 24.9 kg/m²)
Overweight (25-29.9 kg/m²)
Obese (> 30 kg/m²)
Wei M. et al. JAMA 1999;282:1547

Although physical activity or exercise training may not make all people lean, it appears that an active way of life may have important health benefits, even for those who remain overweight.

Physical Activity, Fitness and Pre-Operative Risk Assessment

- **Physically active patients who are hospitalized with acute coronary syndrome have better short-term outcomes.**
- **Reduced cardiorespiratory fitness levels are associated with increased morbidity/mortality after:**
  - **Bariatric and cardiac surgery**
  - **Liver transplantation**
  - **Noncardiac thoracic surgery**
  - **Major abdominal surgery**

McCullough, P et. al. Chest 2006;130;517-525
Epstein, S. et al. Liver Transplantation 2004;10:418-424
Bechard D, Wetstein L. Ann Thorac Surg 1987;44:344-349
Older P, Hall A, Hader R. Chest 1999;116:355-362

Physical Activity Status and Acute Coronary Syndromes Survival*

A landmark investigation of 2,172 patients admitted with ACS evaluated the effect of pre-admission physical activity status on in-hospital mortality and 1-month post discharge CV health outcomes.

Physically active patients demonstrated 0.56 lower odds of in-hospital mortality, and 0.80- lower odds of recurrent CV events within the first 30 days of hospital discharge.

*Pitsavos C et al. JACC 2008;51:2034
ACS = acute coronary syndrome; CV = cardiovascular

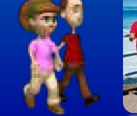
Effect of Cardiorespiratory Fitness on Short-Term Morbidity

Specifically, low preoperative cardiorespiratory fitness (<5 METs) was associated with higher operative and 30-day mortality after CABG ($p<0.05$).

Smith JL et al. AJC 2013; Oct.15

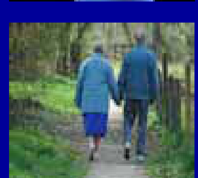
Potential Underlying Causal Mechanisms ?

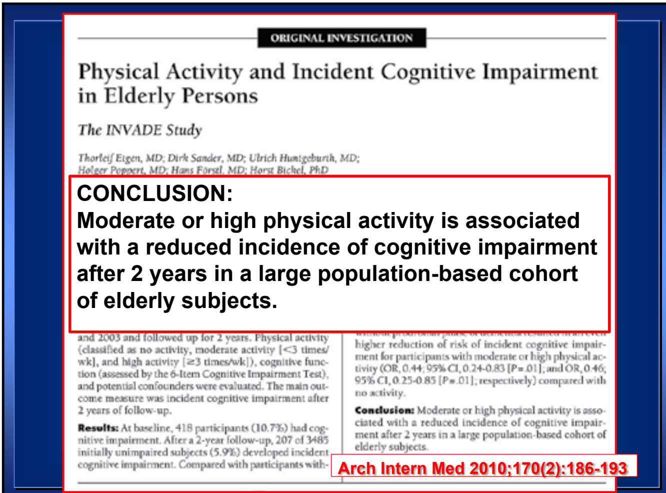
One possible explanation is that physically active or fitter patients are simply better able to cope with the demands created by the trauma of major surgery. A reduced level of CRF may also be associated with greater numbers and greater severity of unhealthy co-morbid conditions, requiring longer operative and intubation times, or by a high-risk proinflammatory state, that may be related to the development of increased post-operative complications.



Outline

- Aerobic Capacity and Muscular Strength/Endurance
- Walking Metrics, Fitness, Fatness, Mortality, and Surgical Outcomes
- Cognitive & Sexual Function
- Aging and Disability
- Exercise Prescription: High Risk Activities




ORIGINAL INVESTIGATION

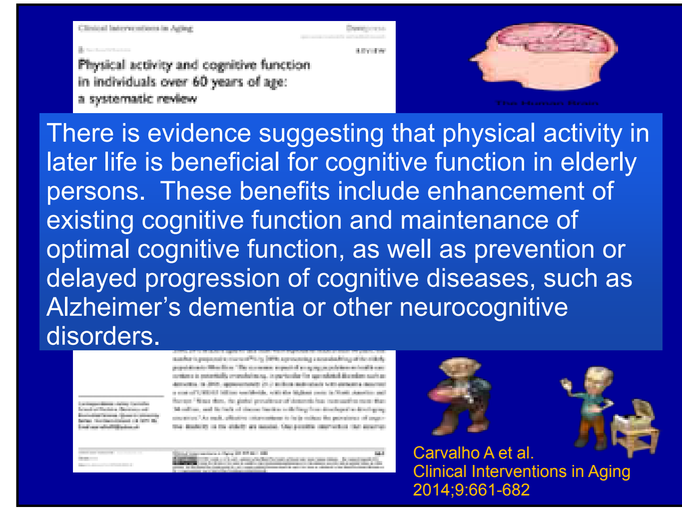
Physical Activity and Incident Cognitive Impairment in Elderly Persons

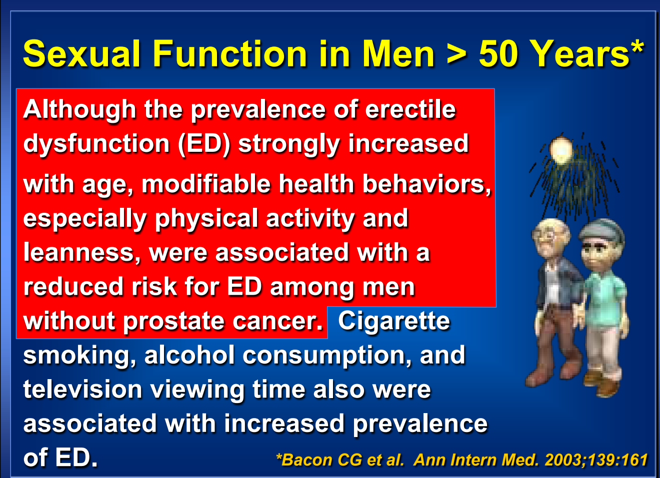
The INVADE Study

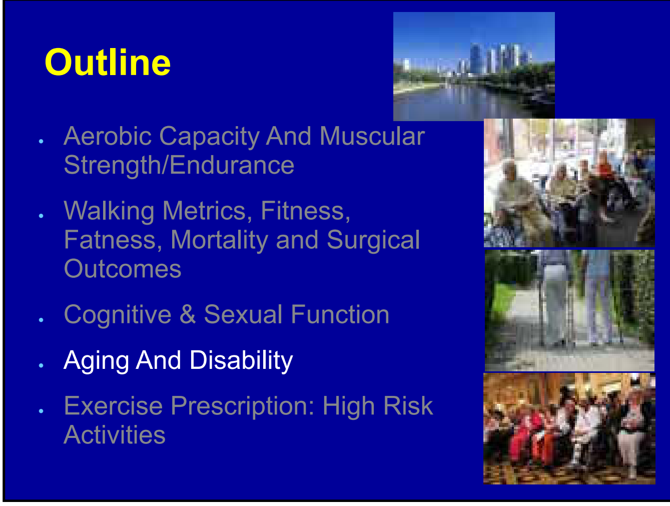
Thorleif Etgen, MD; Dirk Sander, MD; Ulrich Huntgeburth, MD; Holger Poppert, MD; Hans Förstl, MD; Horst Bickel, PhD

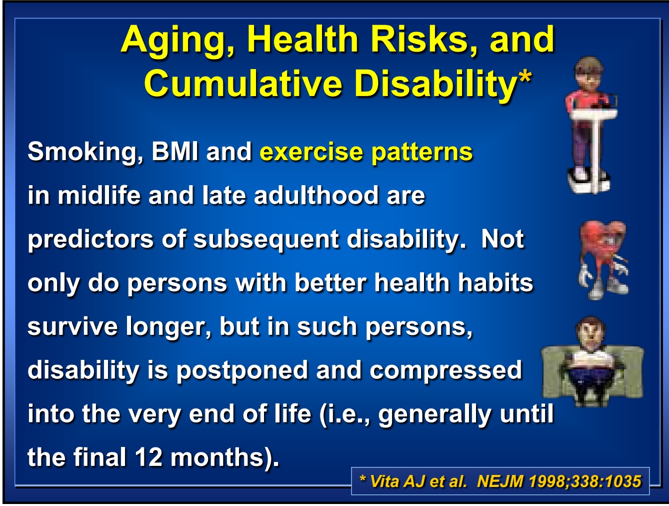
CONCLUSION:
Moderate or high physical activity is associated with a reduced incidence of cognitive impairment after 2 years in a large population-based cohort of elderly subjects.

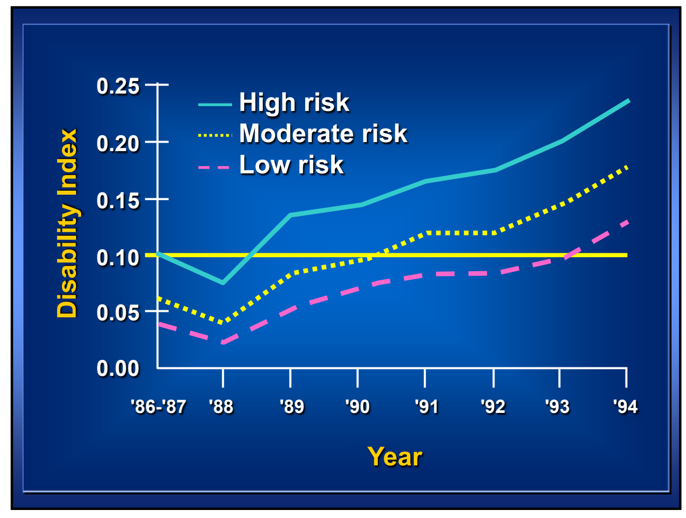
Arch Intern Med 2010;170(2):186-193



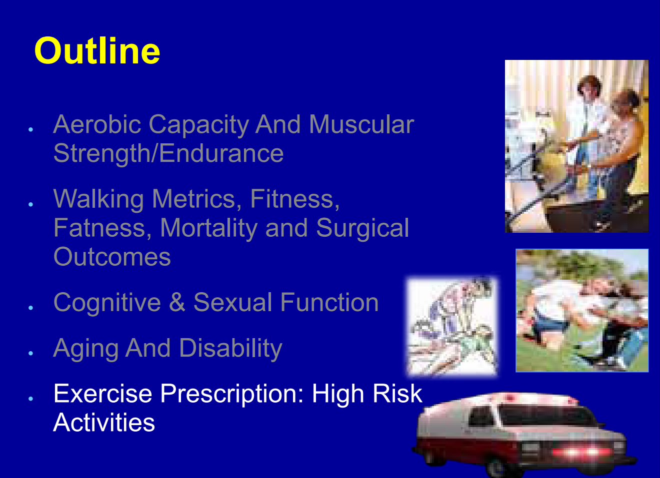








The researchers referred to this phenomenon as:
"COMPRESSION OF MORBIDITY"
Vita AJ et al. NEJM 1998;338:1035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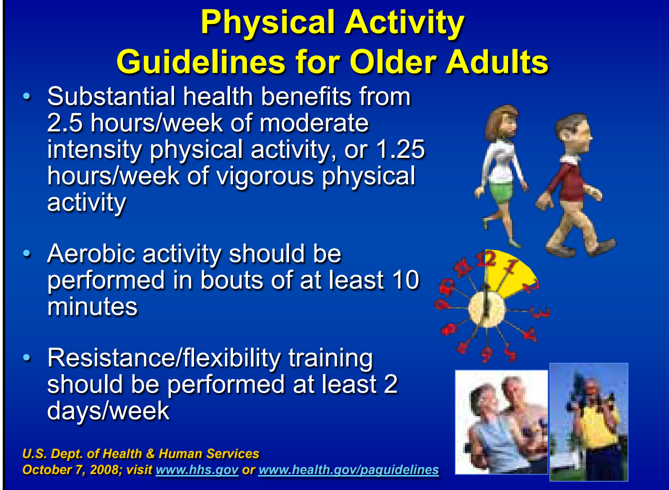
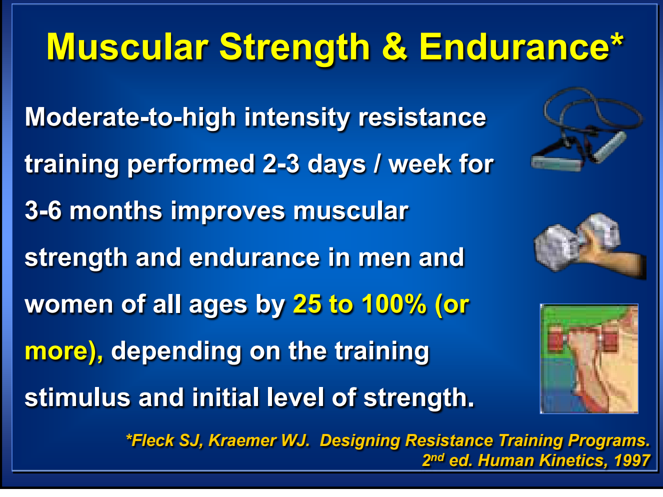
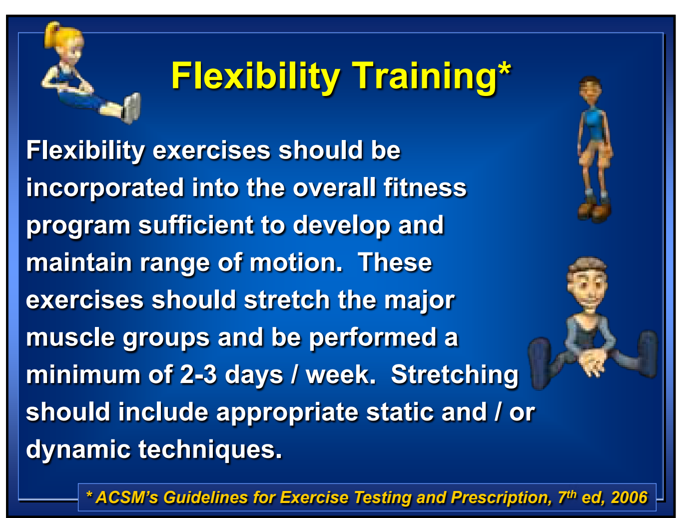
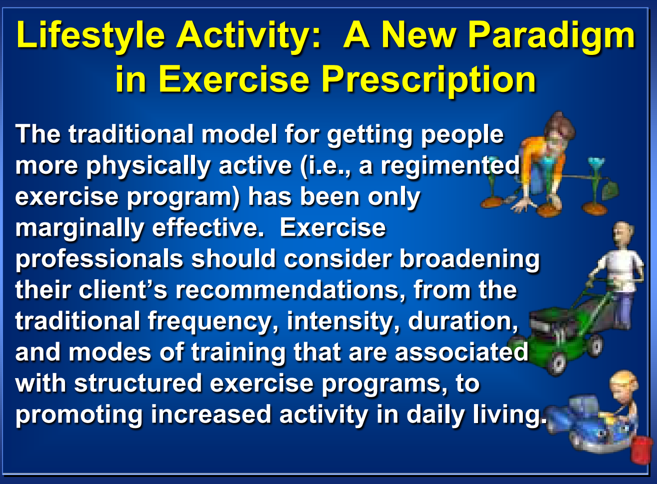
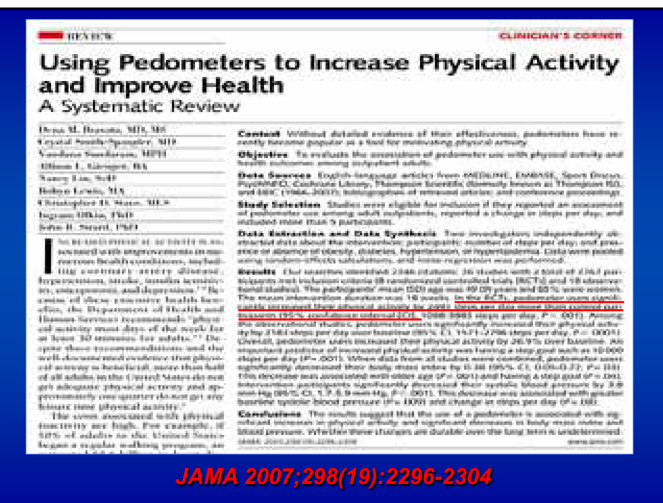

Physical Activity Guidelines for Older Adults
Substantial health benefits from 2.5 hours/week of moderate intensity physical activity, or 1.25 hours/week of vigorous physical activity
Aerobic activity should be performed in bouts of at least 10 minutes
Resistance/flexibility training should be performed at least 2 days/week
U.S. Dept. of Health & Human Services
October 7, 2008; visit www.hhs.gov or www.health.gov/paguidelines


Muscular Strength & Endurance*
Moderate-to-high intensity resistance training performed 2-3 days / week for 3-6 months improves muscular strength and endurance in men and women of all ages by 25 to 100% (or more), depending on the training stimulus and initial level of strength.
*Fleck SJ, Kraemer WJ. Designing Resistance Training Programs. 2nd ed. Human Kinetics, 1997


Flexibility Training*
Flexibility exercises should be incorporated into the overall fitness program sufficient to develop and maintain range of motion. These exercises should stretch the major muscle groups and be performed a minimum of 2-3 days / week. Stretching should include appropriate static and / or dynamic techniques.
* ACSM's Guidelines for Exercise Testing and Prescription, 7th ed, 2006


Lifestyle Activity: A New Paradigm in Exercise Prescription
The traditional model for getting people more physically active (i.e., a regimented exercise program) has been only marginally effective. Exercise professionals should consider broadening their client's recommendations, from the traditional frequency, intensity, duration, and modes of training that are associated with structured exercise programs, to promoting increased activity in daily living.

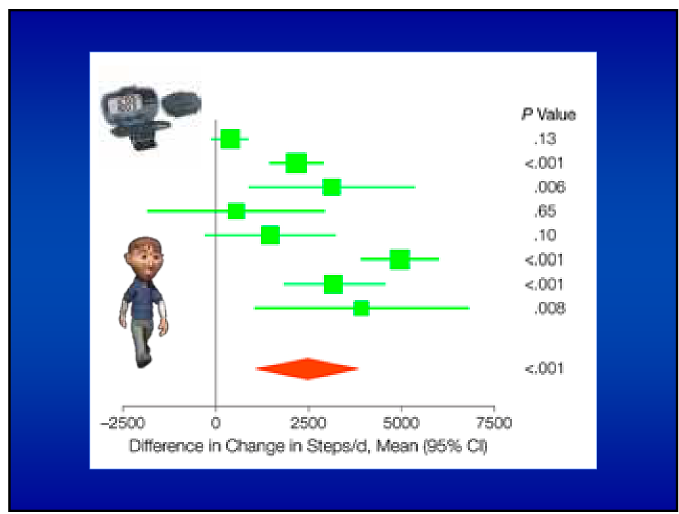

REVIEW

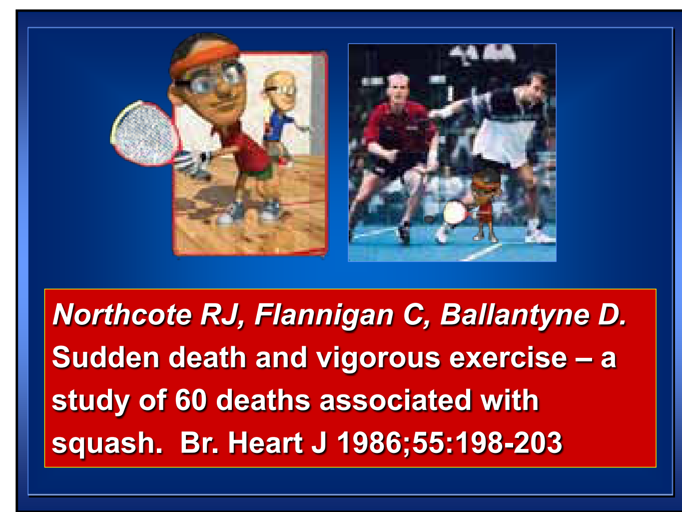
CLINICIAN'S CORNER

Using Pedometers to Increase Physical Activity and Improve Health

A Systematic Review

JAMA 2007;298(19):2296-2304



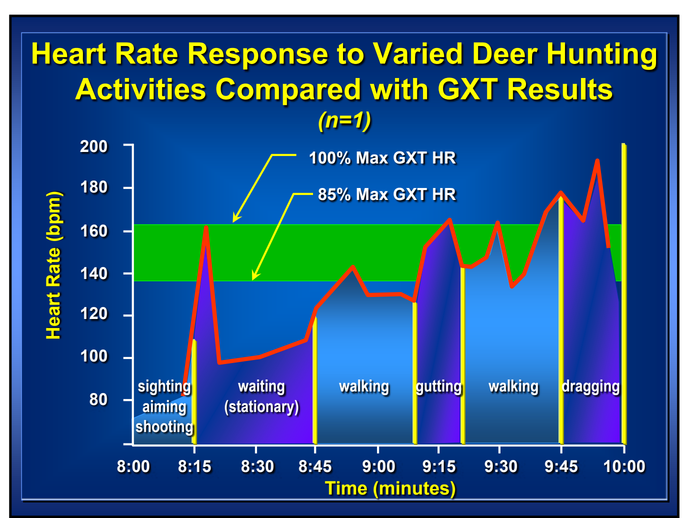


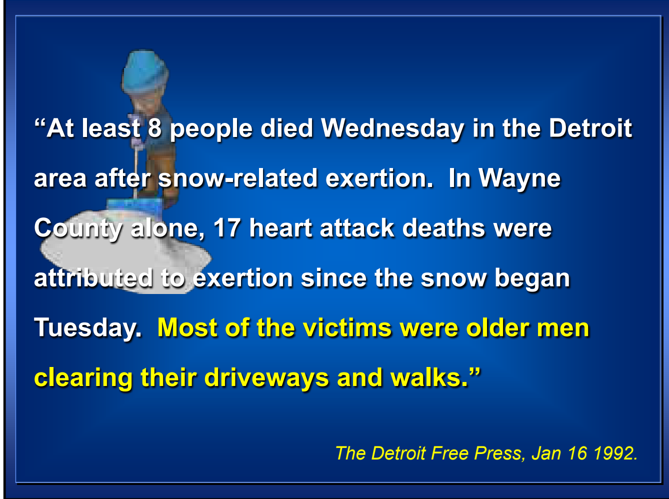
Electrocardiographic Responses to Deer Hunting Activities in Men With and Without Coronary Artery Disease

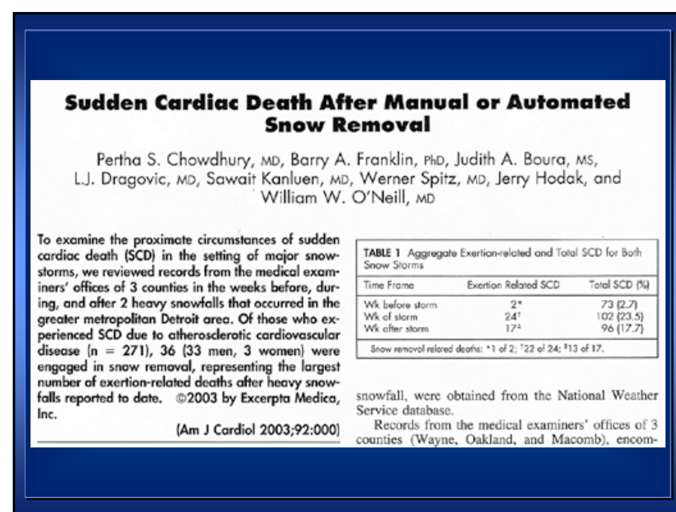
Susan Haapaniemi, MS, Barry A. Franklin, PhD*, James H. Wegner, BS, Shelby Hamar, MA, Seymour Gordon, MD, Gerald C. Timmis, MD, and William W. O'Neill, MD

To evaluate the cardiac demands of hunting deer, continuous ambulatory electrocardiograms were obtained in men with and without coronary artery disease (CAD) and compared with their responses to maximal treadmill testing. A volunteer sample of 25 middle-aged men (mean ± SD 55 ± 7 years of age), 17 of whom had known CAD, completed the study. Peak heart rate (HR) during 7 different deer hunting activities was expressed as the mean percentage of the maximal HR (HRmax) attained during treadmill testing. Periods of sustained sinus tachycardia were identified. Arrhythmias and ST-segment depression during deer hunting that were not apparent during treadmill testing were documented. Overall, 22 of 25 subjects demonstrated HR responses >85% HRmax for 1 to 65 minutes. Ten subjects exceeded the HRmax achieved during treadmill testing for 1 to 5 minutes. The relative HR response during ambulatory activity in the field was inversely related to cardiorespiratory fitness, expressed as METs ($r = -0.59$; $p = 0.0020$). Three subjects had ischemic electrocardiograms during deer hunting, but not during treadmill testing. Complex arrhythmias in the field not detected by treadmill testing included ventricular bi-trigeminy, ventricular couplets, and 8 runs of ventricular tachycardia (3 to 28 beats) in 3 subjects with documented CAD. In conclusion, deer hunting can evoke sustained HRs, ischemic ST-segment depression, and threatening ventricular arrhythmias in excess of those documented during maximal treadmill testing. The strenuous nature of deer hunting coupled with presumed hyperadrenergia and superimposed environmental stresses may contribute to the excessive cardiac demands associated with this activity. © 2007 Elsevier Inc. All rights reserved. (Am J Cardiol 2007;100:175–179)

Am J Cardiol 2007;100:175-179







Sudden Cardiac Death After Manual or Automated Snow Removal

Pertha S. Chowdhury, MD, Barry A. Franklin, PhD, Judith A. Boura, MS, L.J. Dragovic, MD, Sawait Kanluen, MD, Werner Spitz, MD, Jerry Hodak, and William W. O'Neill, MD

To examine the proximate circumstances of sudden cardiac death (SCD) in the setting of major snowstorms, we reviewed records from the medical examiners' offices of 3 counties in the weeks before, during, and after 2 heavy snowfalls that occurred in the greater metropolitan Detroit area. Of those who experienced SCD due to atherosclerotic cardiovascular disease (n = 271), 36 (33 men, 3 women) were engaged in snow removal, representing the largest number of exertion-related deaths after heavy snowfalls reported to date. ©2003 by Excerpta Medica, Inc.

(Am J Cardiol 2003;92:000)

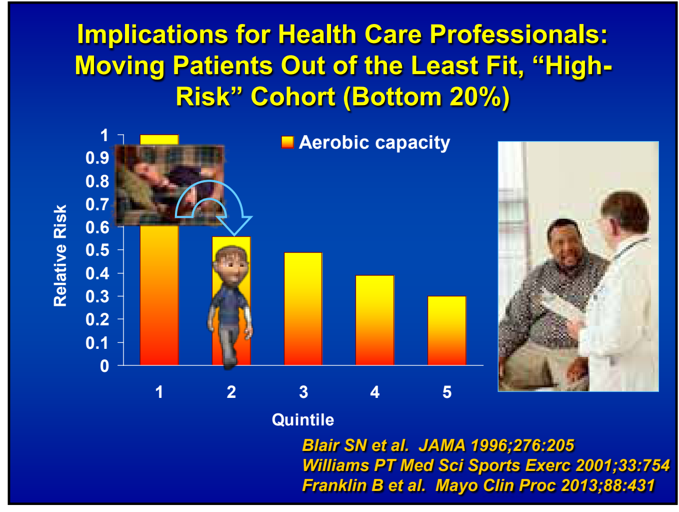
TABLE 1 Aggregate Exertion-related and Total SCD for Both Snow Storms

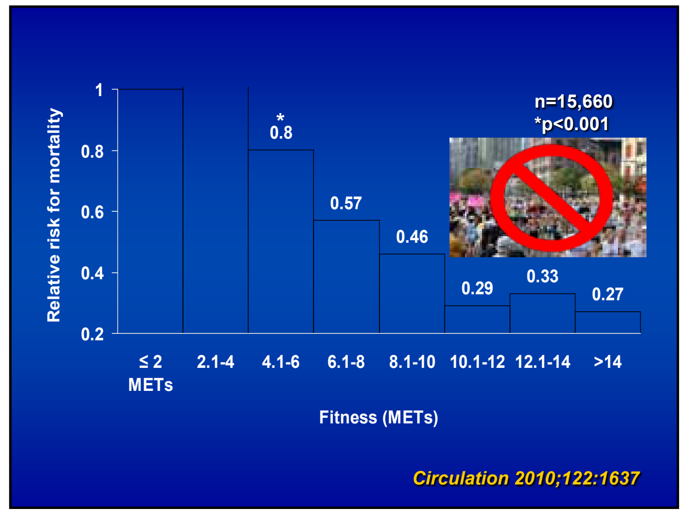
Time Frame	Exertion Related SCD	Total SCD (%)
Wk before storm	2*	73 (2.7)
Wk of storm	24†	102 (23.5)
Wk after storm	17‡	96 (17.7)

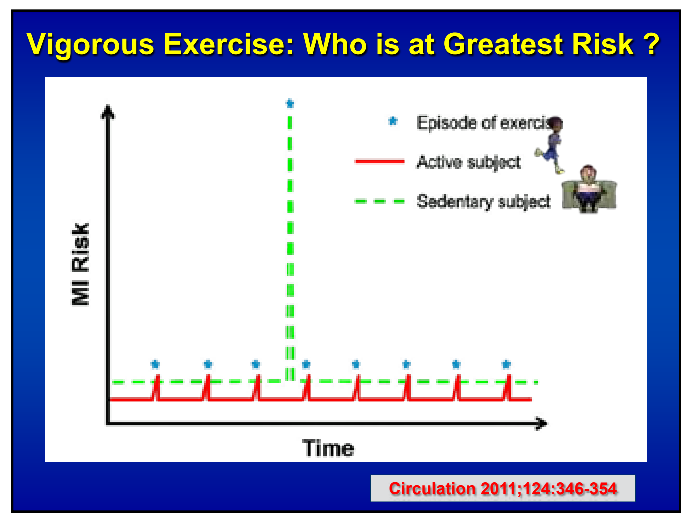
Snow removal related deaths: *1 of 2; †22 of 24; ‡13 of 17.

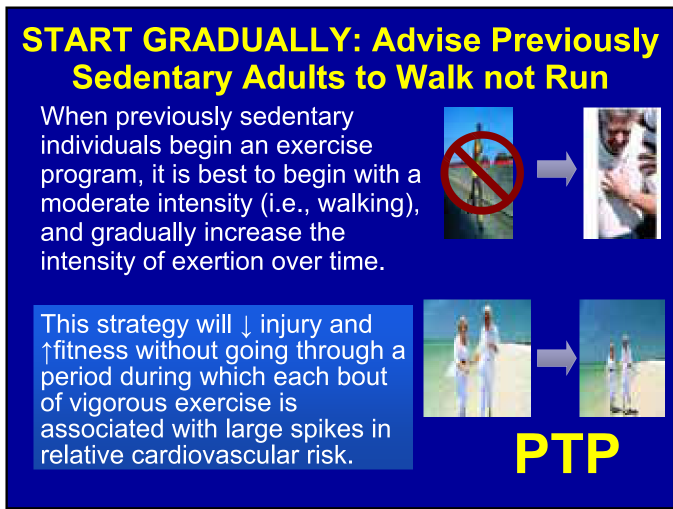
snowfall, were obtained from the National Weather Service database.

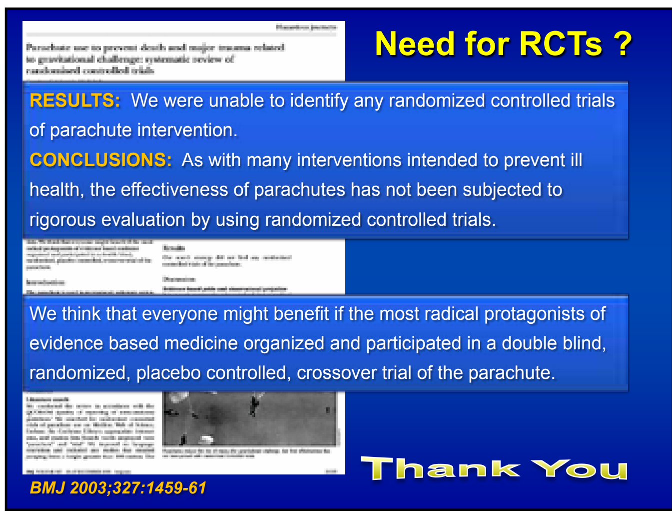
Records from the medical examiners' offices of 3 counties (Wayne, Oakland, and Macomb), encom-











SELF EVALUATION

The Anti-aging Benefits of Exercise and Cardiorespiratory Fitness

1. True/False - As a general rule, the physically trained 60-year old can achieve the same fitness level as the inactive 40-year old.

2. Between the ages of 20 and 70, individuals lose about _____% of their lean body tissue (muscle mass).
- a. 20
- b. 30
- c. 50
- d. 70

3. The Census Bureau projects that 41% of the women and 18% of the men who turn 50 this year will live to celebrate their ____th birthday.
- a. 70
- b. 80
- c. 90
- d. 100

4. True/False - A classic report on 700+ older men, involving a 12-year follow-up, found that the mortality rate among the men who walked less than 1 mile/day was nearly twice that among those who walked greater than 2 miles/day.

5. True/False - Pre-operative cardiorespiratory fitness has little or no relation to short-term complications (morbidity/mortality) after bariatric and cardiac surgery.

6. Older adults who wear pedometers to track their daily steps take, on average, _______ more steps each day than their counterparts who don't use these devices.
- a. 1000
- b. 1500
- c. 2500
- d. 10,000

7. The longest living populations in the world today, including Adventists, Sardinians, and Okinawans, share which of the lifestyle habits listed below?
- a. eat lots of fruits, vegetables, and whole grains
- b. keep socially isolated
- c. get at least 6 hours of sleep each night
- d. none of the above

8. True/False - Sarcopenia is associated with marked increases in muscular strength and endurance, along with associated hypertrophy.

Answer Key: 1. T, 2. B, 3. D, 4. T, 5. F, 6. C, 7. A, 8. F

Amy J. Cerruti

Amy J. Cerruti, of Boston, Massachusetts, is Vice President of Coding Services with MediRevv, a healthcare revenue cycle management company. She has over 20 years of experience in the industry with deep expertise in revenue cycle management. Prior to joining MediRevv, Ms. Cerruti served as Senior Vice President, Consulting & Management for the Advisory Board Company, a leading provider of insight-driven technology, research and services. She provides guidance to physician practices, academic medical centers, and community hospitals on professional fee revenue cycle, central business office, coding and clinical documentation compliance, ICD-10 project management, and patient access.

You may contact Ms. Cerruti with your questions or comments at (781) 635-7678, or by email at acerruti@medirevv.com.

Optimizing the Healthcare Practice Revenue Cycle
Amy J. Cerruti

Revenue Cycle Functions

- Front End
- Mid Cycle
- Back End

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Revenue Cycle Functions- Front End

- Scheduling
- Registration
- Eligibility Verification
- Referrals
- Pre-Authorization
- Payment expectations
- Time of Service Collections

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Revenue Cycle Functions- Mid Cycle

- Coding
- Charge Capture
- Pre-claim Edit Resolution

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Revenue Cycle Functions- Back End

- Claim Submission
- Payment Posting
- Accounts Receivable Follow Up
- Patient Collections
- Denials Management

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Revenue Cycle Success

- Dedicated revenue cycle leadership with span of control over the entire cycle
- Investment in staff
- Optimized information systems
- Reporting
- Physician engagement

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Physician Engagement

- Transparency
- EMR must support workflow
- Access to coders and coding education
- Feedback loop
- Participation in revenue cycle committee

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Patient Responsible Dollars

- **Old world was fairly straightforward:** Uninsured/Self-Pay, Bad Debt, Charity Care
- **New World in increasingly complex:** High Deductible Health Plans, HSAs, HRAs, & FSAs, Health Insurance Exchanges, Cost-sharing Subsidies, Uncovered Services, Patients electing not to utilize insurance

7

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Patient Responsible Dollars

- It is harder to collect these dollars
- Put strategies in place for pre-visit, time of service and post visit

8

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Strategies to Collect: Pre Visit

- Verify eligibility and screen for enrollment
- Set payment expectations
- Provide payment estimates
- Require deposits
- Hold a credit card
- Offer financing options/payment plans

9

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Strategies to Collect: Time of Service

- Verify information
- Collect co-payments
- Collect past-due balances
- Real-time claim adjudication

10

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Strategies to Collect: Post Visit

- Can be done in-house or outsourced
- Send statements
- Make it easy to pay with a variety of options including on line
- Screen for payment likelihood
- Focus outbound calls

11

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Monitor Performance

• Co-pays collected at TOS	>90%
• A/R over 90	<12%
• Gross days in A/R	<32
• Self Pay as % of A/R	<5%
• Bad debt as % of net revenue	<4%

12

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SELF EVALUATION

Optimizing the Healthcare Practice Revenue Cycle

1. True/False - Revenue cycle is the same thing as billing and collections.

2. True/False - Physician engagement is critical to revenue cycle success.

3. How can physician engagement in revenue cycle be fostered?

a. Having access to coders and coding education
b. Receiving reports on revenue cycle performance
c. Participating on revenue cycle committee
d. All of the Above

4. True/False - We should be collecting co-payments and past due balances at the time of service.

5. True/False - Patient responsible (or self-pay) dollars are typically harder to collect than third party dollars.

6. True/False - Patient responsible (or self-pay) dollars are decreasing.

7. Name 3 strategies to increase the likelihood of collecting patient responsible (self pay) dollars.

a. Set payment expectations in advance of the visit
b. Send statements and hope your patients pay
c. Hold credit cards on file
d. Offer financing options
e. a,c,d

Answer Key: 1. F, 2. T, 3. D, 4. T, 5. T, 6. F, 7. E

Ike Z. Devji, Esq.

Ike Z. Devji, Esq., of Phoenix, Arizona, has 13 years' experience devoted exclusively to asset protection and risk management for a national client base that includes over two thousand physicians and for whom he helps protect over $5 billion in personal assets. He has written over 200 nationally published articles that have been featured in a dozen plus medical journals and is a noted national CLE and CME provider for physicians and their financial and legal advisors. He is AVVO rated "10.0 Superb" for six years in a row, and he is included in *Arizona's Finest Lawyers* among other distinctions.

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Identifying Professional Risks and Insuring Against Them

What Exactly is "Asset Protection"?

Most of us implement some form of asset protection every day without thinking of it as such; we create LLC's for various enterprises, buy disability and car insurance, lock our doors, use our burglar alarms and change our account passwords, as just a few common examples.

This can understandably be a confusing term for consumers, especially given that it's currently a fashionable marketing phrase used by everyone from insurance and annuity salesmen to loss prevention specialists and, perhaps even worse, a wide variety of both lawyer and non-lawyer "promoters" advancing various legal and financial legal schemes of subjective value.

For our purposes here, the term "Asset Protection" refers to the holistic legal practice of proactively managing your assets, risk and liabilities, both personal and professional.

It's also at, the broadest level, a combination of four core disciplines that protect individuals and their assets from hostile attack, waste and spoilage. These include:

- Insurance (including liability, life, health, disability, etc.)
- Legal Tools
- Financial Planning
- Proper Tax Planning

TIMING IS EVERYTHING

It cannot be strongly enough emphasized that **prevention always beats treatment** with legal and financial exposures; **the best asset protection is always preventative and proactive.** Timing is crucial and of the essence; you may be legally unable to act, (fraudulent conveyance, voidable transaction, etc.) or at best, end up with results that are more expensive and less predictable if you wait and try to manage *crisis* instead of *risk*. Litigation is managing crisis, bankruptcy is managing crisis as just two examples. **Even the best asset protection strategies *will fail* against a known and preexisting exposure and create additional financial and legal risk up to the level of being *criminal*.**

4 Vital Questions About Protecting Your Wealth and Success

1. If you lost what you have today, or some significant portion of it, are you at an age, earning level and financial condition that will allow you to maintain your family's goals and expenses?

2. Have you consulted with qualified counsel to help identify and manage your personal and professional risks with the right kinds and amounts of insurance and legal tools??

3. Do you have assets that would be difficult or impossible to replace given your age, health and current economic conditions?

4. Are you financially and legally prepared for a lawsuit that is either uncovered by liability insurance or which often produces verdicts above the limit you are carrying?

How Is "Asset Protection" Different From "Estate Planning"?

Traditional Estate Planning is **"death planning"** that provides details and controls who gets your assets when you pass, how they are administered, who is appointed to manage your estate, and in many cases helps mitigate your estate tax exposure. This year, a married couple can pass roughly the first $10.8 Million dollars of their

estate (or roughly $5.4 million each) to anyone they like free of federal estate tax. There is no estate tax on assets passed between spouses. **ASSET PROTECTION** is **LIFE PLANNING**; how you can help ensure that you and your family get to keep the wealth **DURING** your life and that it will ultimately be there to go to your estate plan and protect your heirs at the end of your life as well. Most People omit a good **LIFE PLAN**.

SAYING "I ALREADY HAVE A TRUST" IS ONE OF THE MOST COMMON FINANCIALLY FATAL MISTAKES MADE BY DOCTORS

Many medical professionals mistakenly rely on their **REVOCABLE LIVING TRUST (RLT)** as Asset Protection. **IT ISN'T.** These individuals usually have their homes, investments and other valuables in the name of the RLT. **The RLT is ZERO Asset Protection of <u>your assets</u>, from <u>your creditors</u>, during <u>your life</u>**, as it is REVOCABLE – the court will simply order you to revoke and tender the assets. The RLT is a **great estate planning tool** and is a tool you probably should have, but it has a specific set of purposes and jobs to do for you.

Asset Protection Is a System of Layers

Think of asset protection they way you teach your clients about wellness; it's a **system and lifestyle** that requires some discipline and good habits in **four core areas**.

• **A culture of good habits, procedures, accountability and compliance,** starting with you. Avoiding or eliminating higher risk behavior often starts with having good, professionally drafted, legally compliant policies and procedures on a variety of risk management issues and consistently implementing and enforcing them uniformly. There is no more dangerous and ineffective manager than one who is conflict averse or who wants to be everyone's friend. Leadership requires that you help everyone be and do their best by managing them actively and creating expectations and boundaries.

• **Proactively managing all your predictable risks, not just those related to medial malpractice.** We won't dwell on this issue beyond this; medical malpractice lawsuits are a real threat and no matter what various experts tell you about statistics, how many actually go trial, and etc. we have seen the devastating first hand effects of these claims and the best way I can share my concern on this issue, no matter how remote a risk you feel it may be, is this; **what if it is you?** Are you emotionally, legally and financially prepared for a claim or judgment that could potentially stop your income, cost you your hospital privileges or practice, trigger a payor audit and take seven figures off your life's work and net worth? Most physicians are not.

• **Insurance, all the right kinds and in the right amount. Insurance needs to be thought of as an "insurance program", not a line item and works as a system of overlapping coverage.** Most physicians have an overly simplified vision of what they should have in place, mainly some form of professional liability insurance typically a "1-3" policy meaning $1MM per occurrence and $3MM aggregate. **As an attorney I advise physicians to buy, "Every dollar you can afford, then have a back-up plan."** This goes far beyond your professional liability or malpractice insurance and includes half a dozen or more varieties of specialty insurance that I've discussed before, and that can be well covered with the help of a top-notch property and casualty (P&C) insurance agent. **A word of caution, having an asset protection plan consisting of defensive legal tools in place without the complimentary insurance, commonly known as "going bare", is never the best idea and if nothing else, subjects you the exposure of massive legal fees for defense costs which are easily six figures.**

• **Defensive legal structures.** There will inevitably be gaps in the number of things that can be covered or the dollar limit to which you can insure yourself. Do not ever rely on your "umbrella" policy as effective universal coverage. This is where all the trusts, LLCs, partnerships, corporate structures and estate-planning techniques that we lawyers are so fond of come into play. You must have good policies and procedures, insurance against instances those fail and have a legal back up plan if the first two layers fail. Remember that asset protection is fact specific and use your facts. Every doctor seeking asset protection must have a thorough review of her own assets, have her personal and professional risks identified and have tools and solutions implemented by a qualified and experienced professional. **In other words, the familiar pattern of exam, diagnosis and then**

personalized treatment. There may be a reasonable and proven course of treatment for any particular problem, but your advisors should always know what the problems are **before** they start proposing specific solutions.

Below is my "Asset Protection Pyramid", as explained above, the first and largest layer of defense is behavioral and risk management related, the second layer is an insurance program that covers as many risks as possible and the last line of defense is comprised of well proven defensive legal structures that attorneys like myself add to the picture and ideally help you implement along with the first two layers. "Just" providing either legal services or selling insurance or consulting on a compliance program on their own are ineffective and in some cases may be malpractice. Make sure your planner is informed *about all these areas* and makes them part of your comprehensive plan. **If all they talk about is the specific trust, insurance, or service they sell, get better help.** It is the strength and redundancy of all three of these layers that creates an effective wealth preservation plan and you must have all three to have effective and predictable results.

What Does Asset Protection Achieve?

- Remove the economic incentive to sue, or aggressively pursue you
- Create an incentive to settle within limits of applicable liability coverage if there is real liability coverage if there is real settle within limits of applicable liability coverage if there is real settle within limits of applicable liability coverage if there is real settle within limits of applicable liability - MAKE THE INSURANCE WORK
- Make you largely uncollectible in the event of a lawsuit judgment
- Allow clients to own little but enjoy everything
- Legally separate personal and business assets and exposures
- Protect you from the internally generated liability of certain assets, like real estate
- Add additional surety and control to assets that will be distributed at your death by your estate

Which of these two is most likely to be pursued above and beyond the limits of their insurance coverage?

Which one has the greatest degree of predictability and greatest segregation of assets from personal and professional liabilities?

What Are The Risks You Need To Protect Yourself Against?

- The U.S. has the world's most litigious legal system, up to 70,000 lawsuits filed per day
- Cost of defending a frivolous lawsuit can exceed $91,000
- **A total of $3.6 billion was paid out for medical malpractice lawsuits in 2012,** and 48% of those payouts occurred in just five states, according to Diederich Healthcare's 2013 Medical Malpractice Payout Analysis.
- In 2012, there were a total of 12,142 medical malpractice payouts in the United States – accounting for **one about every 43 minutes**. The medical malpractice insurance company based its analysis on 2012 data from the U.S. Department of Health and Human Services' National Practitioner Data Bank.

All that said, another common mistake by doctors is failing to think beyond medical malpractice risk. As mentioned, as significant as I think this risk is for every doctor in America, it's not the only, or even the most predictable and recurring exposure you face. You are a physician, but you are also potentially an executive, a parent, a business owner, a compliance officer, a breadwinner, the driver of vehicle, the owner of a home and wear a variety of other hats you may not even think about. Having experienced help in properly identifying as many of these other, non-malpractice related risks as possible and addressing them proactively both personally and professionally is a key part of any defensive strategy. Here are some of the most common risk factors, and while this list is by no means complete, I'd guess the majority of people seeing this have more than half these risk factors.

RISK FACTORS OF THOSE NEEDING ASSET PROTECTION

- **They are high net-worth, high liability, or- they will be soon (i.e. new doctor, rookie athlete, new business owner)**
- They drive a vehicle and/or own a home
- **They are a board member, officer or director of a public or private business**
- They are a board member of a charitable, school private foundation or other board
- **They have assets that would be difficult to replace if lost or reduced**
- They have employees
- **They own their own business**
- They have professional liability
- **They own liability generating assets like investment real estate**
- They are highly visible locally or nationally and are perceived to hold substantial wealth
- **They have children, spouses and other extended family in their homes and driving their vehicles**
- They are selling a business and replacing recurring income with a single lump sum

Other Significant Threats To Your Wealth, It's Not Just About *Lawsuits*

- Current Economic Conditions
- Decreasing Compensation and Insurance Reimbursement Rates
- Increasingly Hostile Litigation System
- Stalled or Negative Investment Momentum
- Social and political environment hostile to wealth (subjective)
- Increasing Overhead and Liability Insurance Costs (payroll, healthcare, etc.)
- Decreases in Liability Insurance Protection due to large awards, consent to settle and defense inside the limits clauses in current coverage
- Increasing burdens of Income and Estate Taxes

Protect Your Greatest Asset, Your Ability To Earn – Disability Insurance (All 3 Kinds)

Don't fall for the trap of **"self insuring"** against risks – this really means "un-insured" – transfer the risk to someone else. Even the affluent must examine **disability** and **long term care insurance** – 40% of American bankruptcies are related to medical bills.

- **Is your family, lifestyle and overhead based on your income? How long could you go without it?**
- Don't take **BIG** risks to avoid *small* expenses
- Just because you are doctors does not mean that you can not get sick or hurt, just like everyone else

While most doctors are familiar with and hopefully have sufficient *personal disability insurance coverage* in place to offset any loss to their income due to illness or injury, **there are two other key areas of disability coverage that could seriously, if not fatally, affect your practice.**

1. Protecting Yourself Against the Loss of an Important Employee: Key Person *Disability* Insurance

Many practices have doctors, practice executives, and other employees key to significant revenue covered with "key-man" *life insurance* coverage that provides payment to help offset the economic effects of the loss of an employee (death). This insurance death benefit is meant to help cover temporary income loss and the costs or locating, recruiting, and training a suitable successor. The population at large is twice as likely to become disabled than they are to die by age 65. Despite these statistics and the fact that most physicians are already familiar with them, I find that many practices have failed to address either one of these exposures, with the key–man disability issue being most commonly overlooked.

Employees are among any practice's most valuable assets. Medical administrator duties are increasingly specialized and require a higher level of knowledge and compliance than ever before and when providers have greater patient contact and billing rates, the loss of more than just the doctor is a serious risk that needs to be addressed. As with the key man *life insurance* coverage mentioned above, the key-man disability component can help offset the significant investment required to replace important staff as well cash to offset the losses you may actually sustain if they are disabled. Practice owners and managers should consider some specific questions when considering which employees would be wise to insure this way:

- Would our patients leave the practice?
- Would business continuity be affected and would revenue and profitability be lost?
- Do other employees have the training, time or legal capacity to perform those responsibilities?
- Do you have the excess cash to cover the costs of locating, hiring or training a replacement?

2. Protecting Your Practice Against the Loss of Your Income Production With <u>Disability Overhead Expense Insurance</u>

What about the portion of the revenue you generate that stays in the practice and is vital in covering a variety of fixed recurring business overhead expenses? For the few medical practices that have vast amounts of reserve capital and/or owners that are willing and able to capitalize those expenses out of their personal savings, this isn't a significant issue. **The other 95 percent of you should consider this very carefully.**

In the best cases, the disability will be short term and you'll be able to return to your practice at full capacity with minimal loss of income. In other cases, where the disability is either longer term or permanent, the lack of this coverage could significantly have an effect on your personal assets and force the sale or dissolution of your practice at an unfavorable time or term, under severe financial pressure. I encourage practice owners and managers to do the math and consider this as part of their business plan.

Add Up These and Any Other Significant Recurring Costs

Rent, Utilities, Professional dues and license fees, Maintenance (including repairs, cleaning services, etc.)

Loan Payments, Taxes *(including real estate, property, payroll)*, Interest on business loans, Insurance premiums *(including liability, casualty, malpractice)*, Legal and professional fees *(including accounting, legal, billing, etc.)* Employee salaries and benefits.

The total is the exposure that must be considered in protecting your business and personal financial solvency. If you're uncomfortable with the exposure that either scenario above presents, the time to act is today, proactively

A Word About Protecting Your Practice Against Divorce

- Doctors of BOTH sexes don't get pre-nups because they fall victim to emotional blackmail. "If you really loved me you wouldn't ever ask me to sign it". THIS IS A LIE.
- The odds of a second marriage ending in divorce are over 60 percent and climb to 70 percent in a third marriage. Moreover you will have less time to earn, save, and rebuild wealth than you did the first time around in a substantially more demanding medical business climate.
- I routinely talk to doctors who have had years of high income and who amassed significant wealth but didn't investigate protecting it until they had already lost half or more of their hard earned net worth to a divorce. When I ask if they had a pre-nup the response is nearly always the same, in fact alarmingly identical, "We didn't have anything when we got married, we ended up successful and never thought it would happen to us…"

Protect Your Practice Against Your Automobile Accident Exposure

We see that MANY of our clients come to us with their car and their spouse's vehicle titled in the name of their business or the corporate entity that owns it. In most cases, this has been done at the suggestion of the CPA, who has correctly told the Doctor that this is a great way to get a tax deduction. **Unfortunately, if you, your spouse, child or anyone else who has your keys gets into an accident you have jeopardized the source of your income by making your practice the vehicle's owner and a party to the suit.**

Which of the following would you be most excited about suing if you were a personal injury attorney?

a. John Smith
b. Dr. Smith
c. Smith and Associates Medical Specialists Inc.

This one of several areas where a **personal liability umbrella policy** is vital. You should have a minimum of $1 Million in umbrella coverage on your home and automobile and that coverage should ideally include "UIM and UM" which stands for underinsured and uninsured motorist protection for you in case the person who hits you is underinsured or uninsured. It's also vital that you don't rely on your umbrella as a one step asset protection, it isn't. It covers some very specific risks, mainly issues related to your **home and autos only** and typically will not help you with any business related risks.

Keep your personal use vehicles in your personal name and insure them to the highest possible amount you can afford. If you want a tax benefit, discuss talking a car allowance form the practice your CPA instead of making the practice an owner of lessor.

OTHER COMMON RISKS

Employee Related Liability

- Most common and likely exposure
- You are 5 times more likely to be sued by an employee than for any other reason
- Average sexual harassment verdict is $530K
- EEOC website brags of 100's of millions of dollars collected EACH YEAR from people like you
- Suing more often winning more often, winning more money
- Many cases come down to a popularity contest
- Is there really such a thing as a jury of your peers?

Data Breach Exposure

- Penalties more onerous and expensive than ever and carry heavy statutory penalties and fines
- You are responsible for both healthcare and financial info like SS#'s and credit card info
- Hacking is an international business, they target people who have the most/best info
- Offices are more "connected" than ever, the liability extends to every tablet, smartphone, laptop and even your equipment like faxes, printers, scanners and etc.
- Beware of disposal issues and practices

RAC AUDITS – MEDICARE / MEDICAID AND OTHER THIRD PARTY PAYORS WANT THEIR MONEY BACK FROM YOU

- The govt. collected more than $1 Billion in refunds from doctors last year
- Auditors are paid on contingency of up to 12.5% of what they take back from you
- An audit could wipe out a small practice with audit and defense costs and the LABOR that may be called for
- They can request up to 400 files every 45 days
- This does not even mention the INCOME DISRUPTION
- This is a revenue retention exercise meant to fight fraud, but often "runs over" compliant practices

Executive Liability

- Most doctors forget they have not only the professional liability associated with delivering care, a.k.a. "Malpractice Liability" but also executive liability if they are a practice owner with some additional title as an "officer or director"
- This liability includes the usual CEO, director, president but also extends to CMO, CFO, CTO and even board members
- This liability extends to service on boards for outside businesses, charitable foundations and even religious institutions and can cover issues ranging from employment policies to accounting policies, business practices, administration of employee benefits like 401K plans and even hazardous materials disposal

Drug Based Treatment Liability

Medical specialties that use drug-based treatments administered by the physician's office as a routine part of their treatment regimes face some additional risks as well. This usage presents several expanding liability issues that require serious proactive risk management.

Using specialty-compounded drugs is increasingly common, one recent report says they account for a full 6 percent of medical-error claims, and so are the associated risks for medical practices. A recent case that made national headlines involved the unknowing use of infected epidural steroid compounds by pain management practices across the country. Over 200 patients across more than twelve states came suffered meningitis infection and a variety of other serious ailments with nearly 50 causalities.

Drug-injury lawsuit websites makes it clear that the administering doctor is part of the lawsuit chain in such circumstances. One website reads, in part, "The doctors who prescribed (or administered) the drug that injured

you may also be liable for your injuries because they are part of the chain of distribution of the drug." Having and enforcing a drug-quality policy regardless of whether you work in pain management, cardiology, or any other specialty is vital. Regardless of actual fault or causation lawsuits always seek deep, easy pockets like yours for redress.

Steps to Protect Your Patients and Practice

1. Have a written plan. Just as with HIPAA liability a key issue in attributing blame to a medical practice and its owners is whether or not they took any reasonable efforts to ensure quality and prevent harm.

2. Delegate responsible for enforcing it and implement at least one secondary check and failsafe.

3. Keep records of the quality assurance program and note each time you check the responsible party's work for compliance. Also maintain notes and examples of the correspondence and marketing between with your vendors. Common red flags for suspect drugs include billing from outside the United States, drugs that have been re-labeled or those labeled in foreign languages instead of or in addition to English, and prices that are substantially below the market rate.

4. Perform due diligence on your vendors. Check their licensing, look for lawsuits and complaints, and get specific representations in writing about the quality and source of any pharmaceuticals you personally administer in your office.

5. Review the informed-consent procedures you have in place in connection with such treatments. This area has been key in establishing liability for the doctors themselves.

Remember that many insurance programs you bill for treatment, including the use of drugs, require that all pharmaceuticals are sourced from licensed U.S. providers. If you use and bill for tainted drugs that do not meet these conditions you have both the risk of injury to the patient and the potential to face a Medicare fraud claim, another exceptionally onerous issue that will have to be litigated and defended separately if you think you can prove you were an "innocent purchaser".

Managing Premises Liability Risk

One common issue we see surprise medical professionals is the liability they face as the owners or operators of a physical facility that is open to the public. This issue extends beyond your office to your home and other investment real estate as well and is more common than you think.

How Great is The Risk?

Slip and fall accidents requiring medical treatment, as just one example of a premises liability, happen half a million times a year and account for some 1500 emergency visits a day. Such accidents are the leading cause of work related injuries and even deaths, causing an estimated 25,000 deaths a year and follow only auto accidents as the leading accidental cause of death in the U.S. Judgments for such injuries can be financially devastating and range from relatively small amounts to millions of dollars for death and permanent or disfiguring injuries.

Whose Injuries Are You Responsible For?

Pretty much everyone's, but to differing degrees and standards of care. Loosely paraphrased, if you created, knew or should have known of dangerous conditions and allowed them continue or failed to provide warnings, you may be on the hook. The law breaks the "duty of care" for property owners and operators down as follows, from highest to lowest liability:

Invitees are generally defined as those on the property by express or implied invitation for a business purpose.
Licensees or guests are persons on the property at the express or implied invitation for a social purpose. A higher degree of care is typically due to a child guest.

Trespassers are defined as persons on the property without actual or implied permission. A higher degree of care may be owed to trespassing children under the attractive nuisance doctrine.

Risk Management Issues To Address Today

Being proactive about maintenance and safety issues is vital, especially during months where water and ice pose additional and often unseen risks that arise over the course of a single day or less or cause even durable property like stairs, railings and sidewalks and parking lots to deteriorate. A good maintenance program including a record of what was done and when it was inspected is a good start and will help prove-up the fact that you make serious efforts to inspect and maintain the property for any safety related conditions. Both owners and tenants share this risk, so don't assume that you are off the hook if you lease a property, especially if the condition is in an area you limit access to or control completely. Likewise if you are property owner that leases to others, don't assume dangers the tenant creates will not flow up to you.

The first level of defense is as always a good liability insurance policy with limits that are adequate to cover the true scope of the liability as outlined above. I instruct my clients that $1 Million is the bare minimum in bodily injury a commercial insurance policy should cover and should ideally be higher and backed up by a higher limit umbrella policy.

Some Specific Examples: Are there dangerous conditions in your office or have you allowed patients or employees to create them?

* In a scene right out of Portlandia an elderly medial office patient was injured by the expensive bicycles of two patients who asked the front desk for permission to bring them inside because of fears that they'd be stolen. The senior citizen tripped over the bikes upon entering and injured his knee and had his cheek pierced by a section of the bike's break cable that barely missed his eye;

* Inattentive mother leaving doctor's office lets child run out from between parked cars and is child injured by vehicle driven by another patient. Doctor sued for contributory negligence in not having enough warnings and speed bumps in his very small parking lot;

* Tree branch falls on expensive, collector car in Doctor's parking lot on windy day. Doctor sued for diminution in value of auto due to the improper maintenance of landscaping on her property;

* Employee of medical practice moves warning signs and a bucket covering a hole in the floor that a contractor was working on then the same day, steps in hole, injures foot and sues her employer;

* We've seen a variety of lawsuits where very heavy people have also been injured by falling when a chair, bench or toilet broke under their weight. These lawsuits sometimes even include an emotional distress claim;

* Large flat screen TV installed in waiting area of high-end dentist office was accidentally pulled over by children toddler, falling on top of a toddler and injuring him severely.

As you can see from these examples, wherever possible liability is going to be attributed to the practice that is often seen as a more exciting "deep pocket" corporation than just another patient. It makes more financial sense to the lawyers (as one real example) to sue a doctor's office for not having enough signs and speed bumps in their parking lot than it does to sue the retired widow on a fixed income who hit a child in the parking lot.

Someone in the practice should be responsible for a variety of issues like cleaning crew schedules, waiting room construction and furniture selection, public access to electricity or electronics with electrocution risks, including medical devices that can cause harm, access to dangerous materials including biohazards, drugs and chemicals like cleaning products that may be stored in a bathroom cabinet (restaurants are famous for this unsafe practice) or other publicly accessible space as just a few specific examples. Considering outsourcing this, at least for an initial review of issues to correct or watch for. Professional safety inspectors can be hired to walk your facility

from the parking lot to the exam room and look for potential issues. I've also suggested clients walk through the entire facility as if they are childproofing it (another common issue) while making sure they wouldn't limit access by a handicapped person.

ADA Compliance Liability – Is your facility "Accessible"?

Properly addressing this issue covers basics like having the legally required handicapped-accessible parking and restrooms all the way through specific legal requirements for the construction of public spaces like entrances, thresholds, pathways, elevators, counters, even your practice signage. **Lawsuits on this issue have hit businesses across the United States and can be generated by people who are not even your patients when a scout spots a condition that is not ADA complaint as the basis for a lawsuit.** Specialists in ADA compliance are available in nearly every jurisdiction to inspect your facility and provide list of violations and the required corrective actions. What "fully abled" people take for granted surprises even physicians and there's a significant ROI from a risk management perspective as the relatively small costs of a compliance review are always less than the cost of responding to an ADA complaint or lawsuit. This is especially true given that fact that some states provided ADA plaintiffs punitive damages, attorney's fees and fines and on top of that your practice will still have to make the changes legally required.

Equipment Disposal Liability

Medical practices replacing obsolete computer and electronic equipment must safely and securely dispose of a variety of devices including:

- Networked printers, faxes, scanners, etc.
- Computer servers and arrays
- Devices that combines hardware and software for a specific function, medical or administrative
- Networking equipment
- Electronic data storage devices and backups
- Desktop and laptop computers, tablets and smartphones that have been used to access or relay protected data

Computers themselves were listed last and pose only the most obvious threat to the financial and HIPAA-protected information that every medical office in the United States stores and is legally responsible for. The partial list of other devices that store and transfer this data illustrates the true size of the exposure that practices must deal with. Just one example of just how onerous the a liability the equipment itself can be is that a printer can have thousands of patient's PPI and treatment data stored in its memory.

You Cant's Just Throw Them Away or Donate Them

You may donate and perhaps take a tax deduction for certain peripherals after determining if they pose a storage risk or not, (things like mice, keyboards, and monitors are the most basic examples), but the computers themselves and most other devices that transfer, copy, or store data present a serious exposure to your business. Your responsibility does not tend when it goes out the door. Regardless of whether the devices are going to be destroyed, donated, or recycled, it's vital that all data on them is permanently wiped out as a basic first step.

Drive-cleaner type software programs or those available at most office stores may already be part of your operating system or part of anti-virus programs. Remember that data on personal computers is not actually "erased" unless the hard drive itself is destroyed. In many cases a professional ID thief (or an average 12-year-old) will be able to retrieve the info from a computer that you think you "wiped" clean.

Five Simple Equipment Security Tips

These steps will help mitigate your practice's legal and financial exposures for the data, potentially encourage the use of the equipment by a worthy charity or individual and help your practice be greener.

1. Be proactive about equipment security. Far too often medical practices put old equipment into a storage closet that no one takes inventory on or responsibility for until there's problem;
2. Disconnect old machines, sign all users out of them and disconnect them from your network where they are often not maintained or updated and where they may actually create a security risk.
3. Make someone specific responsible for a specific written plan. Create a written chain of custody and inventory and educate the responsible party about the risks and gravity of the task at hand;
4. Have specific records of how many devices you have and are destroying or donating (make a copy for the CPA including depreciated value and replacement cost) and where they went or how they were disposed of.

Using Layers of Specialty Liability Insurance, A Few Common Examples

Risk Management With Liability Insurance, How Many Layers Are **You** Missing?

1. EPLI– Employee lawsuit exposure – external and internal
2. D&O – Director's and Officer's
3. Data Breach and Cyber Liability
4. Worker's Comp Insurance
5. Professional liability Insurance (i.e. malpractice, E&O, etc.)
6. RAC Audit Insurance
7. Personal liability Insurance with seven figure umbrella (home and auto)
8. Adequate general business loss and liability coverage

Directors and Officers Coverage: D&O

- Side A: For the individual director and officer
- Side B: For corporations and their balance sheets if they are contractually obligated to indemnify their directors and officers for a suit.
- Side C: For security claims

Exposures for Privately Owned Companies

- Outside advisers to management
- Domination by a small group of shareholders
- Limited time of commitment by directors
- Claims by third parties

- Alleged trade secrets were stolen
- Not delivering goods on time as told by the president of their company
- President and Vice President held liable for a corporation's illegal dumping

Employment Practices Liability Insurance – EPLI

- Protects management against suits from employees
- Discrimination
- Wrongful failure to promote
- Wrongful failure to employ
- Wrongful termination
- Sexual harassment
- Retaliation
- Defamation
- Invasion of privacy
- Fraud
- Negligence

CYBER LIABILITY OR DATA BREACH COVERAGE

- What is Cyber Liability?
    - – Started as a professional liability for companies that had hardware and software services.
    - – Today it has expanded to cover third party claims but has still maintained the same name.
  - **Same professional insurance coverage as when started**
  - **Privacy Liability**
    - **Covers loss of personal identifiable employee and customer information**
  - **Security Liability**
    - **Covers failure to prevent hacker or viruses**
- **– Website Media Liability**
    - **Covers libel, slander, and copyright infringement from your website content**
    - **First Party Cyber Extortion**
    - **Covers expenses to respond to a threat to harm or release your data as well as cover ransom payments if necessary.**

First Party Privacy Breach Response

- Customer notification expense
- Credit monitoring expense
- Computer and legal forensic Expense
- Credit and identity repair expanse
- First Party Business Interruption and Data Recovery Extra Expense
- Regulatory Defense and Penalty

RAC AUDIT INSURANCE is for ANYONE that bills insurance

Who do RAC Audits Affect?

- Almost any healthcare provider (including hospitals, doctor's offices, home health care providers, nursing home, or anyone else who submits bills to government programs such as Medicaid or Medicare) should prepare to be audited at some point.

What are the Risks and Burdens of a RAC Audit?

- The auditors themselves work on a contingency fee basis and the five regional firms contracted by the government are paid up to 12.5% of all claims they successfully identify as invalid and which they collect. The burden this places on healthcare providers from both a resource, financial liability and record keeping standpoint is significant, they can go back as far a three years and the maximum number of requests per 45 days is 400.

A good policy may also cover expensive related exposures like:

- Medicare & Medicaid Audit (RAC Audit)
- Commercial Payor Audits
- STARK Violations
- HIPPA Compliance
- EMTALA Violations

As you can see, managing your professional risks is process that involves several professional disciplines and significant act specific analysis. Use this as starting point for your own discussions and self-exam. As always, nothing in a general presentation meant to address the only the most common and predictably recurring exposures is a substitute for legal advice from an experienced professional. AEI students should, as always, feel free to contact me with additional questions or for professional resources.

SELF EVALUATION

Identifying Professional Risks and Insuring Against Them

1. Your estate plan or revocable living trust protects your assets, during your life time, against which of the following?

a. Claims against me and my family for something that happens at our home
b. Professional liability, malpractice and other business related claims only
c. Claims against me caused by an auto accident
d. None of the above
e. All of the above
f. Claims by creditors and disgruntled heirs against my estate and trust property

2. An “umbrella policy” can help protect you against which of the following? Pick all that apply.

a. Claims involving my personal autos
b. Claims outside the scope of my malpractice liability like an employment lawsuit, or a slip and fall at my office
c. Actions of my family members like children and spouses

3. You are both personally and professionally liable for which of the following issues at your facility?

a. Theft and break-ins targeting drugs and equipment
b. Exposures and personal safety issues to patients and staff caused by third parties
c. ADA accessibility compliance
d. Dangerous conditions on the property that could lead to personal injury or property damage
e. Administering drugs during in-office treatment that you bought from a 3rd party distributor
f. All of the above

4. Which of the following are vital to an asset protection plan?

a. Insurance
b. Compliance and Management Skills
c. Legal Structures
d. All of the above
e. None of the above

5. Which of the following business equipment items can be safely donated or thrown away when broken or obsolete?

a. Printers
b. Scanners
c. Faxes
d. Laptops, Smartphones, Data Storage devices and backups
e. Servers
f. Monitors, mice, keyboards and other access devices

6. Which of the following exposures can you insure yourself against?

a. A disability that affects my personal, take-home income
b. The disability of an employee or partner that is a key revenue generator to my practice
c. The inability to pay all of my business operating expenses in the event of a disability
d. All of the above
e. A and B only

7. Having your personal use vehicle owned or leased by your practice is a great way to protect yourself from car accident liability because the corporation protects you.

a. True
b. False

Answer Key: 1. D, 2. A, C, 3. F, 4. D, 5. F, 6. D, 7. False

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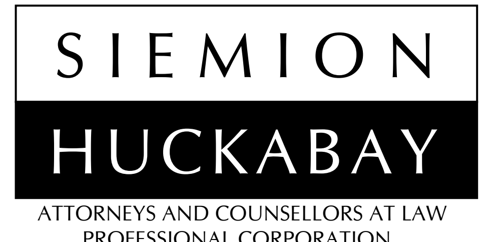

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Winning *before* Trial: The Role of the Expert and Defendant Physician Witness

Robert P. Siemion, Esq.

Prologue

This presentation will discuss the critical importance of expert testimony, both by retained experts and testimony of the defendant physician. All of the following material is generally applicable to both a retained or hired expert and the defendant physician who is also considered an expert.

Expert opinion guides the defense and usually determines whether a case will be resolved or defended.

Expert opinions must be analyzed and decisions made. Many cases are defended through trial even though some experts could not support the defense.

A. IF THE COURT DETERMINES THAT A SIGNIFICANT, TECHNICAL OR OTHER SPECIALIZED KNOWLEDGE WILL ASSIST THE TRIER OF FACT TO UNDERSTAND THE EVIDENCE OR TO DETERMINE A FACT IN ISSUE, A WITNESS QUALIFIED AS AN EXPERT BY KNOWLEDGE, SKILL, EXPERIENCE, TRAINING OR EDUCATION MAY TESTIFY

1. What is the role of an expert in a medical malpractice lawsuit?

2. Why are experts basically required in medical malpractice litigation?

3. What if a party has no expert witness?

4. The “Daubert” doctrine and recent requirements regarding expert testimony (no longer can just say that the opinion is based on “my experience and training”).

B. DISQUALIFICATION OF EXPERT BY COURT

C. VARIOUS TYPES OF EXPERTS

1. Subsequent treater “expert.”

2. Confidential consult expert.

3. Retained expert expected to testify regarding the applicable standard of care.

4. Court appointed expert.

5. Expert on issue of proximate causation not standard of care.

6. “Independent” medical exam expert.

7. Retained expert for patient who examines patient/plaintiff before trial testimony (Expert examining witness who gives opinion in writing regarding patient’s condition, and bolsters their credibility by

having actually examined the patient/plaintiff).

8. Life expectancy expert (usually involves analysis of comorbidities of patient).

D. DO YOU HAVE AN "OBLIGATION" TO ACT AS AN EXPERT MEDICAL WITNESS? (HOW WOULD YOU FEEL IF EXCELLENT PRACTITIONERS IN YOUR SPECIALTY WERE TOO BUSY TO HELP YOU?)

E. LEGAL REQUIREMENTS FOR THE MEDICAL EXPERT WITNESS

1. Generally, in most states the expert testifying as to standard of care must be in the same speciality (no longer "similar speciality"). The witness must be licensed and spend the majority of their professional time in the active clinical practice or teaching of the particular medical specialty in the year preceding the incident.

F. WHAT THE DEFENSE ATTORNEY EXPECTS FROM THE MEDICAL EXPERT WITNESS AND THE DEFENDANT PHYSICIAN

1. The expert witness must have a complete and intimate knowledge of all significant facts of the case. There are no exceptions to this rule. Being factually unprepared is a prescription for disaster.

   a. Obviously you must be totally proficient and a competent expert regarding the particular medical issue or issues involved in the litigation.

2. You should have a clear understanding of what is expected with regard to testimony. If you agree to testify you should make every effort to be reasonably available for a courtroom appearance, which is far more effective than videotape or having your testimony read to a jury. If you will not come to court and will only agree to a deposition on your terms, make that clear to the retaining attorney who may wish to go elsewhere.

3. The expert witness should promptly submit a fee schedule or data regarding billing. Unless there has been a prior relationship with the retaining attorney, the expert witness should require a reasonable retainer.

4. The expert witness should have a clear understanding of exactly what the retaining attorney expects. Standard of care and/or proximate causation and/or damages and/or life expectancy and/or cause of death? This should be clearly defined before commencing a review.

5. The expert witness should be reasonably available for conferences and, more importantly, respect the fact that the legal system many times does not give the retaining attorney much leeway as far as scheduling. The expert witness should literally be ready to "drop everything" to give a trial deposition or appear in court. This includes canceling patients. Deposition trial testimony read to a jury or given via videotape is far less effective than "live" expert testimony.

6. The expert witness should never attempt to offer opinions outside their area of expertise.

7. The expert witness should consider and discuss the opposing sides' view of the case and the opinion of their experts.

8. The expert witness, when testifying, should never lose their temper and become sarcastic, overly argumentative or bitter.

9. The expert witness should reveal to the retaining attorney any important prior testimony, affidavits, speeches or publications, job assignments or lawsuits even if they appear remotely relevant (as far as can be remembered).

10. The expert witness should attempt to provide the retaining attorney with incisive cross examination questions to be used on the opposing expert. In most situations, the defense expert has the terrific advantage of reading the discovery deposition of the plaintiff's expert before the defense expert testifies.

11. Never lie. An expert witness has a legal, moral and ethical obligation to tell the truth and remember you are testifying under oath. There is always the slight possibility of criminal prosecution for perjury or civil suits for negligence or revocation or suspension of a professional license. There are also board certification organizations that review transcripts and take a dim view of unusual, bizarre or inaccurate positions taken by an expert witness.

12. Learn how to handle the cross examining attorney. Example "this is a matter of judgment;" "Not necessarily;" Could you please repeat the question?"

13. <u>If the expert witness has agreed to give a particular opinion, he/she should stick to the opinion</u>.

14. The expert witness should not prepare a written report unless one is requested.

15. The expert witness should not speak to the defendant during the time they are retained as the defendant's expert, nor should you make any effort to contact the plaintiff, the witnesses, or plaintiff's attorney. If you are contacted by the attorney from the other side, do not speak to the attorney and call the attorney who has retained you.

16. The expert witness should have an accurate, complete "non-boastful" curriculum vitae or resume which could be impressive to a lay person on a jury. Cover only academic and medical and some personal issues only, do not put anything in your CV about testimonial clients or experience.

G. IMPORTANT POINTS FOR GIVING TESTIMONY FOR THE DEFENDANT PHYSICIAN, A PHYSICIAN ACTING AS A FACTUAL WITNESS, AND FOR A PHYSICIAN TESTIFYING AS A RETAINED EXPERT WITNESS

1. Thoroughly review all aspects of the case, including legal documents, before giving testimony. You will be expected to know every detail.

2. Respond slowly in order to give yourself a chance to think carefully.

3. Answer only the question asked – no more, no less.

4. Avoid absolute or superlative words like, “I never,” or “I always.”

5. Do not let opposing counsel put words in your mouth. Force the attorney to restate the question if it is more of an argument and not a pure question, or restate the question yourself.

6. If you are being cross-examined, you will be given a series of “leading questions.” Listen carefully to what is contained within the question.

7. Listen to your attorney’s objections. He may be giving you a message as to how to answer.

8. You should strive to be relaxed, calm, cool and friendly and, above all, be an effective teacher. Try to use simple analogies and do not be afraid to give a short “mini lecture” if it will help. Speak at the level of an intelligent 16-year-old, but do not underestimate the intelligence of the jurors. Keep in mind, the people who will decide the case have no background in your field; try to keep it simple.

9. Dress conservatively; do not wear expensive jewelry. Look at both the questioner and to the jury as you give your answer.

10. Do not have an active cell phone or beeper during your deposition testimony or trial appearance.

11. Do not be afraid to indicate that you have testified in the past and that you are charging for your time. Jurors are never shocked by this since both sides generally pay the same amount to their experts. (If you testify in federal court you will probably be required to prepare a written list of cases where you have acted as an expert and how much you have charged.)

12. Do not engage in any clever joking or cynical remarks directed at the other side or the cross-examining attorney.

13. Be professional at all times. You are not being paid for your sense of humor or to mock the other side.

14. If you cannot come to court and must give a deposition instead, it should not be in your office or the hospital where you are on staff. It should be at a neutral location or the retaining attorney’s office where you will not be disturbed or interrupted.

15. Do not volunteer anything when undergoing direct or cross examination. The retaining attorney will bring out what they feel is necessary during direct, and if something important should be brought out on redirect, they will certainly cover it.

16. Beware of the “learned treatise.” In many state courts you can be impeached by what is contained in a published treatise, periodical, textbook, or journal to the extent that the document has been established as a reliable authority. Do not declare any treatise, periodical, or journal as being “authoritative” or “reliable” unless you are willing to agree with everything therein contained.

17. Remember, deposition transcripts will “follow you.” Be consistent.

18. Readily admit that you have discussed your testimony with one lawyer or more than one lawyer and that you may have done so on numerous occasions. This is totally expected and it can only hurt your position if you try to minimize contact with the retaining attorney.

19. If there is any way you can use a "demonstrative aid" (i.e. an anatomical chart, or list, or using a chalk and blackboard), this is very effective in front of a jury and gives you the mantle of a very qualified teacher.

20. If you are called as part of the defense case, you should have a clear understanding of what occurred during the plaintiff's case and if there have been any new issues raised or any previous issues totally removed from the case. You should have a complete and clear understanding of the opposing expert's testimony.

H. COMMON MISTAKES MADE BY PHYSICIANS

Common Mistakes Made by Physicians **Prior to Suit**:

1. Not recognizing significance of preparing report to third party (which can haunt you later).

2. A report helping a patient obtain disability or Social Security benefits may be used to amplify damages against you if the patient brings suit.

3. Failing to follow recommendations of consultants.

4. Failing to obtain prior or concurrent medical records (review EKG's in prior records).

5. Failing to keep accurate record of prescriptions, failing to photostat prescriptions and document refills. It is generally a bad idea to continually allow phone refills without seeing the patient.

6. Committing to a plan in the chart, and then failing to follow charted plan.

7. Failing to refer.

8. Having no system to follow up on screening tests for repeat patients, i.e., pap smears, mammography, prostate testing, imaging study reports.

9. Losing records; Have proof of reason for absence.

10. Failing to make addition to records in the proper manner, deceptive alterations can be a felony.

11. Photostating copy of chart for patient or third party and changing it later.

12. Failing to document refusal of patient to follow medical advice. Have patient sign the chart! (Quote patient, even profanity.)

13. Write legibly.

14. Never turn over your original chart, except to counsel under special circumstances.

15. Be very, very hesitant to capitulate to patient's unreasonable demands which are against your better judgment. Sometimes trying to please a patient can make your more vulnerable to a malpractice claim.

Common Mistakes Made by the Physician **as a Defendant**:

1. Failing to prepare adequately for deposition or trial. Preparation, preparation, preparation. Preparation should begin with a comprehensive meeting with your attorney. Complete knowledge of the facts is essential. If the attorney cross-examining you knows the facts better than you, your deposition will most likely be a disaster. The physician should approach their deposition knowing that it is sworn testimony that can be read to the jury instead of the physician being put on the witness stand.

2. Volunteering too much during deposition, i.e., literature search or quoting colleagues. Just answer the question posed, nothing more. If an important point should be brought out, your attorney will ask you at the end of plaintiff attorney's cross-examination.

3. Losing temper or becoming sarcastic or angry during a deposition. Let your attorney handle opposing counsel, if that is necessary.

4. Having deposition late in day and becoming fatigued. Do not be afraid to ask for a break during your deposition. It allows you to collect your thoughts and also consult with your attorney. Try to schedule your deposition to take place in the morning when you are sharp.

5. Being constantly paged or interrupted during deposition.

6. Having the deposition in your own office rather than at the attorney's office. The plaintiff attorney can see textbooks, pamphlets and things that could lead to further questions. You also will most likely be interrupted by your staff.

7. Giving inaccurate testimony regarding number of times taking board certification tests, licensing issues, staff privilege issues; do not give incorrect testimony.

8. Contacting plaintiff-patient after patient has attorney.

9. Not being totally familiar with the medical issues involved in the litigation. Not being completely familiar with the facts of the case. The lawyer cross-examining you will be prepared.

10. Filing your attorney's correspondence with patient records. Unsophisticated office personnel, in response to a records subpoena, could send your chart and your attorney's privileged thoughts on to other attorneys in the case. This has happened. The chart of a patient litigation should be separate from all other charts and locked away in a secure location.

11. Making flippant, disparaging, or politically incorrect remarks. Some women are offended by being referred to as "girls." (Example: the comment was made by a defendant physician at the end of a long and tiring deposition, "Not every drunk deserves a CT scan!")

12. Making sudden volunteered statements "out of the blue." In a recent trial, a defendant decided to tell the jury that he had performed 40,000 of the procedures in question. It is unknown if the jury would be impressed with the experience, or wonder if the surgeon ever turns down any surgical candidates. Statements like that should be discussed with counsel before testifying, and if it is important data your attorney will bring it out during direct examination.

13. Failing to recognize the importance of your deposition as a defendant. (The deposition cannot be approached as an inconvenience that must be squeezed into an already busy schedule. The

deposition can make or break the defense of your case.) YOUR DEPOSITION COULD BE YOUR TRIAL TESTIMONY.

I. PET PEEVES OF EXPERIENCED MEDICAL MALPRACTICE DEFENSE ATTORNEYS AND INSURANCE CLAIMS EXAMINERS

1. Physicians who do not read correspondence from counsel and are not very helpful in preparing defense of case. Good physicians send their attorneys multiple-page letters explaining the issues in the case and why they believe the case is defensible.

2. Not sending all of the records to defense counsel or insurance carrier. Do not delegate this important task to employees at the low end of the totem pole. The same goes for requesting, receiving, and sending charts to other physicians.

3. Attempting to add or alter medical records. There is an appropriate method to add to the chart. Changing the chart with the intent to deceive can be a crime. There are many scientific methods available to determine that a chart has been altered.

4. Failing to properly prepare for meetings and deposition. Prepare, prepare, prepare – know the facts and the medicine.

5. Not being available or not allotting enough time for meetings with defense attorney.

6. Not understanding that most meetings that last an extended period of time should be in the attorney's office allowing for privacy and limiting interruptions by the physician's employees.

7. Not attending the deposition of the expert against the defendant physician, even if it requires an out-of-town trip. Insurance carriers will pay the expenses for the physician to attend, which will be of great help to the defense attorney.

8. Not attending the deposition of a plaintiff if recommended by the defense attorney.

9. Not understanding that the medical records are EVIDENCE. They are usually the only exhibits in a trial.

10. Expressing angry, sarcasm, or cynicism with your defense attorney or insurance representative. You should work together as a team even if you do not like attorneys. When testifying, you should come across as an intelligent, humble person who was trying to do the best they could for their patient.

July ___, 2016

(Patient's Name)
(Patient's Address)

Dear (Patient):

This letter is being sent to you out of concern. You did not show for your followup appointment scheduled on (_____ date). When we contacted you to reschedule, you stated that the level of service provided was good, but you did not want to return to the office for care and you requested that we cancel any future appointments.

Please be advised that I will no longer be able to treat you as a patient. The termination of our physician-patient relationship will be effective in 30 days from the date of this letter. I will remain available to provide medical services to you, on an emergency basis only, until _____ (date), while you have the opportunity to arrange for another physician to assume your care. Your medical condition is very critical, requires immediate attention, and requires close continuous physician supervision. (Or, it is important that you continue a physician-patient relationship for your medical problems and that you select another physician as soon as possible.)

Other physicians that may help you could be available at:

(Name of Institution or Physician), phone number: (____________)
(Name of Institution or Physician), phone number: (____________)

or you may contact your insurance plan for names of other physicians.

Upon written authorization, I will provide a copy of your medical record to your new physician. A release form is enclosed to expedite the process. Any delay could jeopardize your health, so I urge you to act promptly.

Sincerely,

(Physician's Name)

Sent via: Certified Mail
Regular U.S. Mail

SELF EVALUATION

Winning *before* Trial: The Role of the Expert and Defendant Physician Witness

True/False

1. If you plan to make yourself available as an expert witness, you can give expert testimony on the standard of care in cases both within and outside of your specialty.

2. You do not need to spend excessive amounts of time becoming familiar with the facts of the case since your defense attorney will fill in the blanks.

3. There have been malpractice cases where experts who have testified have been restricted or censured by their certification board.

4. Your trial testimony, should the case be tried, is far more important than your pretrial discovery deposition.

5. Those who attend an American Educational Institute seminar find the seminars most informative and very helpful.

6. When you accept records from a previous physician, you are not obligated to review the record and know all of the important data in the chart.

7. A physician may not terminate the physician-patient relationship without the express written consent of the patient who is being discharged.

Answer Key: 1. F, 2. F, 3. T, 4. F, 5. T, 6. F, 7. F

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HIV/AIDS Update

HIV in the United States

1. More than 1.2 million people in the United States now have HIV
2. Approximately 12-46% infected are unaware of their HIV status.
3. Incidence of new cases is 40,000/year with approximately 20,000 deaths per year

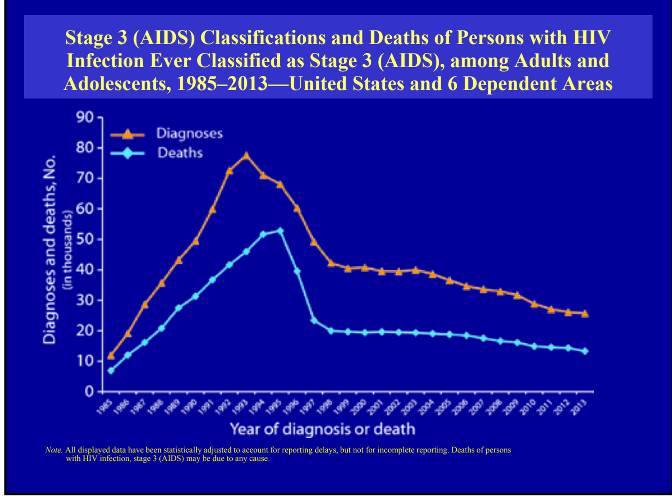
Lifetime Risk of HIV Diagnosis CDC 2016

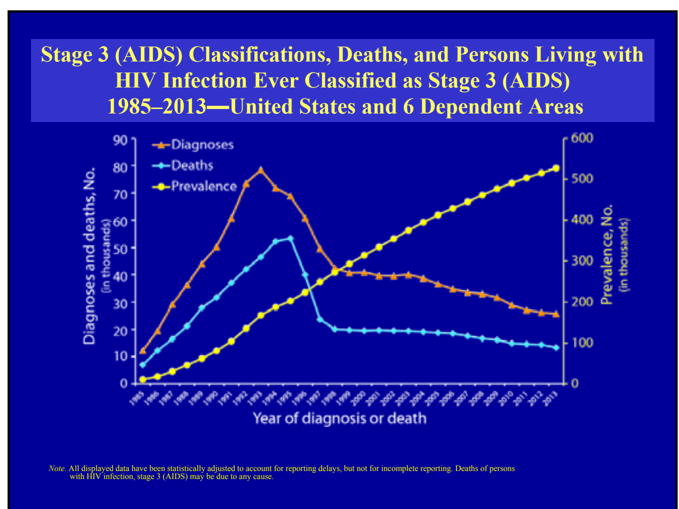
Lifetime risk of HIV diagnosis in the US is now 1 in 99

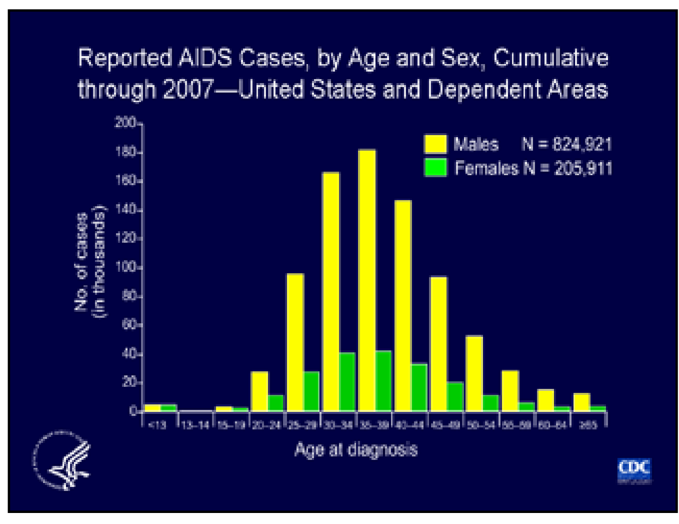
Gay/bisexual men 1 in 6 MSM

Black MSM in 1 in 2, Latino MSM 1 in 4

Women IDU 1 in 23, Men IDU 1 in 36







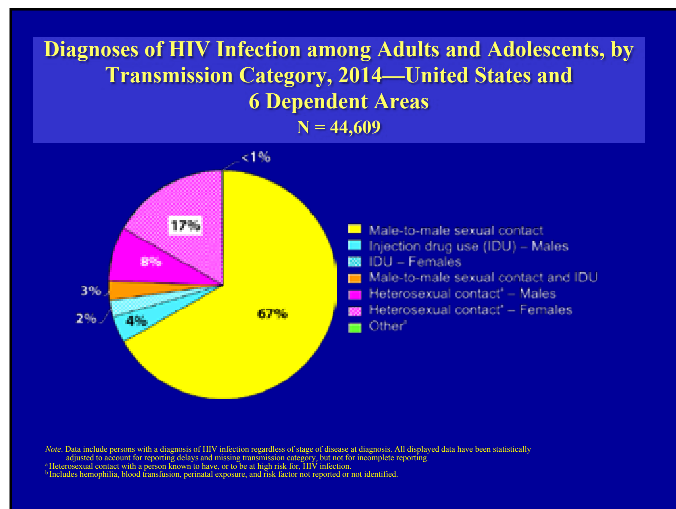
Transmission

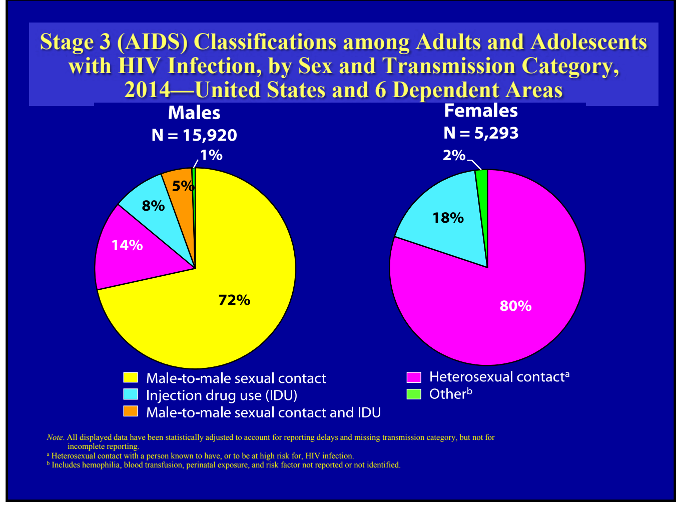
- Sexual transmission
- Blood and blood products
- Maternal-fetal/infant transmission

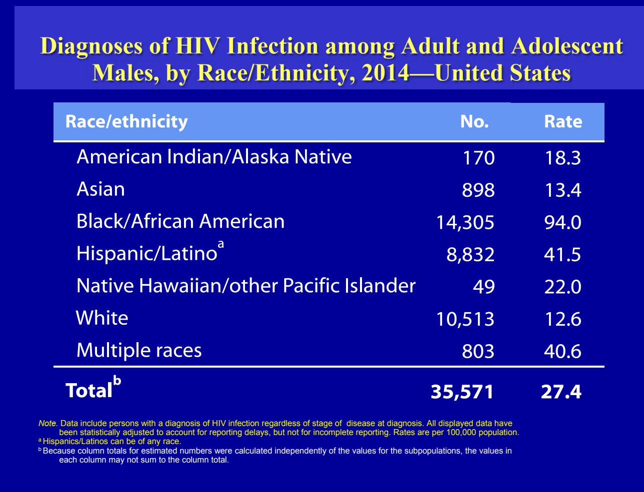
The risk is increased with viral load, lack of circumcision, genital ulcers, and host and genetic factors.

HIV-1 Transmission Risks Vary by Route of Infection

- Heterosexual
  - Female genital tract – 1 in 200 – 1 in 2000
  - Male genital tract – 1 in 700 – 1 in 300
- MSM
  - Intrarectal – 1 in 20 – 1 in 300
- MTC
  - Intra-partum/breast milk – 1 in 5 – 1 in 10
  - Intra-uterine – 1 in 10 – 1 in 20
- IDU
  - Intravenous – 95 in 100 – 1 in 150



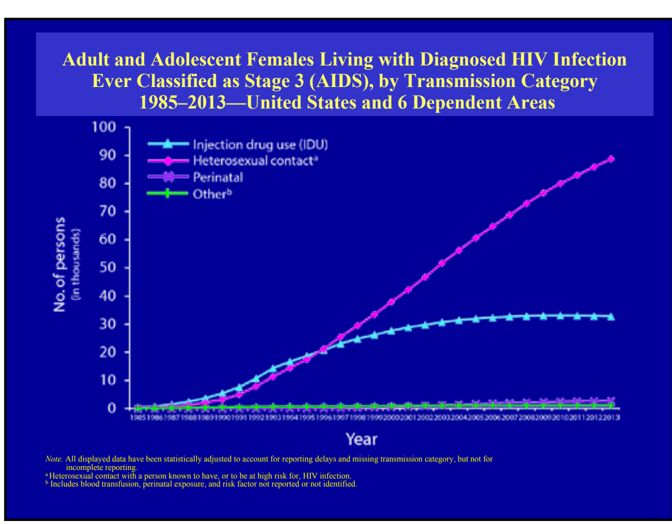


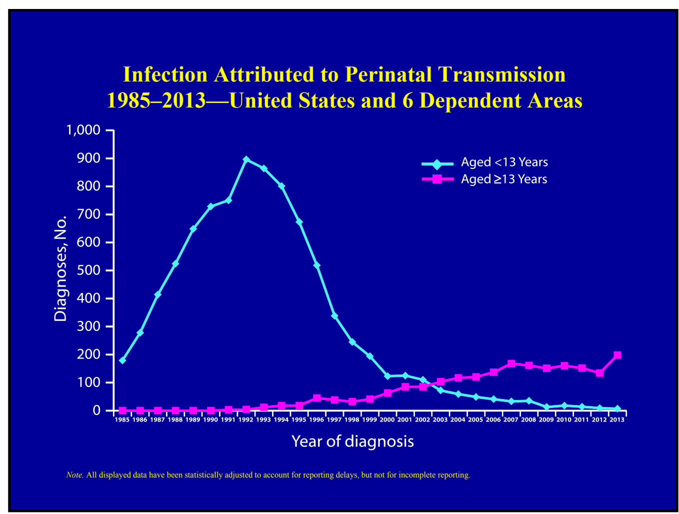


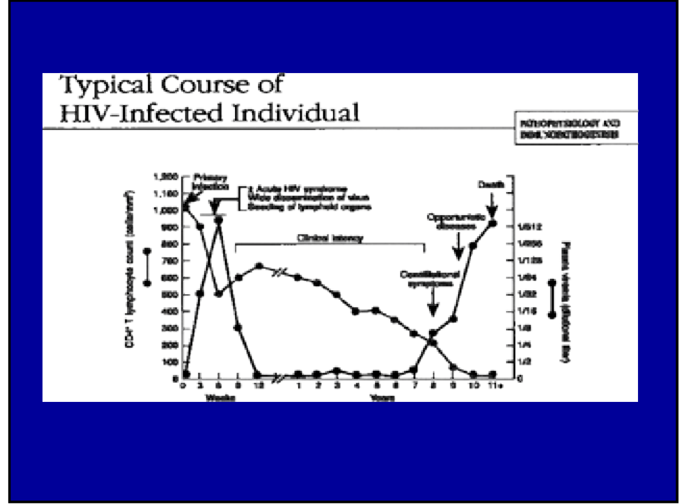
Diagnoses of HIV Infection among Adult and Adolescent Males, by Race/Ethnicity, 2014—United States

Race/ethnicity	No.	Rate
American Indian/Alaska Native	170	18.3
Asian	898	13.4
Black/African American	14,305	94.0
Hispanic/Latino[a]	8,832	41.5
Native Hawaiian/other Pacific Islander	49	22.0
White	10,513	12.6
Multiple races	803	40.6
Total[b]	**35,571**	**27.4**

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting. Rates are per 100,000 population.
[a] Hispanics/Latinos can be of any race.
[b] Because column totals for estimated numbers were calculated independently of the values for the subpopulations, the values in each column may not sum to the column total.







Acute Retroviral Syndrome(Primary HIV)

1. Non specific illness, within 2-6 weeks after infection, lasts<2 weeks.
2. Occurs in 50-90% of acutely infected patients.
3. HIV Ab (-) takes 4-10 weeks, HIV RNA (+), culture (+)
4. Ab to p24 are first Ag declines with Ab appearance
5. Patient recovers and moves into the asymptomatic phase

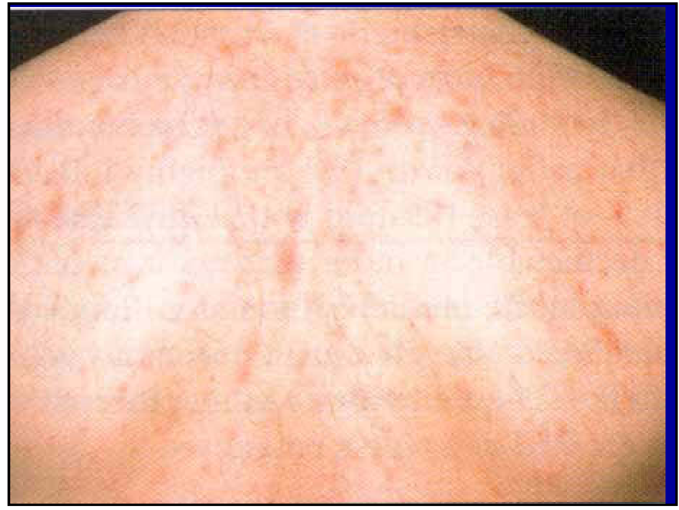
(clinically latent), no proven long term benefit of therapy.

Acute HIV Syndrome

Mono: Fever (96%), pharyngitis (70%) and lymphadenopathy (74%)

Neurologic (12%): Meningitis, encephalitis and peripheral neuropathy

Dermatologic: Erythematous maculopapular rash



Clinical Characteristics of Early Symptomatic Disease

CLINICAL MANIFESTATIONS

- Generalized lymphadenopathy
- Thrush
- Oral hairy leukoplakia
- Shingles
- Thrombocytopenia
- Molluscum contagiosum

AIDS Defining Malignancies (1992-2002)

Site	#Cases	Standardized Rate	Gen Population Rate	Standarized HIV observed
KS	2497	1167	3.3	354 (338, 369)
NHL	1023	525	18.3	28 (26,30)
Cervical Cancer	95	223	13.1	17 (14,20)

Patel, 11th CROI # 813

Non AIDS Defining Malignancies

Site	# Cases	Standardized Rate	General Population Rate	STD HIV Observed
Anal	78	25	1.4	18.3
Hodgkins	142	57	3.3	17.5
Liver	49	27	4.6	4.5
Testicular	22	25	7.8	3.3
Melanoma	38	37	17.8	2.1
Oropharyngal	66	31	15.8	2.0
Lung	163	91	51.4	1.6
Colorectal	74	49	41.8	1.2
Renal	24	10	11.6	0.9
Breast	36	104	151	0.7
Prostate	31	43	147	0.3

Patel, 11th CROI, 2006 #813

Pt diagnosed with HIV 1986, AIDS 1993

PCP
HSV genital infection
Eczema
d4T neuropathy
AZT mylelosuppression
Cellulitis
Osteomyelitis

Candida esophagitis
Pneumococcal pneumonia
Molluscum contagiosum
Squamous Cell Cancer –Anal
Squamous Cell Ca- Larynx
Progressive lateral sclerosis

Date	CD4	VL	Meds
1986	245	NA	AZT
8/93	<1	NA	AZT+ddI
11/95	<1	>1,600,000	
3/96	<1	623,000	
10/96	54	207,000	d4T, 3TC, IND
4/97	288	200,000	3TC, IND, NLF
10/97	616	200,000	
4/98	530	51,000	
11/98	632	5,130	
7/99	618	171	IND,NLF,EFV
11/99-2009	686-1198	undetectable	
2010-2016	1126-1460	undetectable	Atripla

CD4 Count Monitoring

- CD4 count
  - The major indicator of immune function
  - Most recent CD4 count is best predictor of disease progression
  - A key factor in determining urgency of ART or need for OI prophylaxis
  - Important in determining response to ART
    - Adequate response: CD4 increase 50-150 cells/µL per year

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OI Prophylaxis

Agent	Drug	CD_4 Threshold
PCP	TMP-SMX	<200
	Dapsone	
	Atovaquone	
	Pentamidine	
Toxoplasmosis	TMP-SMX	<100
	Dapsone + Pyrimethamine	
MAC	Azithromycin	<50
	Clarithromycin	
	Rifabutin	

HIV RNA Monitoring

- HIV RNA
  - May influence decision to start ART and help determine frequency of CD4 monitoring
  - Critical in determining response to ART
    - Goal of ART: HIV RNA below limit of detection (ie, <20-75 copies/mL, depending on assay)
  - Commercially available assays do not detect HIV-2

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HIV RNA Monitoring (2)

- RNA monitoring
  - Check at baseline (x2)
  - Monitoring in those not on ART – optional
  - Immediately before initiating ART
  - 2-4 weeks (not more than 8 weeks) after start or change of ART, then every 4-8 weeks until suppressed to <200 copies/mL
  - Every 3-4 months with stable patients; may consider every 6 months for stable, adherent patients with VL suppression >2 years
  - Isolated "blips" may occur (transient low-level RNA, typically <400 copies/mL), are not thought to predict virologic failure
    - ACTG defines virologic failure as confirmed HIV RNA >200 copies/mL

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Testing for Drug Resistance

- Before initiation of ART:
  - Transmitted resistance in 6-16% of HIV-infected patients
  - In absence of therapy, resistance mutations may decline over time and become undetectable by current assays, but may persist and cause treatment failure when ART is started
  - Identification of resistance mutations may optimize treatment outcomes
  - Resistance testing (genotype) recommended for all at entry to care
  - Recommended for all pregnant women
- Patients with virologic failure:
  - Perform while patient is taking ART, or ≤4 weeks after discontinuing therapy
  - Interpret in combination with history of ARV exposure and ARV adherence

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Goals of Treatment

- Reduce HIV-related morbidity; prolong duration and quality of survival
- Restore and/or preserve immunologic function
- Maximally and durably suppress HIV viral load
- Prevent HIV transmission

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Rating Scheme for Recommendations

- Strength of recommendation:
  - A: Strong
  - B: Moderate
  - C: Optional
- Quality of evidence:
  - I: ≥1 randomized controlled trials
  - II: ≥1 well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes
  - III: Expert opinion

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Recommendations for Initiating ART

- ART is recommended for *treatment*:

"ART is recommended for all HIV-infected individuals, regardless of CD4 T lymphocyte cell count, to reduce the morbidity and mortality associated with HIV infection." (A1)

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Recommendations for Initiating ART (2)

- ART is recommended for *prevention*:
  "ART also is recommended for HIV-infected individuals to prevent HIV transmission." (A1)

Recommendations for Initiating ART: Considerations

- ART should be initiated as soon as possible
  - On a case-by-case basis, ART may be deferred because of clinical and/or psychological factors
- Patients should understand that indefinite treatment is required; ART does not cure HIV
- Address strategies to optimize adherence

Potential Benefits of Early Therapy

- Untreated HIV is associated with development of AIDS and non-AIDS-defining conditions
- 2 randomized controlled trials showed significant reductions in both AIDS and non-AIDS events in persons who started ART with CD4 counts >500 cells/µL
- Early ART may prevent HIV-related end-organ damage; deferred ART may not reliably repair damage acquired earlier

Potential Benefits of Early Therapy (2)

- Potential decrease in risk of many complications, including:
  - HIV-associated nephropathy
  - Liver disease progression from hepatitis B or C
  - Cardiovascular disease
  - Malignancies (AIDS defining and non-AIDS defining)
  - Neurocognitive decline
  - Blunted immunological response owing to ART initiation at older age
  - Persistent T-cell activation and inflammation

Potential Benefits of Early Therapy (3)

- Prevention of sexual transmission of HIV
- Prevention of perinatal transmission of HIV

Current ARV Medications

NRTI
- Abacavir (ABC)
- Didanosine (ddI)
- Emtricitabine (FTC)
- Lamivudine (3TC)
- Stavudine (d4T)
- Tenofovir DF (TDF)
- Tenofovir alafenamide (TAF)*
- Zidovudine (AZT, ZDV)

NNRTI
- Delavirdine (DLV)
- Efavirenz (EFV)
- Etravirine (ETR)
- Nevirapine (NVP)
- Rilpivirine (RPV)

PI
- Atazanavir (ATV)
- Darunavir (DRV)
- Fosamprenavir (FPV)
- Indinavir (IDV)
- Lopinavir (LPV)
- Nelfinavir (NFV)
- Saquinavir (SQV)
- Tipranavir (TPV)

Integrase Inhibitor (INSTI)
- Dolutegravir (DTG)
- Elvitegravir (EVG)
- Raltegravir (RAL)

Fusion Inhibitor
- Enfuvirtide (ENF, T-20)

CCR5 Antagonist
- Maraviroc (MVC)

Pharmacokinetic (PK) booster
- Ritonavir (RTV)
- Cobicistat (COBI)

* TAF available only in coformulation: EVG/COBI/TAF/FTC

Initial Treatment: Choosing Regimens

- 3 main categories:
  - 1 II + 2 NRTIs
  - 1 PK-boosted PI + 2 NRTIs
  - 1 NNRTI + 2 NRTIs
- Combination of II, boosted PI, or NNRTI + 2 NRTIs is preferred for most patients
- NRTI pair should include 3TC or FTC
- Few clinical end points to guide choices: recommendations based mostly on rates of HIV RNA suppression and severity of adverse effects
- Advantages and disadvantages to each type of regimen
- Individualize regimen choice

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Initial Regimens: Recommended

INSTI based	▪ DTG/ABC/3TC; only if HLA-B*5701 negative (AI) ▪ DTG (QD) + TDF/FTC (AI) ▪ EVG/COBI/TDF/FTC; only if pre-ART CrCl >70 mL/min (AI) ▪ EVG/COBI/TAF/FTC; only if pre-ART CrCl ≥30 mL/min (AI) ▪ RAL + TDF/FTC (AI)
PI based	▪ DRV/r (QD) + TDF/FTC (AI)

Note:
3TC can be used in place of FTC and vice versa; TDF: caution if renal insufficiency

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Initial Regimens: Alternative

NNRTI based	▪ EFV/TDF/FTC (BI) ▪ RPV/TDF/FTC; only if pre-ART HIV RNA <100,000 copies/mL and CD4 >200 cells/µL (BI)
PI based	▪ ATV/c + TDF/FTC; only if pre-ART CrCl >70 mL/min (BI) ▪ ATV/r + TDF/FTC (BI) ▪ (DRV/c or DRV/r) + ABC/3TC; only if HLA-B*5701 negative (BIII for DRV/c, BII for DRV/r) ▪ DRV/c + TDF/FTC; only if pre-ART CrCl >70 mL/min (BII)

Note:
3TC can be used in place of FTC and vice versa; TDF: caution if renal insufficiency

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Improving Adherence

- Support and reinforcement
- Simplified dosing strategies
- Reminders, alarms, timers, and pillboxes
- Ongoing patient education
- Trust in primary care provider

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Other Assessment and Monitoring Studies

- HLA-B*5701 screening
  - Recommended before starting ABC, to reduce risk of hypersensitivity reaction (HSR)
  - HLA-B*5701-positive patients should not receive ABC
  - Positive status should be recorded as an ABC allergy
  - If HLA-B*5701 testing is not available, ABC may be initiated after counseling and with appropriate monitoring for HSR
- Coreceptor tropism assay
  - Should be performed when a CCR5 antagonist is being considered
  - Phenotype assays have been used; genotypic test now available but has been studied less thoroughly
  - Consider in patients with virologic failure on a CCR5 antagonist (though does not rule out resistance to CCR5 antagonist)

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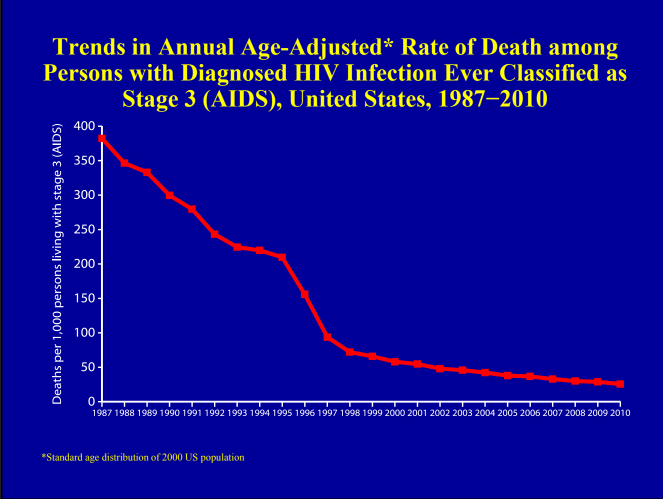
Hepatitis C and HIV

- 30-40% of HIV patients are coinfected with hepatitis C (5-10% with hepatitis B)
- 70% are genotype 1
- HIVincreases hepatitis C persistence, HCV RNA and HCV related cirrhosis, end stage liver disease and hepatoma.
- HCV increases the risk of dying and progression to AIDS
- Treatment of choice is sofosbuvir for12 weeks for gt1.



HIV Serology Recommendations from the CDC

Rationale: Quality of test and need to know (prevention and care)

Recommendation:

Routine test ages 13-64 years (not risk based)

Consent included in consent for care (" opt out")

Do it yourself HIV test

Frequency of HIV Testing

Low risk – 1x

Annual testing

- IDU
- MSM (CDC recommends every 6 months)
- Persons who exchange sex for money or drugs
- Sex partners of HIV (+), IDU or MSM
- Person who have sex with partners whose HIV status is unknown
- Pregnant women

Areas where prevelance is <0.1% (e.g. North Dakota) are exempt from this recommendation

CDC PrEP

- Sexually active MSM
- Heterosexually active men and women
- Injection drug users
- Discordent couples

Provide risk reduction support

Truvada 1/day

Long Term Control of HIV by Stem Cell Transplantation

40 year old with AML (FAB M4 Subtype) with a past history of HIV-1 for 10 years and HAART for 4 years. CD_4=415 VL=ND

Chemotherapy ledto hepatotoxicity, HAART stopped VL=6,900,000 copies HAART resumed VL=ND

AML relapsed, allogeneic stem cell transplantation from a donor homozygous for CCR5 delta- 32 allele (1% US)

Closing the Implementation Gap: Remaining Challenges

- 54% of HIV-infected people know their status
- 220,000 infants infected in 2014 globally
- Of people on ART, rates of viral suppression suboptimal
- Fewer than ½ of targeted 20 million adult male circumcisions have been performed
- Stigma and discrimination persist

SELF EVALUATION

HIV/AIDS Update

1. Anti retroviral therapy should be indicated based on

- a. CD4 <200
- b. CD4<350
- c. Viral Load >100,000
- d. CD4 >500
- e. Any CD4 count and viral load

2. HIV testing should be performed

- a. Only in high risk groups
- b. Based on history obtained by the primary physician
- c. On all patients 13-64 years of age unless the endemic rate is <0.1%
- d. Only based on history of prior sexually transmitted disease

3. Patients who are candidates for pre exposure prophylaxis include

- a. Sexually active men who have sex with men
- b. Heterosexually active men and women
- c. Injection drug users
- d. Discordant couples
- e. All of the above

4. DHSS guidelines for first line initial therapy include

- a. An integrase inhibitor and two nucleoside reverse transcriptase inhibitors
- b. Three nucleoside agents
- c. Atripla (EFV/TDF/FTC)
- d. Darunavir/r + ABC/BTC in and HLAB 5701 (+) patients

5. Which of the following is true?

- a. The majority of HIV infected individuals do not know their status
- b. The mortality for AIDS remains high
- c. HIV and HCV co-infection is common
- d. Perinatal transmission has been drastically reduced

6. What is true about HIV transmission

- a. Circumcision increases the risk of HIV transmission
- b. Men are at greater risk from heterosexual transmission than women
- c. Breast milk poses a greater risk of transmission than intrauterine transmission
- d. CD4 is a good prediction of HIV transmission

Answer Key: 1. E, 2. C, 3. E, 4. A, 5. C, 6. C

David B. Mandell, JD, MBA

David B. Mandell, JD, MBA, of Ft. Lauderdale, Florida, is a practicing attorney and a principal of the financial consulting firm OJM Group. He specializes in risk management, asset protection and financial planning and has authored a number of books for doctors including, *For Doctors Only: A Guide to Working Less and Building More,* and *WEALTH PROTECTION, M.D.* Mr. Mandell also created the Category 1 CME monograph, *Risk Management for the Practicing Physician*. His articles have appeared in over 100 publications, including over 30 medical specialty journals, and he has addressed many of the nation's leading medical conferences.

Mr. Mandell holds a bachelor's degree from Harvard University, from which he graduated with honors, a law degree from the UCLA School of Law, where he was awarded the American Jurisprudence Award for achievement in legal ethics, and earned his MBA from UCLA'S Anderson School of Management.

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Reducing Stress by Increasing Financial Efficiency

David B. Mandell, JD, MBA

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OJM MATERIALS FREE TO AEI PARTICIPANTS

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TODAY'S PRESENTATION

1. Background on physician financial stress
2. Financial efficiency in benefit planning for all physicians
3. Using small captive insurance companies to create efficiency's in private practices
4. Efficiency in retirement planning

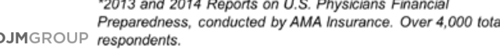
PHYSICIAN DEMAND: FINANCIAL STRESS*

1. 87 percent of respondents said they are moderately-to-severely stressed/burned out on an average day.
2. 63 percent said they were more stressed or burned out than they were three years ago;
3. The top three things that they felt would help them reduce stress:
   a. better work hours and/or less call (32.5 percent)
   b. more or better work/life balance (30.7 percent)
   c. improved finances, compensation, reimbursement (29 percent)

*Of 2,000 physicians as reports by Bouchard, Stephanie, "Impact of Physician Stress Underestimated," *HealthCare Finance News*, December 2, 2011

Physician Stress: Financial Preparedness

- Providing a comfortable retirement for themselves and spouse/partner is the #1 financial goal – having enough to retire is their #1 personal financial concern.
- Half of physicians are behind where they would like to be in retirement preparedness; only 6 percent "ahead of schedule."
- Physicians reports gaps in personal financial knowledge in a wide array of areas including retirement savings, life and disability insurance, and estate planning.

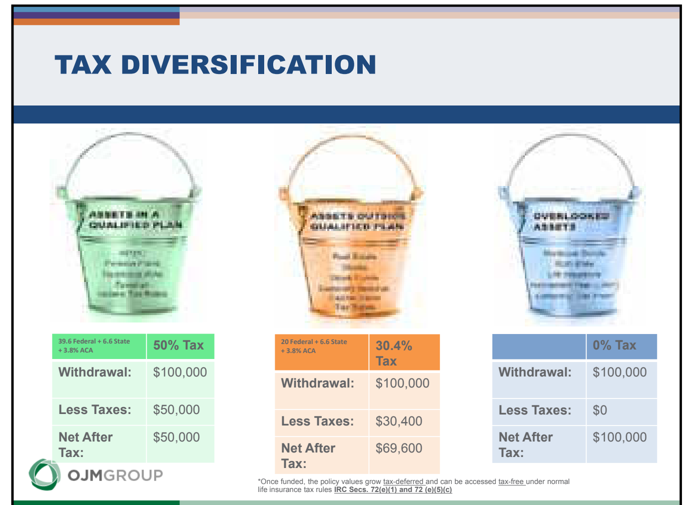


**2013 and 2014 Reports on U.S. Physicians Financial Preparedness, conducted by AMA Insurance. Over 4,000 total respondents.*

What is a "Retirement Plan"

- For many physicians, they mean a qualified retirement plan (QRP)
  - ✓ Many different types
- At OJM, we see a QRP as one "bucket" in a multi-bucket plan
  - ✓ Other benefit plans, after-tax assets, securities/real estate, other asset classes
- Tax Diversification is Key

TAX DIVERSIFICATION



39.6 Federal + 6.6 State + 3.8% ACA	50% Tax
Withdrawal:	$100,000
Less Taxes:	$50,000
Net After Tax:	$50,000

20 Federal + 6.6 State + 3.8% ACA	30.4% Tax
Withdrawal:	$100,000
Less Taxes:	$30,400
Net After Tax:	$69,600

	0% Tax
Withdrawal:	$100,000
Less Taxes:	$0
Net After Tax:	$100,000

*Once funded, the policy values grow tax-deferred and can be accessed tax-free under normal life insurance tax rules **IRC Secs. 72(e)(1) and 72 (e)(5)(c)**

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QRP Ground Rules

- 2 different categories
- Asset protection is excellent
- Must cover all eligible employees
- Full deduction for contributions/income taxation on withdrawals
- Penalties on withdrawals before 59
- Funds left in estate taxed up to 70%

QRP: DEFINED CONTRIBUTION PLANS

- IRS defines the contribution amount
- 401(k)s, 403(b), and 457 plans
  - ✓ 18,000 employee deferral amount
- PS: Defined contribution maximum $53,000
- Flexibility on funding
  - ✓ No penalties for underfunding or termination
- Proper plan design is key

QRP: DEFINED BENEFIT PLANS

- Actuarially-determined contribution amount
- Physicians contributing $200,000+ annually
- Employee costs can be high
- Penalties for underfunding or termination
- Planning design/commitment is key

SEP-IRAS

- Similar rules to the defined contribution plan
- $25% or $53,000 whichever is less in 2016
- Flexibility on funding
- Asset protection not as strong in some states as with QRP

QRP Ground Rules: REVISITED

- Full deduction for contributions/income taxation on withdrawals
  - ✓ You are ‘trading’ today’s tax rates for tax rates in retirement___
  - ✓ QRPs are a “bet” that your tax rate will be lower (or at least the same) as it is today: Do you believe this?
  - ✓ Value of tax deferral is significant
- Example: Charles Mandell, MD

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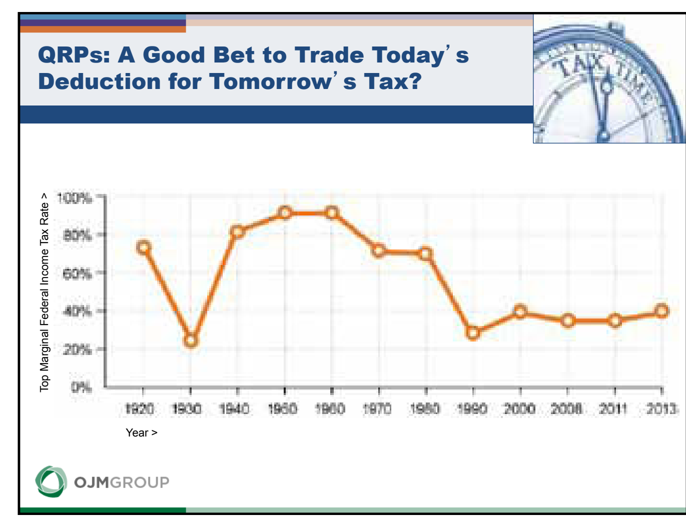

TRADING ORDINARY INCOME FOR CAPITAL GAINS TAXES

Nearly all physicians use after-tax investments as part of their “retirement plan”

- Securities
- Closely-held businesses, artwork, commodities
- Real estate
  - ✓ Rents taxed as Ordinary Income
  - ✓ Sales may trigger depreciation recapture (ordinary income)
  - ✓ Home: special tax treatment

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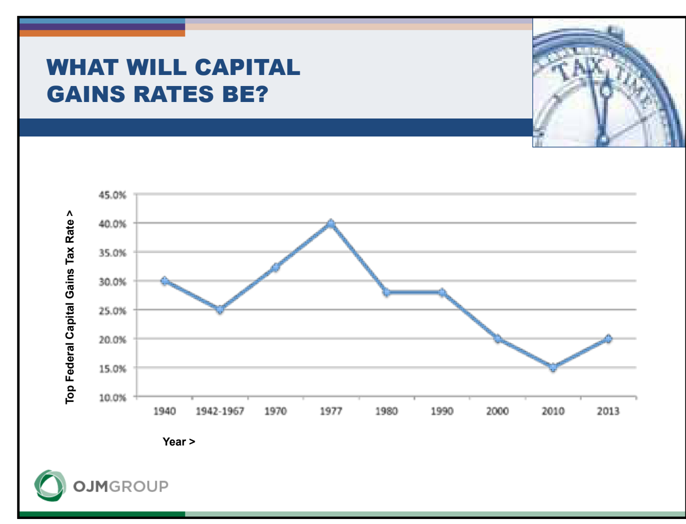

USING BENEFIT PLANS TO HEDGE YOUR LONG-TERM TAX BET

- Roth IRA
  - – Contributions after-tax; tax free growth and distributions
- Non-qualified plans; 162 bonus plans
  - – Contributions after-tax; tax free growth and distributions
- – Life Insurance as a retirement plan

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NON-QUALIFIED PLAN AS OPTION

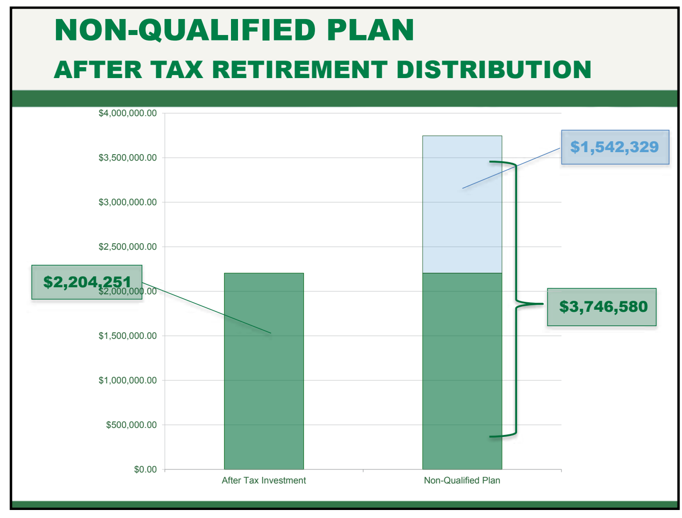
- No limitations on contributions – reasonable compensation
- In addition to 401k, profit-sharing, pension
- Owners can vary how much/if they participate
- Employee participation not required
- No tax deduction, tax-free growth and on withdrawal
- **Ideal hedge against future income/cg tax increases**

ASSUMPTIONS FOR CASE STUDY

Example taken from Actual OJM Group Client:

- 45 Year Old Male
- Ohio Resident
- $100,000 Annual Contribution for 10 Years
- Growing at 6.5% annual gross rate of return
- Investment management fee of 1%
- Assuming taxed at 20% Short Term Rates/ 80% Long Term Rates
- 39.6% Federal & 6.0% State
- 20% Long Term Capital Gains & 3.8% ACA Tax
- Distributions at age 65 for 20 years

NON-QUALIFIED PLAN
AFTER TAX RETIREMENT DISTRIBUTION



NON-QUALIFIED PLAN
TAXES & FEES VS. POLICY EXPENSES

$1,200,000.00
$1,000,000.00
$800,000.00
$600,000.00
$400,000.00
$200,000.00
$0.00

$844,300

$1,193,099

$348,799

After Tax Investment
Non-Qualified Plan

CONCLUSION: BENEFIT PLANS

- Realize the tax bet of QRPs
- Make sure your QRP is maximized, if you have one
- Understand personally-held assets like securities and real estate are subject to capital gains taxes
- Consider other benefit plans/buckets which are hedged against ordinary income and capital gains tax rate increases

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SMALL CAPTIVE INSURANCE COMPANIES: EFFICIENT TOOLS FOR PRIVATE PRACTICES

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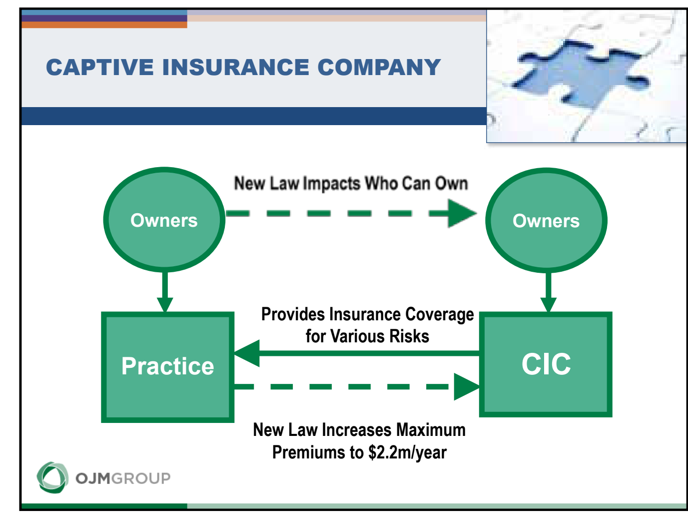
SMALL CAPTIVE INSURANCE COMPANIES

- Financial Efficiency
  - Risk Management for presently uninsured risks
  - Excess, deductibles, litigation expense, etc.
  - Capture insurance co. profits
  - Buy-out fund/retirement wealth
- Tax Efficiency
  - Up to $2.2 million non taxed premium income 831b as of 1/1/17

NEW LAW ON CAPTIVES

- I.R.C. 831(b): since 1986
- New law passed in December 2015
  - "Tax Extenders" bill titled H.R. 34, which included Section 262 titled, "MODIFICATIONS TO ALTERNATIVE TAX FOR CERTAIN SMALL INSURANCE COMPANIES"
  - Goes into effect Jan. 1, 2017
  - Eliminates many estate planning benefits, but increases annual premium from $1.2 million to $2.2 million
- Yet, there is abuse…

CAPTIVE INSURANCE COMPANY



TYPES OF CIC POLICIES

- **Everything a business currently self-insures:**
  - Deductibles; excess losses above coverage limits
- **Loss of income as a result of:**
  - Losing key employee/salesperson
  - Rising interest rates/economic factors (developers, real estate)
  - Loss of license/professional risks (professionals)
  - Loss of a key contract (Gov't. contractors)
  - Weather, terrorism, etc.
- **Liability defense expenses:**
  - Employee lawsuits – sexual harassment, wrongful termination, discrimination, etc.
  - Professional claims
- **Anything that might be consider a "Lloyd's" risk**

KEY ROLES

1. **Law Firm / Insurance Manager / Actuarial Firm**
   - Handle the formation of the CIC, its tax treatment, all tax & legal issues related to the transaction on an ongoing basis
   - Make sure that the CIC is compliant with all state insurance department rules and procedures on an ongoing basis
   - Draft all insurance policies by the CIC to practice and related entities and value the proper pricing of each policy
   - Represent the client in any audits by the state insurance dept. or the IRS
2. **OJM**
   - Manage the CIC reserves from an investment perspective
   - Propose, explain and implement any benefit plans for the CIC's owners and executives

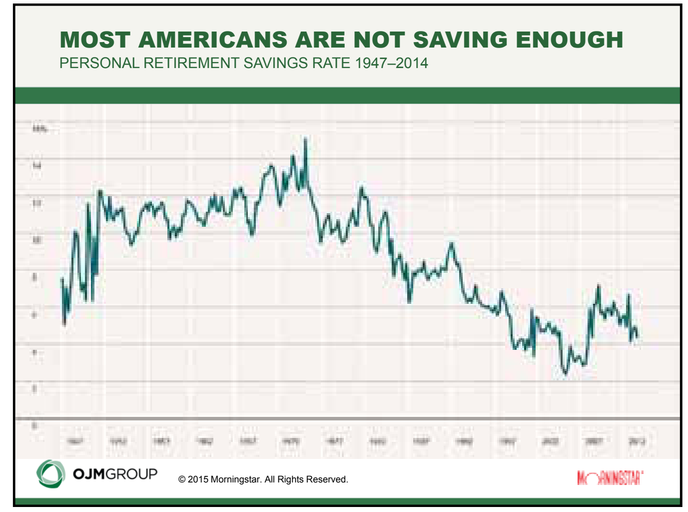
CONCLUSION: SMALL CAPTIVES

- Does your practice have litigation, economic, regulatory and other risks not covered by insurance or present policy exclusions?
- Does your practice generate $3 to $5 million+ in revenues?
- Would you be interested in a tool that provides tremendous risk management, asset protection, recruitment/exit strategy and tax efficiencies?

Retirement is #1 Goal for Physicians

- Providing a comfortable retirement for themselves and spouse/partner is the #1 financial goal – having enough to retire is their #1 personal financial concern.
- Half of physicians are behind where they would like to be in retirement preparedness; only 6 percent "ahead of schedule."

**2013 and 2014 Reports on U.S. Physicians Financial Preparedness, conducted by AMA Insurance. Over 4,000 total respondents.*


MOST AMERICANS ARE NOT SAVING ENOUGH
PERSONAL RETIREMENT SAVINGS RATE 1947–2014
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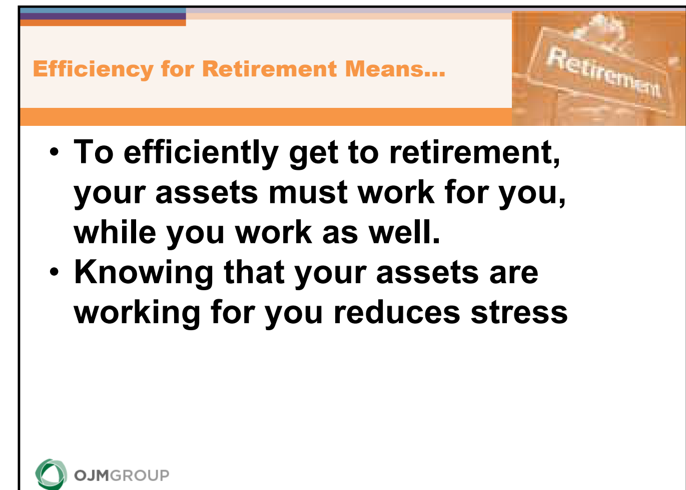
Efficiency for Retirement Means…
Retirement
• To efficiently get to retirement, your assets must work for you, while you work as well.
• Knowing that your assets are working for you reduces stress
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START INVESTING EARLY TO REACH YOUR GOALS
MONTHLY SAVINGS NEEDED TO ACCUMULATE $1 MILLION BY AGE 65
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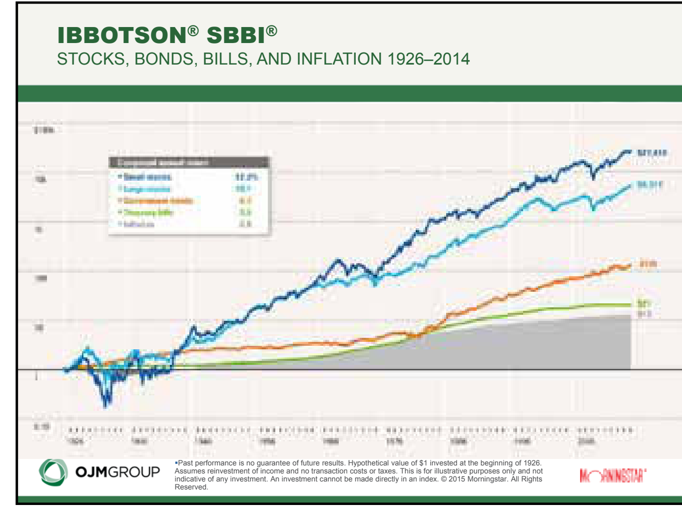
IBBOTSON® SBBI®
STOCKS, BONDS, BILLS, AND INFLATION 1926–2014
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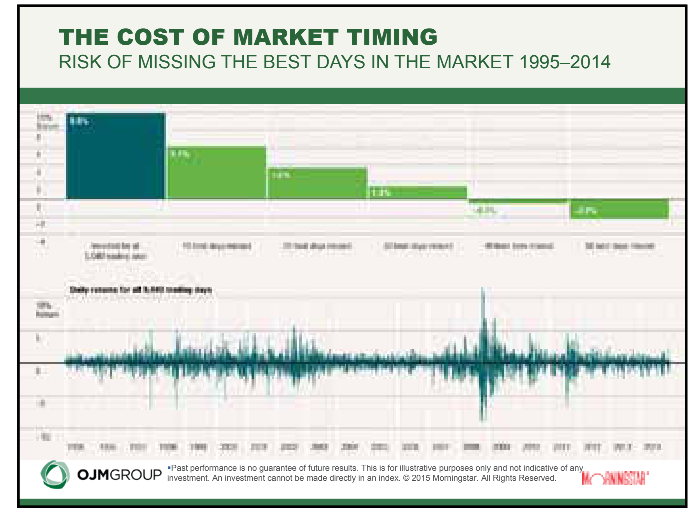
THE COST OF MARKET TIMING
RISK OF MISSING THE BEST DAYS IN THE MARKET 1995–2014
OJMGROUP
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GETTING THE RIGHT ADVICE
▪ Fiduciary standard… as opposed to "suitability"
▪ Transparent, client-aligned business model
▪ Expertise and communication.. Leads to trust
▪ Sees the investments as one part of a holistic wealth plan to get you to your goals: individualized
▪ Is 5% a "good return"?
OJMGROUP

ABOUT OJM GROUP

- Unique, fee-based consulting firm
- 1,000 clients in 48 states
- Multi-disciplinary
- Business/practice and personal planning
- **Our firm commitment: Qualified clients receive 200% of your fee in savings or we return the fee**
- Goal: reducing physician financial stress

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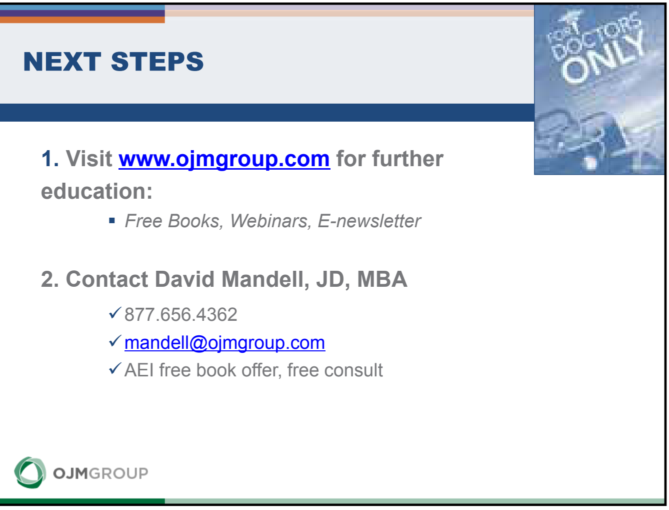

SELF EVALUATION

Reducing Stress by Increasing Financial Efficiency

1. True/False - Providing a comfortable retirement for themselves and spouse/partner is the #1 financial goal of physicians, according to a study of 4,000 physicians.

2. Benefits of qualified plans include (choose best answer):

a. Unlimited contributions
b. Current deduction and tax free growth
c. Tax free access
d. Employees do not have to be offered plan

3. Benefits of non-qualified plans include (choose best answer):

a. Current deduction
b. Unlimited investment options
c. Tax free growth and access
d. Is a good short-term plan

4. True/False - 401(k)s are a type of defined benefit plan.

5. True/False - A new law regarding small captive insurance companies under tax code section 831b was passed by President Obama and Congress in December 2015.

6. Over the period 1995-2014, the data shows that missing out on just the top 20 days in the market, would have reduced a 9.9% annual return, achieved by being invested in all 5,040 trading days, to an annual return of:

a. 9.9% - no significant reduction
b. 9.0% - some minimal reduction
c. 5.0% - a reduction of nearly half of the rate of return
d. 3.6% - a reduction of well over half of the rate of return

7. True/False - Under both a “fiduciary duty” standard and a “suitability” standard, a financial advisor must act in the best interests of his/her client.

Answer Key: 1. T, 2. B, 3. C, 4. F, 5. T, 6. D, 7. F

Bernd Wollschlaeger, MD, FAAFP, FASAM

Bernd Wollschlaeger, MD, FAAFP, FASAM, of North Miami Beach, Florida, is a board-certified family physician and addiction specialist in private practice. He is a fellow of the American Academy of Family Physicians and the American Society of Addiction Medicine, and is a voluntary clinical assistant professor of Family Medicine at the University of Miami School of Medicine, the Florida International and the Florida State University College of Medicine.

Dr. Wollschlaeger was president of the Dade County Medical Association and the Florida Society of Addiction Medicine and was, in 2012, the Florida Academy of Family Physicians' Family Doctor of the Year. He is a member of the Patient Safety Taskforce of the Florida Medical Association and the FAFP Quality Practice Management Committee. Dr. Wollschlaeger is also the author of several books about his life's unique trajectory from the son of a highly-decorated German officer in World War II to his emigration to Israel and service in the Israel Defense Forces. He is a consultant for Indivior.

You may contact Dr. Wollschlaeger with your questions and comments at (305) 940-8717 or info@miamihealth.com.

Aventura Family Health Center

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CERTIFIED MEDICAL REVIEW OFFICER (MRO)

Morbidity and Mortality Weekly Report 07/07/2015

- **Background:** Heroin use and overdose deaths have increased significantly in the United States. Assessing trends in heroin use among demographic and particular substance-using groups can inform prevention efforts.
- **Methods:** FDA and CDC analyzed data from the National Survey on Drug Use and Health and National Vital Statistics System reported during 2002–2013. Trends in heroin use among demographic and substance using groups were compared for 2002–2004, 2005–2007, 2008–2010, and 2011–2013. A multivariable logistic regression model was used to identify characteristics associated with heroin abuse or dependence.
- **Results:** Annual average rates of past-year heroin use increased from 1.6 per 1,000 persons aged ≥12 years in 2002–2004 to 2.6 per 1,000 in 2011–2013. Rates of heroin abuse or dependence were strongly positively correlated with rates of heroin-related overdose deaths over time. For the combined data years 2011–2013, the odds of past-year heroin abuse or dependence were highest among those with past-year cocaine or opioid pain reliever abuse or dependence.
- **Conclusions:** Heroin use has increased significantly across most demographic groups. The increase in heroin abuse or dependence parallels the increase in heroin-related overdose deaths. Heroin use is occurring in the context of broader poly-substance use.

MMWR Key Points

- Heroin use in the United States increased 63% from 2002 through 2013. This increase occurred among a broad range of demographics, including men and women, most age groups, and all income levels.
- As heroin use, abuse, and dependence have increased, so have heroin-related overdose deaths. From 2002 through 2013, the rate of heroin-related overdose deaths nearly quadrupled.
- Persons often use heroin with other substances, including marijuana, cocaine, alcohol, and opioid pain relievers. This practice is especially dangerous.
- Groups with an increased risk for heroin abuse or dependence include men, persons aged 18–25 years, non-Hispanic whites, persons with annual household income less than $20,000, Medicaid recipients, and the uninsured.
- States play a key role in addressing heroin use, abuse, dependence, and overdose. States can implement strategies to reduce the abuse of opioid pain relievers, the strongest risk factor for heroin abuse or dependence. They can also improve access and insurance coverage for medication-assisted treatment for opioid use disorders and expand access and training for naloxone administration to reverse overdoses.

CNN 07/07/2015

- Heroin use is increasing rapidly across the United States among all age, race, income and ethnic groups, the Centers for Disease Control and Prevention announced Tuesday.
- The increase comes with a devastating price: Deaths from heroin-related overdoses nearly quadrupled between 2002 and 2013.
- Heroin use doubled among women and young adults ages 18 to 25, and more than doubled among non-Hispanic whites.
- Some of the highest increases were in groups with historically low rates of abuse: women, people with higher incomes and people who are privately insured.

DEA Response 07/07/2015

- Chuck Rosenberg, the DEA's acting administrator:
- "Approximately 120 people die each day in the United States of a drug overdose....We will continue to target the criminal gangs that supply heroin, and we will work to educate folks about the dangers and to reduce demand. In this way, we hope to complement the crucial efforts of the CDC and our nation's public health agencies."

Prescription Opioid Painkillers and the Epidemic of Drug Abuse and Overdose

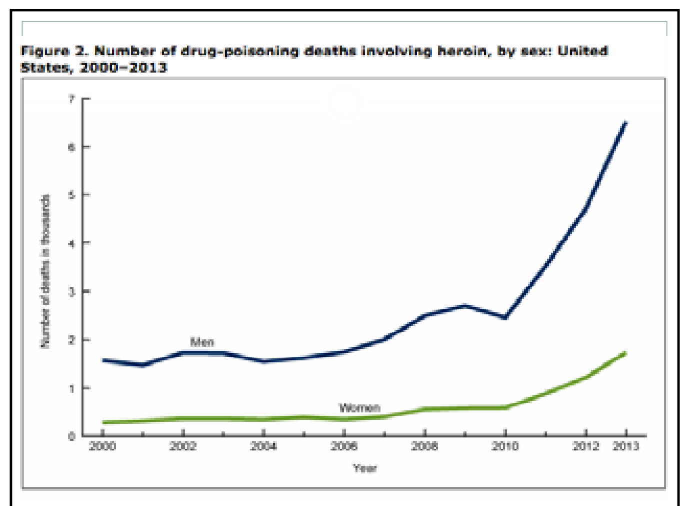
- Drug overdose was the leading cause of injury death in 2013. Among people 25 to 64 years old, drug overdose caused more deaths than motor vehicle traffic crashes.
- There were 43,982 drug overdose deaths in the United States in 2013. Of these, 22,767 (51.8%) were related to prescription drugs.
- Of the 22,767 deaths relating to prescription drug overdose in 2013, 16,235 (71.3%) involved opioid painkillers, and 6,973 (30.6%) involved benzodiazepines.
- People who died of drug overdoses often had a combination of benzodiazepines and opioid painkillers in their bodies.
- Drug misuse and abuse caused about 2.5 million emergency department (ED) visits in 2011. Of these, more than 1.4 million ED visits were related to prescription drugs.

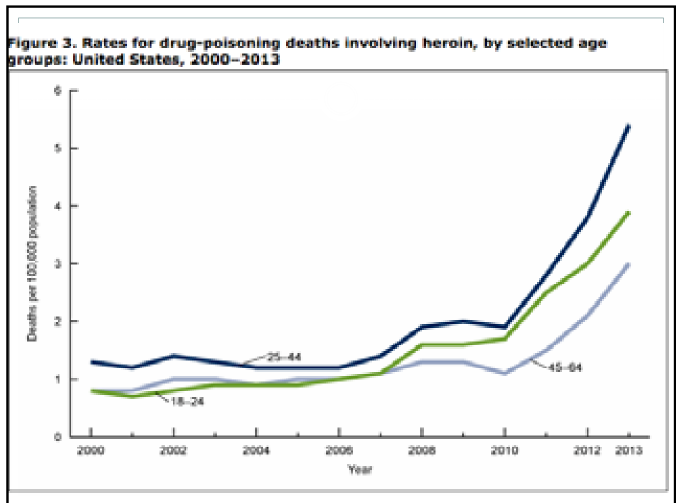
Epidemic

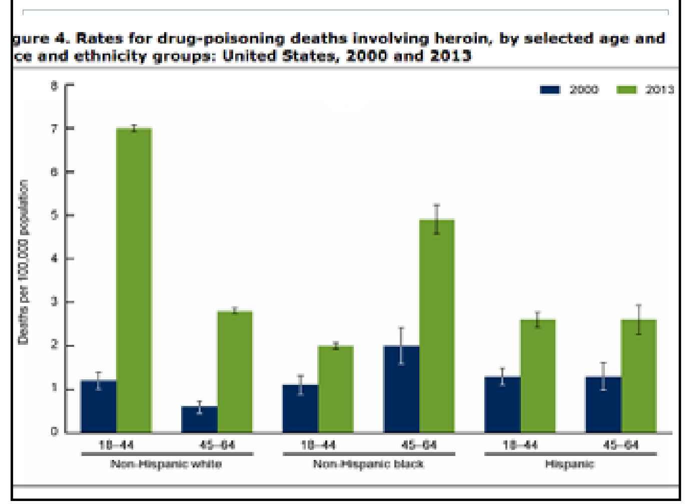
- Deaths from prescription painkillers have quadrupled since 1999, killing more than 16,000 people in the U.S. in 2013.
- Nearly two million Americans, aged 12 or older, either abused or were dependent on opioids in 2013.

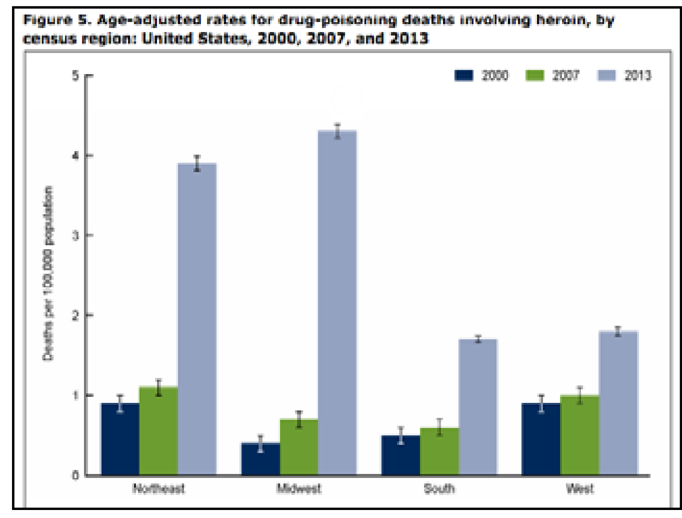
Deaths from Prescription Opioid Overdose

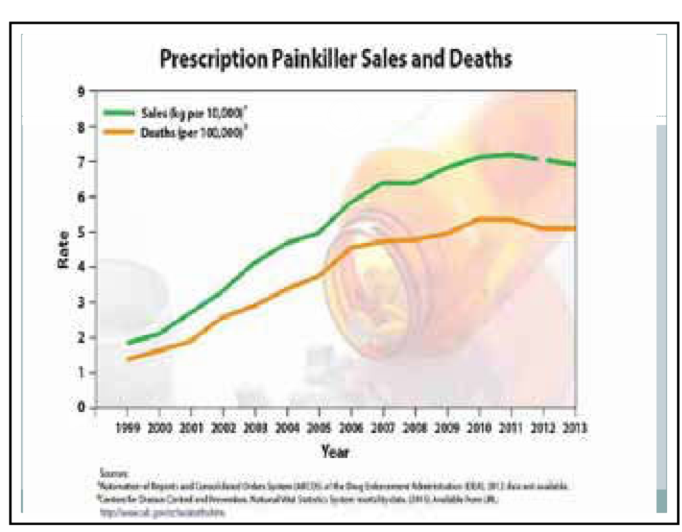
- Among those who died from prescription opioid overdose between 1999 and 2013:
- Most were ages 25 to 54.
- This age group had the highest overdose rates compared to other age groups.
- Overdose rate for adults aged 55–64 increased more than seven-fold during this same time period.





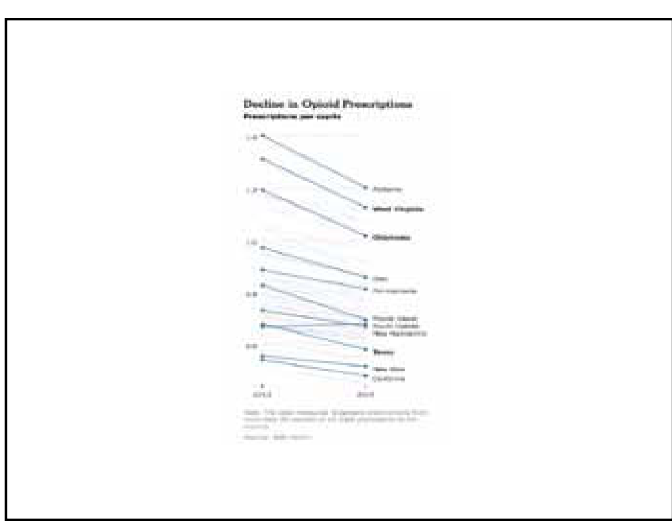




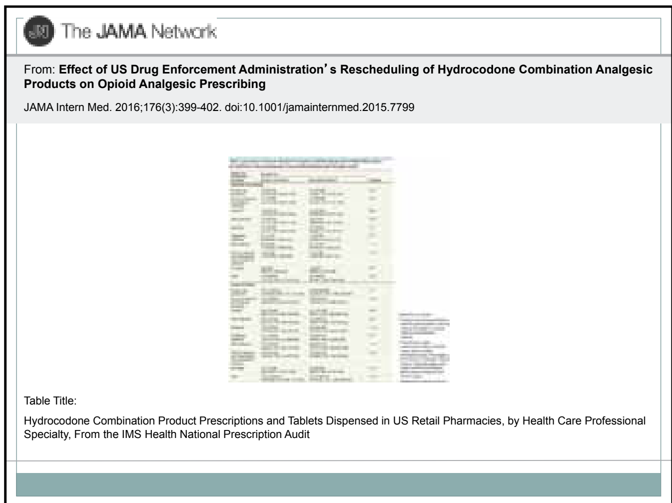


Latest Update: 05/20/2016

OPIOID PRESCRIPTIONS DROP FOR FIRST TIME IN TWO DECADES



- Effect of US Drug Enforcement Administration's Rescheduling of Hydrocodone Combination Analgesic Products on Opioid Analgesic Prescribing
- Christopher M. Jones, PharmD, MPH1; Peter G. Lurie, MD, MPH2; Douglas C. Throckmorton, MD2
- JAMA Intern Med. 2016;176(3):399-402. doi:10.1001/jamainternmed.2015.7799.



The JAMA Network

From: **Effect of US Drug Enforcement Administration's Rescheduling of Hydrocodone Combination Analgesic Products on Opioid Analgesic Prescribing**

JAMA Intern Med. 2016;176(3):399-402. doi:10.1001/jamainternmed.2015.7799

Figure Legend:

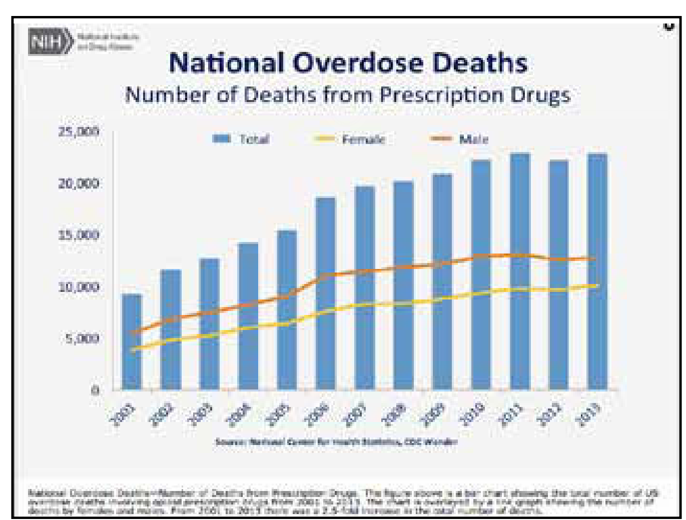
Dispensed and Predicted Hydrocodone Combination Product (Blue) and Nonhydrocodone Combination Product (Orange) Opioid Analgesic Prescriptions and TabletsThe data are from US retail pharmacies by quarter (Q) between October 1, 2011, and September 30, 2015. The solid lines show the number dispensed, and the dashed lines show the number predicted. The black vertical line represents time of rescheduling action by the Drug Enforcement Administration. Error bars indicate 95% CIs.

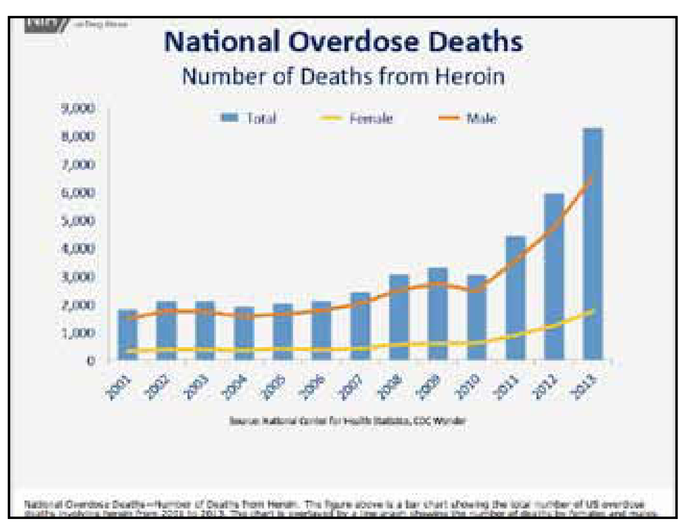
Deaths from Prescription Opioid Overdose

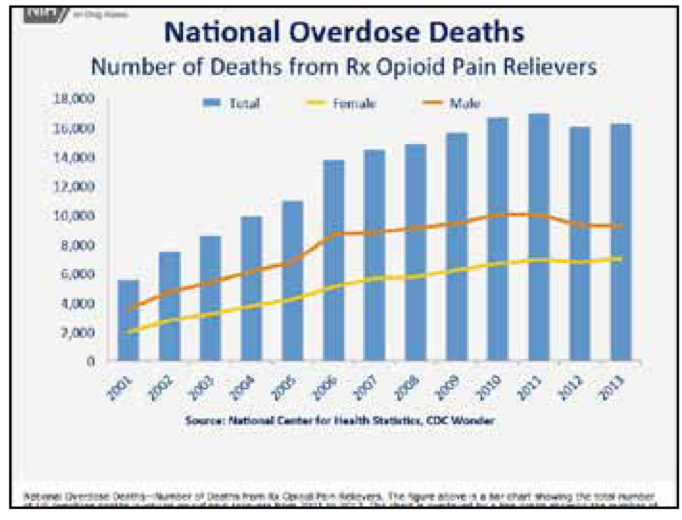
- The large majority were non-Hispanic whites.
- The age-adjusted rate of prescription painkiller overdose deaths among non-Hispanic white persons increased 4.3 times, from 1.6 per 100,000 in 1999 to 6.8 per 100,000 in 2013.
- The rates more than doubled for non-Hispanic black persons, from 0.9 per 100,000 in 1999 to 2.5 per 100,000 in 2013.
- The rates increased only slightly for Hispanic persons, from 1.7 per 100,000 in 1999 to 2.1 per 100,000 in 2013
- The rates for American Indian or Alaska Natives increased almost four fold from 1.3 per 100,000 in 1999 to 5.1 per 100,000 in 2013.1

Prescriptions Down BUT Overdose Deaths are Up

- So far, fewer prescriptions have not led to fewer deaths
- Fatal overdoses from opioids have continued to rise, taking more than 28,000 lives in 2014, according to the most recent federal health data.
- That number includes deaths from both prescription painkillers, like Percocet, Vicodin and OxyContin, and heroin, an illegal opioid whose use has been rising as access to prescription drugs has tightened.

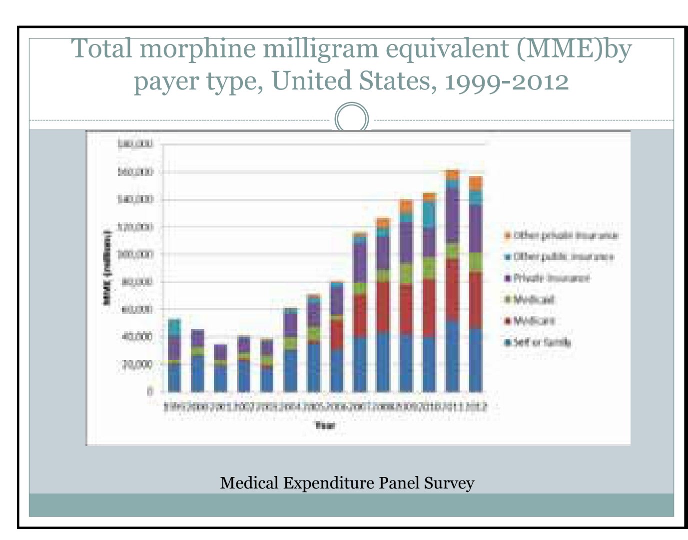


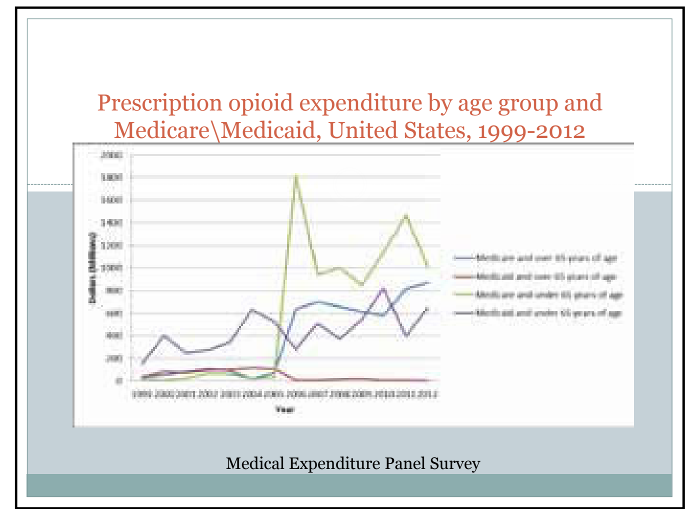


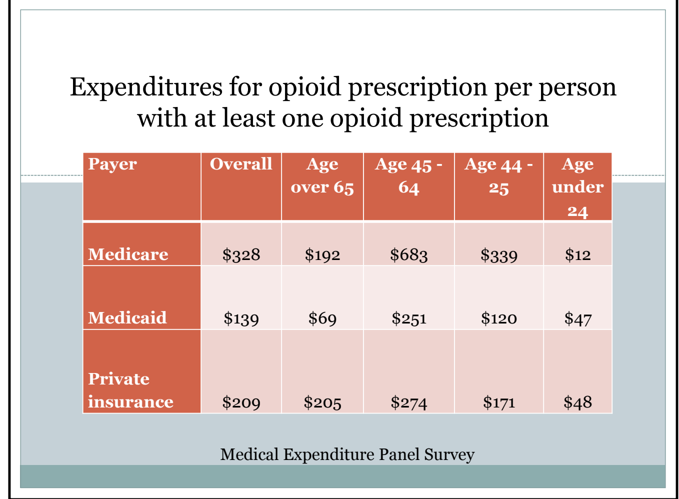


Costs of Prescription Opioid Overdose

- In the United States, prescription opioid abuse costs were about $55.7 billion in 2007.
- Of this amount, 46% was attributable to workplace costs (e.g., lost productivity), 45% to healthcare costs (e.g., abuse treatment), and 9% to criminal justice costs.5







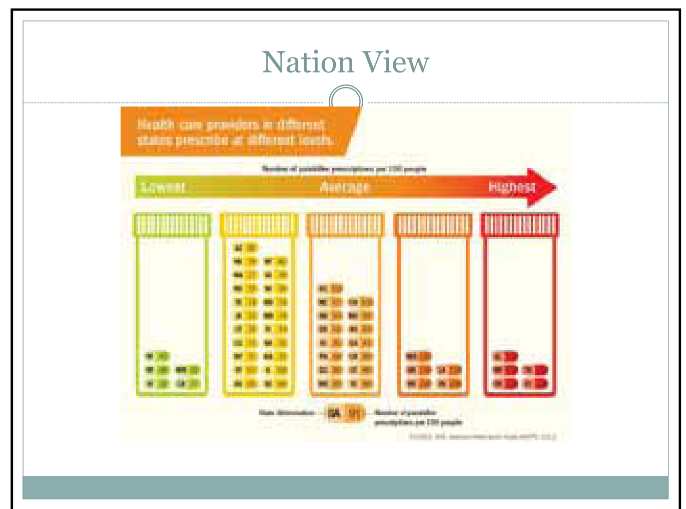
Expenditures for opioid prescription per person with at least one opioid prescription

Payer	Overall	Age over 65	Age 45 - 64	Age 44 - 25	Age under 24
Medicare	$328	$192	$683	$339	$12
Medicaid	$139	$69	$251	$120	$47
Private insurance	$209	$205	$274	$171	$48

Medical Expenditure Panel Survey

Opioid Prescription Payment Trends

- Shift in payer from individuals to private, Medicaid to Medicare from 1999-2012
- The cost to consumers of prescription opioids has declined during this time period
- Large percentage of opioid expenditures are for Medicare recipients less than age 65



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2. Centers for Disease Control and Prevention. Vital Signs: Overdoses of Prescription Opioid Pain Relievers and Other Drugs Among Women — United States, 1999–2010. MMWR 2013; 62(26);537-542.
3. Centers for Disease Control and Prevention. Web-based Injury Statistics Query and Reporting System (WISQARS) [online]. (2014) Available from URL: http://www.cdc.gov/injury/wisqars/fatal.html.
4. Substance Abuse and Mental Health Services Administration. Highlights of the 2011 Drug Abuse Warning Network (DAWN) findings on drug-related emergency department visits. The DAWN Report. Rockville, MD: US Department of Health and Human Services, Substance Abuse and Mental Health Services Administration; 2013. Available from URL: http://www.samhsa.gov/data/2k13/DAWN127/sr127-DAWN-highlights.htm
5. Birnbaum HG, White AG, Schiller M, Waldman T, Cleveland JM, and Roland CL. Societal costs of prescription opioid abuse, dependence, and misuse in the United States. Pain Medicine 2011; 12: 657-667.

Overdose Risk Factors

Demographics

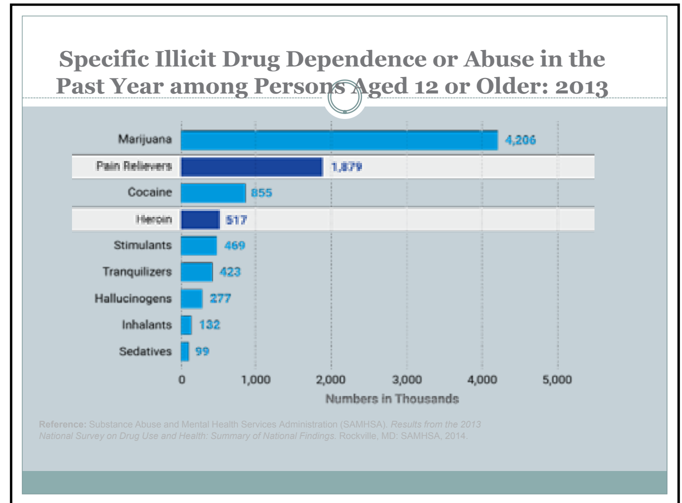
- Men
- 35-54 year olds
- Whites
- American Indians/Alaska Natives

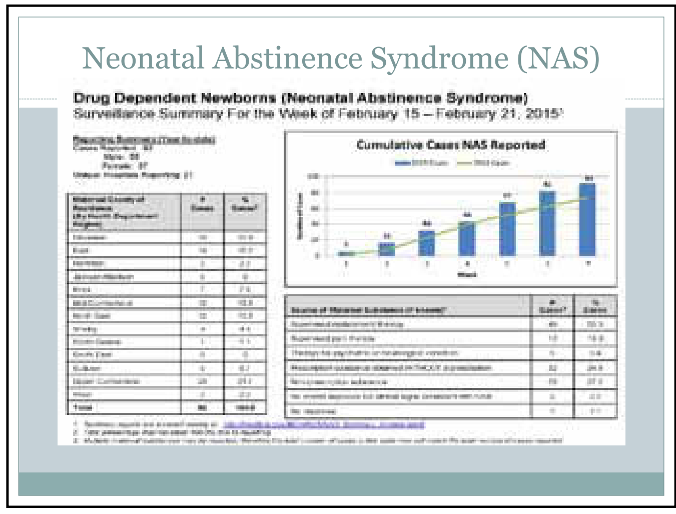
Socioeconomics and Geography

- Medicaid
- Rural

Clinical Characteristics

- Chronic pain
- Substance abuse
- Mental health
- Nonmedical use
- Multiple prescriptions
- Multiple prescribers
- High daily dosage





Overdose Prevention Guidelines

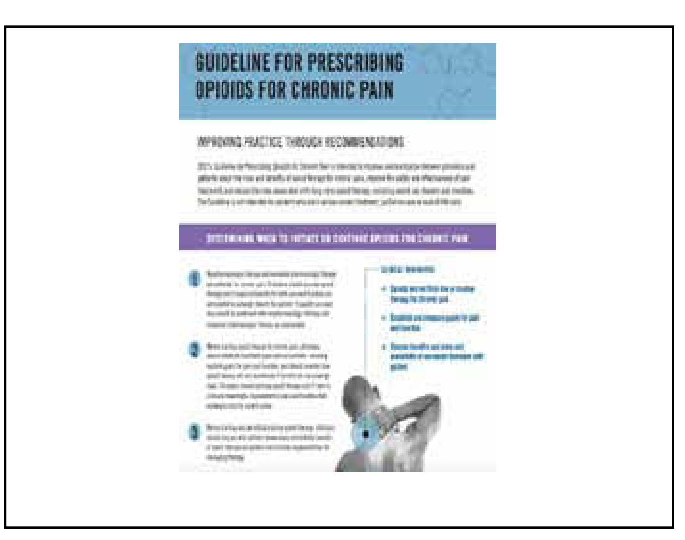
- Follow best practices for responsible painkiller prescribing, including:
- Prescribing the lowest effective dose and only the quantity needed for the expected duration of pain.
- Planning with your patients on how to stop opioids when their treatment is done.
- Providing your patients with information on how to use, store, and dispose of opioids.
- Avoiding combinations of prescription opioids and sedatives unless there is a specific medical indication.

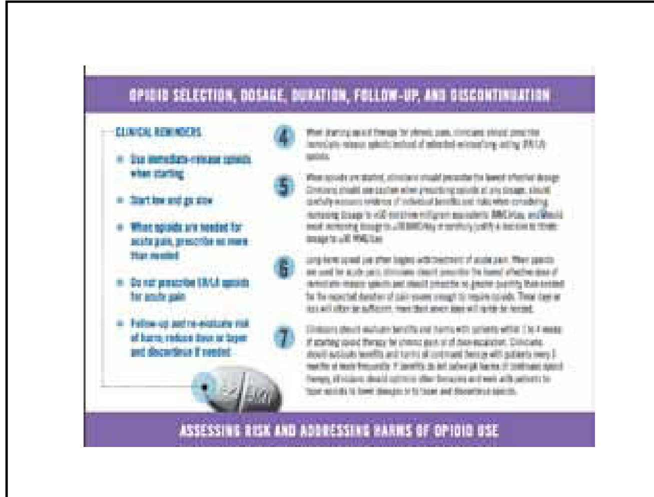
Latest Update: 03/18/2016

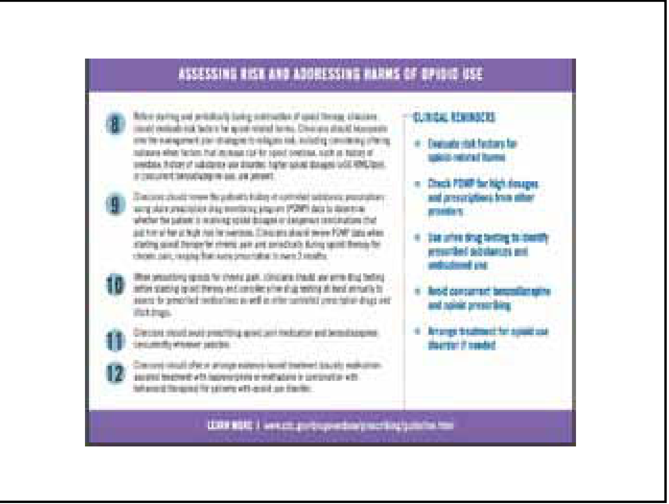
CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN — UNITED STATES, 2016
RECOMMENDATIONS AND REPORTS / MARCH 18, 2016 / 65(1);1–49

CDC Prescribing Guidelines 2016

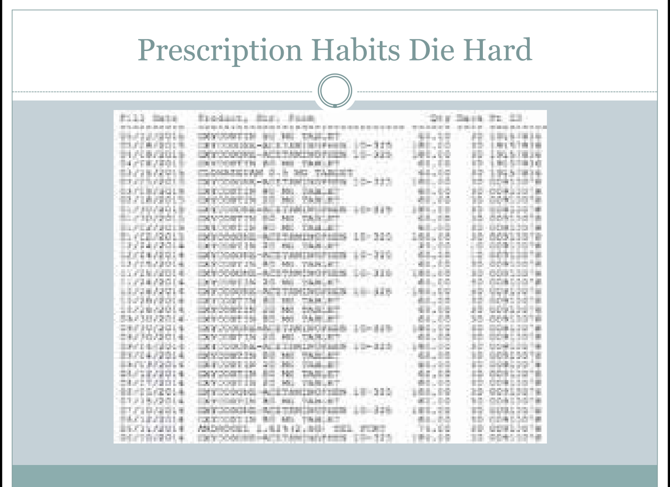
- This guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care.
- The guideline addresses:
  - **1) when to initiate or continue opioids for chronic pain;**
  - **2) opioid selection, dosage, duration, follow-up, and discontinuation; and**
  - **3) assessing risk and addressing harms of opioid use.**







Prescription Habits Die Hard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Benzodiazepine Prescribing

- Florida, Miami-Dade doctors are heavy prescribers of tranquilizers for seniors, report says, Miami Herald, 06/10/2015
- In 2013, the year Medicare started covering benzodiazepines, it paid for nearly 40 million prescriptions, a ProPublica analysis of recently released federal data shows. Generic versions of the drugs — alprazolam (Xanax), lorazepam (Ativan) and clonazepam (Klonopin) — were among the top 32 most-prescribed medications in Medicare Part D that year

Relapse rates for opiate use are high despite available medication-assisted treatment options

Prescription pain relievers that are full μ-opioid receptor agonists are same class of drugs as heroin.

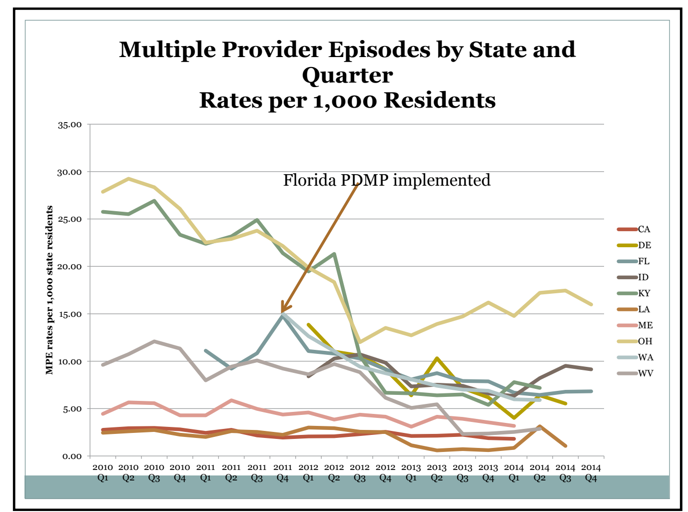
FDA-approved medication-assisted treatments (MAT) for opiate use disorders:
Buprenorphine/naloxone
Methadone
Naltrexone

MAT are adjuncts to evidence-based psychosocial treatments

However, discharges from MAT programs and relapse rates remain high.

Reference: Substance Abuse and Mental Health Services Administration (SAMHSA). *Treatment Episode Data Set (TEDS): 2011. Discharges from Substance Abuse Treatment Services.* Chapter 8. Rockville, MD: SAMHSA, 2014.

Utilization of PDMPs to Identify and Address Problematic Prescribing



Abrupt decline in oxycodone-caused mortality after implementation of Florida's Prescription Drug Monitoring Program.

- BACKGROUND:
  - In Florida, oxycodone-caused deaths declined substantially in 2012. Multiple important law enforcement, pharmaceutical, policy, and public health actions occurred concurrently, including implementation of a statewide Prescription Drug Monitoring Program (PDMP). The effects of the PDMP on oxycodone-caused mortality in Florida were evaluated.
- METHODS:
  - A time-series, quasi-experimental research design with autoregressive integrated moving average (ARIMA) statistical models, including internal and external covariates. Data included 120 repeated monthly observations. Monthly counts of oxycodone-caused deaths, obtained from the Florida Medical Examiners Commission (MEC) was the outcome variable. Models included market-entry of tamper-resistant oxycodone HC1 controlled release tablets (OxyContin(®)), enforcement crackdowns (Operation Pill Nation), and regulation by FL House Bill 7095, measured by the monthly count of Florida pain management clinics closed. Two approaches were used to test the PDMP's hypothesized effect: (1) a binary indicator variable (0=pre-implementation, 1=post-implementation), and (2) a continuous indicator consisting of the number of PDMP queries by health care providers.

Abrupt decline in oxycodone-caused mortality after implementation of Florida's Prescription Drug Monitoring Program.

- RESULTS:
  Oxycodone-caused mortality abruptly declined 25% the month after implementation of Florida's PDMP ($p=0.008$). The effect remained after integrating other related historical events into the model. Results indicate that for a system-wide increase of one PDMP query per health care provider, oxycodone-caused deaths declined by 0.229 persons per month ($p=0.002$).
- CONCLUSIONS:
  This is the first study to demonstrate that the PDMP had a significant effect in reducing oxycodone-caused mortality in Florida. Results have implications for national efforts to address the prescription drug epidemic

Drug Alcohol Depend. 2015 May 1;150:63-8.
Abrupt decline in oxycodone-caused mortality after implementation of Florida's Prescription Drug Monitoring Program.
Delcher C Wagenaar AC, Goldberger BA, Cook RL, Maldonado-Molina MM

What Is an Opioid Overdose?

- **Opioid overdose** happens when a **toxic amount** of an opioid—alone or mixed with other opioid(s), drugs and/or substances—**overwhelms the body's** ability to handle it.
- Many opioid-related overdoses result from **mixing** prescription painkillers or heroin with benzodiazepines (benzos), cocaine and/or alcohol.

What Leads to Overdose Death?

- **Respiratory failure** – lack of sufficient oxygen in the blood
- Vital organs like the heart and brain start to fail
- Leads to unconsciousness, coma, death

Surviving an opioid overdose =

BREATHING and OXYGEN

Recognizing the Signs & Symptoms of an Opioid Overdose

- Loud snoring or gurgling noises
- Body very limp
- Unresponsive
- Skin pale/gray, clammy
- Lips/fingertips turn blue(ish)
- Pulse slow or erratic
- Breathing very slow, shallow, or not at all
- Unconscious

Responding to an Opioid Overdose

1. **Rouse and Stimulate**
2. **Call 9-1-1**
3. **Give Naloxone**
4. **Further Resuscitation**
5. **Care for the Person**

Maryland ORP Core Curriculum

Step 1: Rouse & Stimulate

Noise: Shake person's shoulders a

"[Name!] Are you all right? Wake up!"

Pain: If no answer, do a **sternal rub**

Make a fist, rub your knuckles firmly up and down the breast bone.

Maryland ORP (Overdose Response Core Curriculum

Step 2: Call 9-1-1: Why?

*Get **emergency medical help** for someone experiencing an overdose!*

1. May have **complications** or **other health problems**.
2. **Naloxone** is only **temporary**.
3. May need to give **additional doses of naloxone**.
4. May be a **non-opioid overdose** situation.

Call 9-1-1: What to Say

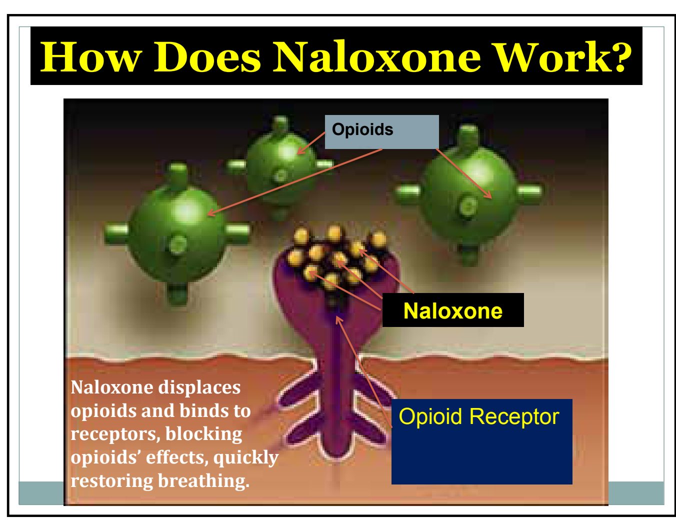
- Tell 9-1-1 operator:
  - ✓ **Where you are**
  - ✓ **What you observe** about the person in distress:
    e.g., gurgling noises, turning blue, won't wake up
- Tell emergency responder on site:
  - ✓ **Drugs**/substances the person used
  - ✓ **Naloxone** administered – how much/when.

Step 3: Give Naloxone

What is Naloxone? (Narcan®)

- Reverses opioid overdose by **restoring breathing**
- No potential for abuse or getting high
- No effect on someone who hasn't taken opioids
- Side effects are minimal and rare
- Safe for children and pregnant women
- Intramuscular, intranasal or intravenous
- Wears off in 30 - 90 minutes

Naloxone is only effective in reversing opioid overdoses



Naloxone Storage & Disposal

Storage:

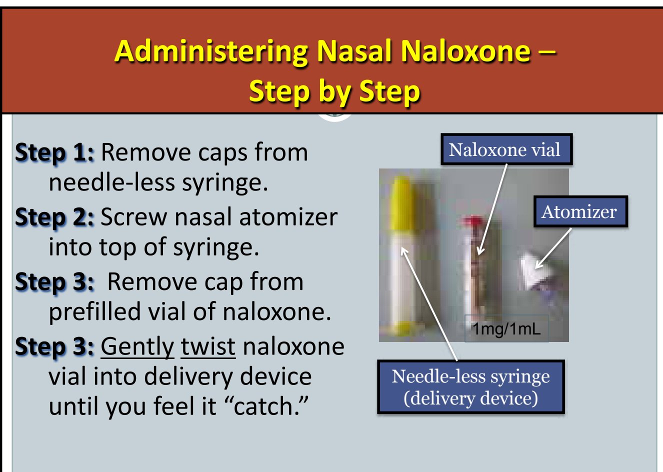
- Do not attach naloxone to delivery device until ready to use
- Store naloxone in original package at room temperature; avoid exposure to light
- Keep in a safe place away from children & pets, but easy to access in case of emergency

Expiration:

- Naloxone loses its effectiveness over time
- Check expiration date on label

Disposal:

- Check with a local health department or pharmacy about properly disposing of expired naloxone



Administering Nasal Naloxone – Step by Step

Step 5:

Tilt back the head so the naloxone will not run out of the person's nose.

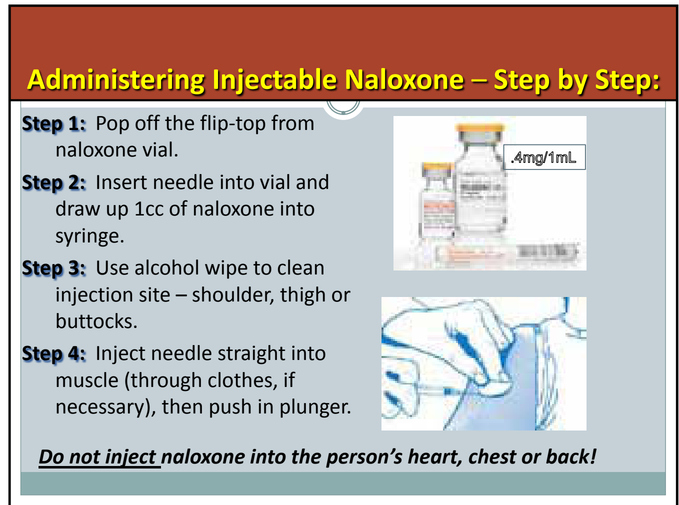
Step 6: Spray **one-half** (1cc) of the naloxone up each nostril.

Administering Nasal Naloxone – Step by Step

Step 7: Allow 1-3 minutes for the naloxone to work. Continue resuscitation as necessary.

Step 8: If breathing is not restored after 2-3 minutes, ***give another dose*** of naloxone (see **Steps 5 & 6**). Continue resuscitation as necessary.

Step 9: Stay with the person and provide care as directed until medical help arrives.

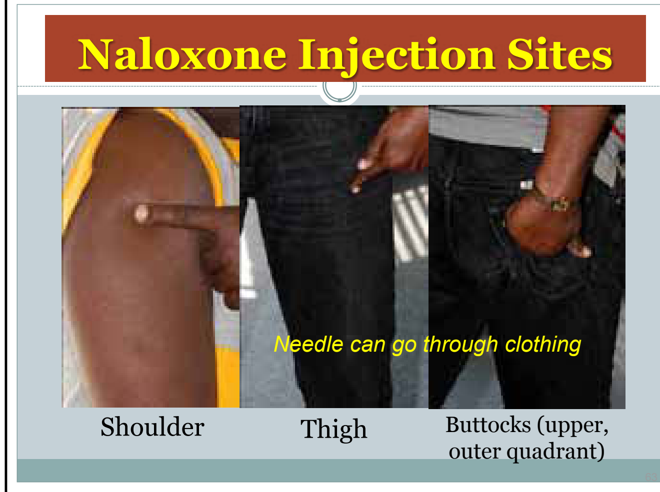


Administering Injectable Naloxone – Step by Step

Step 5: Allow 1-3 minutes for the naloxone to work. Continue resuscitation as necessary.

Step 6: If breathing is not restored after 2-3 minutes, ***give another dose*** of naloxone (see **Steps 1 - 4**).
Continue resuscitation as necessary.

Step 7: Stay with person and provide care as directed until medical help arrives.



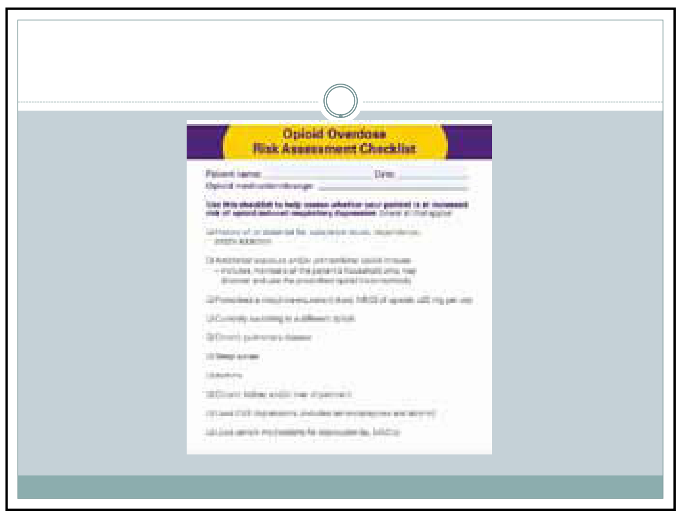
Naloxone Distribution

- Who should receive naloxone prescriptions?
  - Suspected history of illicit substance or prescription opioid abuse
  - Initiation of treatment for addiction
  - Patients recently released from emergency facility after overdose treatment
  - With release from incarceration
  - High doses of prescription opioids
  - Individuals likely to witness an overdose
  - Rural areas

Naloxone Dispensing

- Syringe access programs, drug treatment centers, correctional facilities
- First responders – EMS, firefighters, police officers
- Prescribers – emergency department
- World Health Organization recommends wider distribution of naloxone

WHO Community management of opioid overdose. 2014
http://intranasal.net/Peer%20Reviewed%20literature/WHO-Community%20Management%20of%20Opioid%20Overdose%202014.pdf



Opioid Overdose
Risk Assessment Checklist

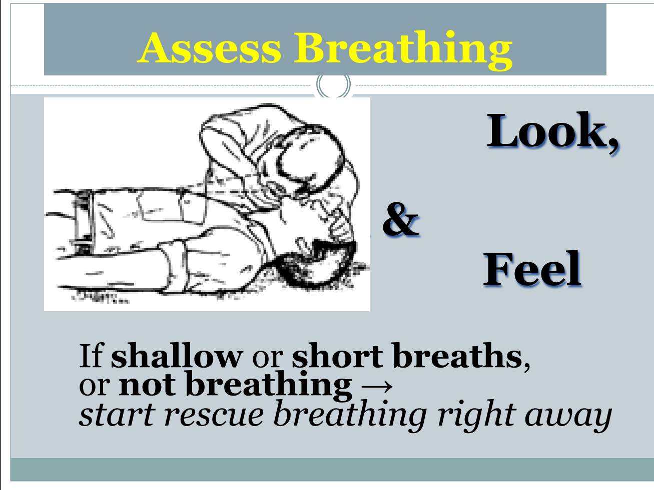
Patient name: Date:

Step 4: Further Resuscitation

Assess breathing: if the person is not breathing, or if breath is shallow or short,

- Give **rescue breaths.**
  - OR
- If you are trained in cardiopulmonary resuscitation (CPR), administer **traditional CPR**, chest compressions with rescue breaths.
  - OR
- **Follow the 9-1-1 dispatcher's instructions.**

Continue until the person wakes up or medical help arrives.



Rescue Breathing Instruction

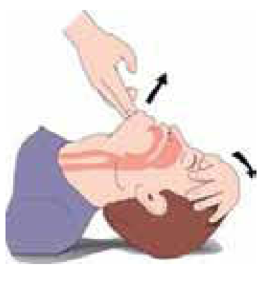
Rescue breathing *is the quickest way to get oxygen into the body and one of the most important things you can do to prevent someone from dying from an opioid overdose.*

Rescue Breathing – Step by Step

Step 1: Lay the person on his/her back on a flat surface.

Step 2: Tilt the chin to open the airway.

Step 3: Remove anything blocking the airway.



Rescue Breathing – Step by Step

Step 4: Pinch the person's nose closed completely.

Step 5: Cover his/her mouth with your mouth and **blow 2 regular breaths** about 1 second each.

Step 5: Care for the Person

- **Stay with the person until medical help arrives**.
- If s/he is unable to sit up, put person in **recovery position**.
- Keep person **calm** and encourage him/her not to take more opioids.
- If overdose re-occurs, give **another dose** of naloxone.

Care for the Person

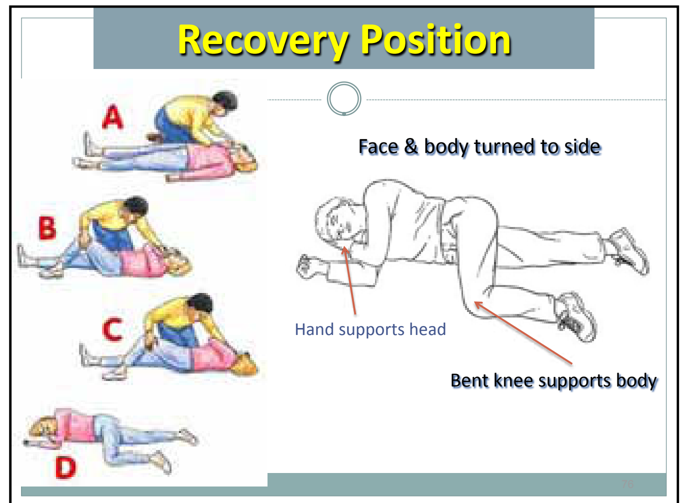
After receiving naloxone, a person may:

- Feel **physically ill**/vomit.
- **Experience withdrawal** symptoms, which can be unpleasant, but not life-threatening.
- Become **agitated and upset** due to withdrawal symptoms or coming off high.
- Have a **seizure**, though this is rare.

Recovery Position

If you have to leave the person—*even briefly*—put him/her into the **recovery position**.

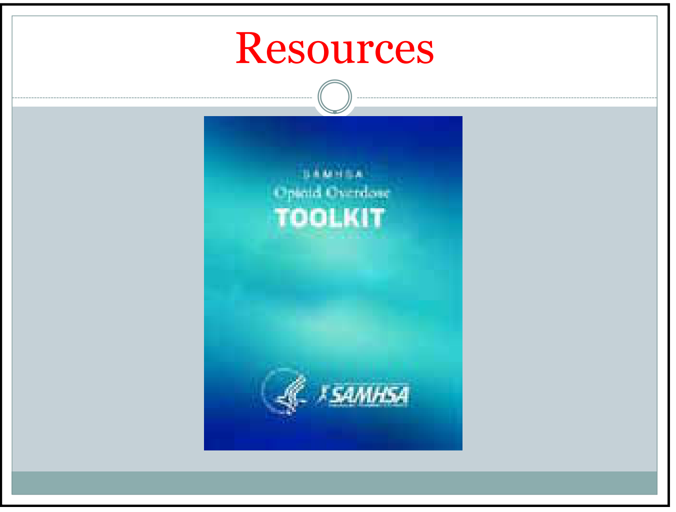
This keeps the **airway clear** and **prevents choking/aspiration** if vomiting occurs.

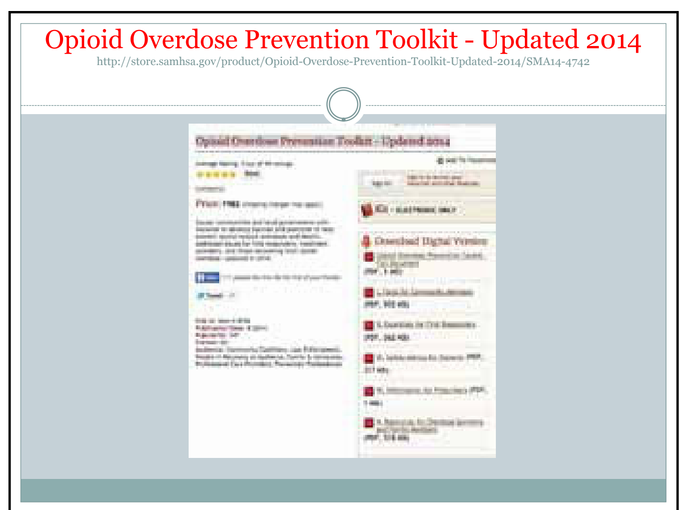


How NOT To Respond to an Opioid Overdose

Anecdotal Remedy		Possible Consequence(s)
Use ice to cool down body	→	Slowed heart rate, arrhythmia
Put person in bath/shower	→	Drowning
Hit/slap or burn fingers/feet	→	Bruising, broken bones, infection,
Give drink/induce vomiting	→	Choking to death
Inject person with cocaine, salt water, milk, epinephrine	→	High blood pressure, infection

Resources





Summary

- Recognize that we are facing an epidemic of opioid overdose deaths.
- We need to identify and recognize risk factors for opioid overdose.
- Implement overdose prevention guidelines.
- PDMP implementation reduce opioid overdose.
- Utilize and deploy Naloxone preparations to treat overdose.

SELF EVALUATION

Understanding, Preventing and Treating Opioid Overdose

1. True/False - Heroin use is increasing rapidly across the United States among all age, race, income and ethnic groups and deaths from heroin-related overdoses nearly quadrupled between 2002 and 2013.

2. True/False - Drug overdose was the leading cause of injury death in 2013. Among people 25 to 64 years old, drug overdose caused more deaths than motor vehicle traffic crashes.

3. True/False - Hispanics comprise the large majority of prescription opioids overdose deaths.

4. Prescription narcotics overdose risk factors include:

a. Chronic pain
b. Substance abuse
c. Mental health
d. Nonmedical use
e. Multiple prescriptions
f. Multiple prescribers
g. High daily dosage
h. All of the above

5. Overdose prevention measures include:

a. Follow best practices for responsible painkiller prescribing, including:
b. Prescribing the lowest effective dose and only the quantity needed for the expected duration of pain.
c. Planning with your patients on how to stop opioids when their treatment is done.
d. Providing your patients with information on how to use, store, and dispose of opioids.
e. Avoiding combinations of prescription opioids and sedatives unless there is a specific medical indication.
f. All of the above

6. True/False - The implementation of a Prescription Drug Monitoring Program (PDMP) in Florida demonstrated that the PDMP had a significant effect in reducing oxycodone-caused mortality.

7. True/False - Many opioid-related overdoses result from mixing prescription painkillers or heroin with benzodiazepines (benzos), cocaine and/or alcohol.

Answer Key: 1. T, 2. T, 3. F, 4. H, 5. F, 6. T, 7. T

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The SPRINT Trial: Should it Change the Way You Practice?

Where to Begin……2007

"The hypothesis that a lower SBP goal (e.g., <120 mm Hg) would reduce clinical events more than a standard goal was designated by a NHLBI expert panel in 2007 as the most important hypothesis to test regarding the prevention of HTN-related complications among patients without diabetes."

Wright JT et al The SPRINT Research Group NEMJ 2015;373(22):2103-2116

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 NOVEMBER 26, 2015 VOL. 373 NO. 22

A Randomized Trial of Intensive versus Standard Blood-Pressure Control

The SPRINT Research Group*

SPRINT: The Agenda

- Is BP lowering to <120 mm Hg vs <140 mm Hg EFFECTIVE?
- Is BP lowering to <120 mm Hg vs <140 mm Hg SAFE?
- If other major clinical trials disagree, which path do we follow?

SPRINT: EFFECTIVE?

If Intensive BP lowering (<120 mm Hg) is EFFECTIVE compared to standard BP lowering (<140 mm Hg), it should provide:

- Reduction in MACE (fatal/nonfatal stroke + MI)
  - Statistically significant
  - Clinically relevant

SPRINT: SAFE?

If Intensive BP lowering (<120 mm Hg) is SAFE compared to standard BP lowering (<140 mm Hg), it should provide:

- No *meaningful* increment in *serious* AEs
- No *meaningful* increment in burden of other AEs
- Sufficiently reasonable accessibility (e.g. $$, regimen complexity) that incremental gains are not outweighed by 'costs'

SPRINT Abstract

BACKGROUND

"The most appropriate targets for SBP to reduce CV morbidity and mortality among persons without diabetes remain uncertain."*

*emphasis added

Wright JT et al The SPRINT Research Group NEMJ 2015;373(22):2103-2116

SPRINT Abstract

METHODS

- Non-diabetic adults (n = 9,361)
- SBP >130 mmHg + 'high CV Risk'
- Randomized to SBP <140 mm Hg ('standard' Rx) vs <120 mm Hg ('intensive' Rx)
- 1⁰ Outcome (composite): MACE
  - MACE = MI, ACS, CVA, HF, CV death

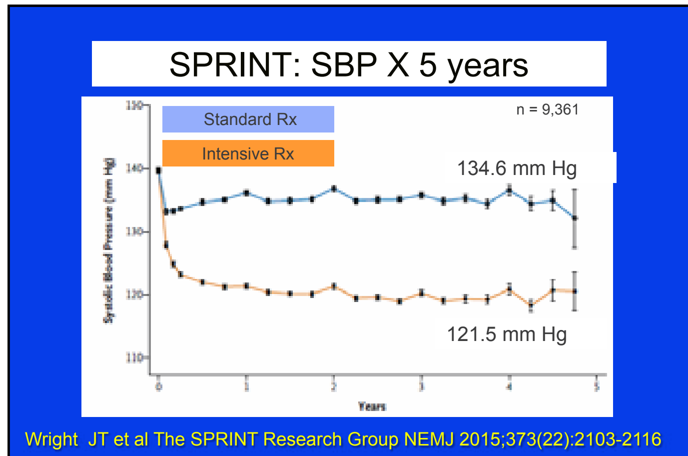
Wright JT et al The SPRINT Research Group NEMJ 2015;373(22):2103-2116

SPRINT Inclusion as 'High Risk' Most Common Criteria

- Age ≥ 50 yrs (mean = 67.9 yrs; 28% > 75 yrs)
- CKD
- CVD
  - Hx of confirmed CVD (not stroke)
  - Framingham 10-yr CV risk ≥ 15%
  - Coronary Calcium Score >400
  - ABI < 0.9
  - LVH

Wright JT et al The SPRINT Research Group NEMJ 2015;373(22):2103-2116

SPRINT: SBP X 5 years



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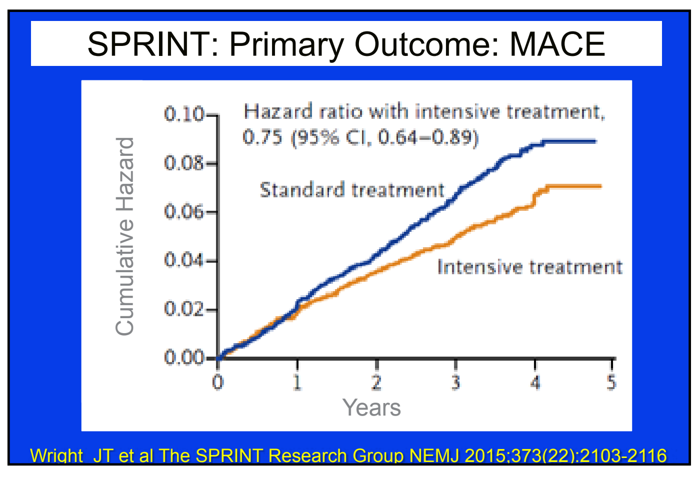
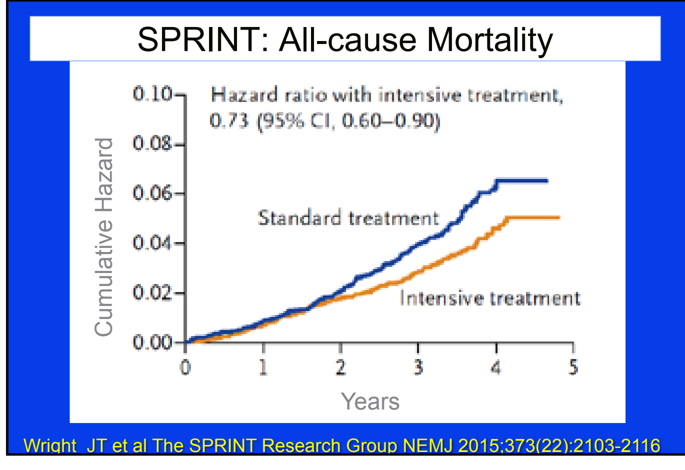
SPRINT: Primary Outcome: MACE



Wright JT et al The SPRINT Research Group NEMJ 2015;373(22):2103-2116

SPRINT: All-cause Mortality



Wright JT et al The SPRINT Research Group NEMJ 2015;373(22):2103-2116

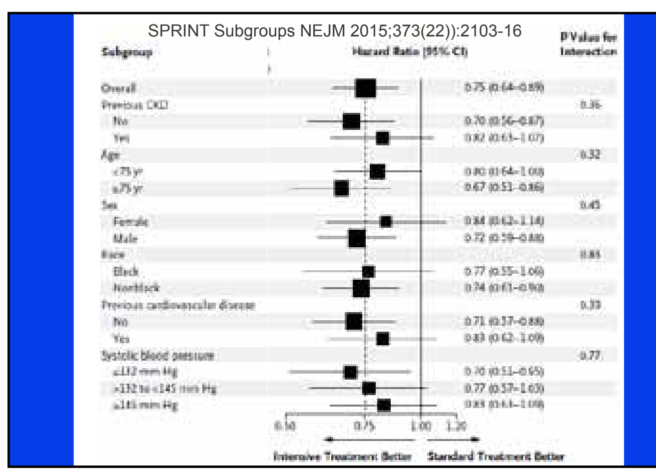
SPRINT

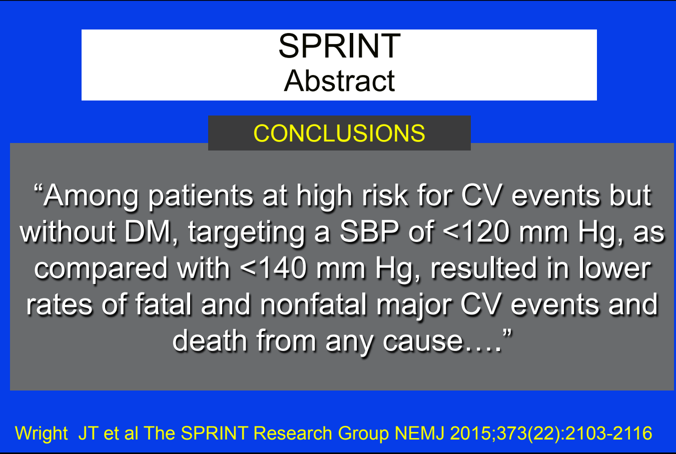
RESULTS (at median 3.26 yrs)

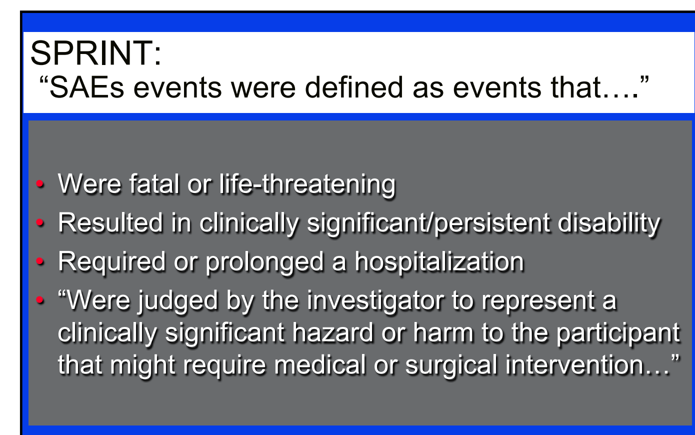
	Standard Rx	Intensive Rx	HR	p
SBP mm Hg	136.2	121.4		
1⁰ Outcome	2.19%/yr	1.62%/yr	0.75	< 0.001
All cause mortality	1.40%/yr	1.03%/yr	0.73	0.003
Stroke	1.5%/yr	1.3%/yr	0.47	0.5
Serious AEs*	2.5%	4.7%	1.88	<0.001

(*hypotension, syncope, electrolyte abnormalities, acute kidney injury possibly or definitely drug-related)

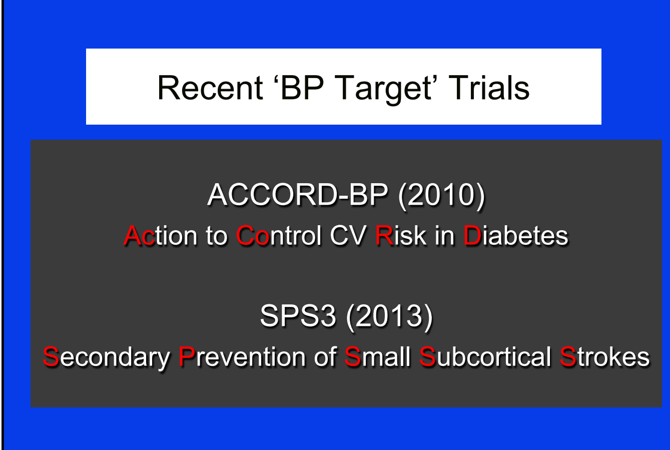
Wright JT et al The SPRINT Research Group NEMJ 2015;373(22):2103-2116

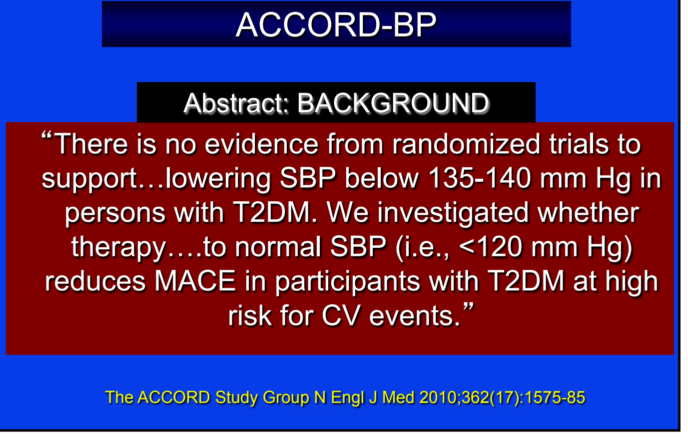

SPRINT Subgroups NEJM 2015;373(22)):2103-16
Subgroup
Hazard Ratio (95% CI)
P Value for Interaction
Overall
Previous CKD
Age
Sex
Female
Male
Race
Black
Nonblack
Previous cardiovascular disease
Systolic blood pressure
0.50
0.75
1.00
1.20
Intensive Treatment Better
Standard Treatment Better

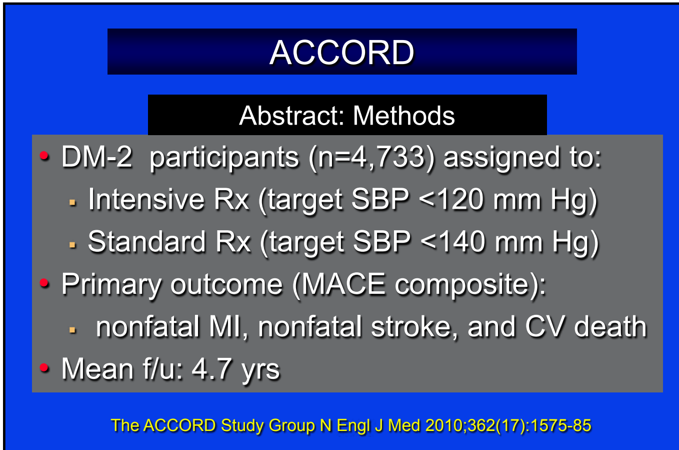

SPRINT
Abstract
CONCLUSIONS
"Among patients at high risk for CV events but without DM, targeting a SBP of <120 mm Hg, as compared with <140 mm Hg, resulted in lower rates of fatal and nonfatal major CV events and death from any cause…."
Wright JT et al The SPRINT Research Group NEMJ 2015;373(22):2103-2116


SPRINT
Abstract
CONCLUSIONS
" ….although significantly higher rates of some adverse events were observed in the intensive treatment group."
*emphasis added
Wright JT et al The SPRINT Research Group NEMJ 2015;373(22):2103-2116

SPRINT:
"SAEs events were defined as events that…."
Were fatal or life-threatening
Resulted in clinically significant/persistent disability
Required or prolonged a hospitalization
"Were judged by the investigator to represent a clinically significant hazard or harm to the participant that might require medical or surgical intervention…"
Wright JT et al The SPRINT Research Group NEMJ 2015;373(22):2103-2116


Recent 'BP Target' Trials
ACCORD-BP (2010)
Action to Control CV Risk in Diabetes
SPS3 (2013)
Secondary Prevention of Small Subcortical Strokes


ACCORD-BP
Abstract: BACKGROUND
"There is no evidence from randomized trials to support…lowering SBP below 135-140 mm Hg in persons with T2DM. We investigated whether therapy….to normal SBP (i.e., <120 mm Hg) reduces MACE in participants with T2DM at high risk for CV events."
The ACCORD Study Group N Engl J Med 2010;362(17):1575-85



ACCORD

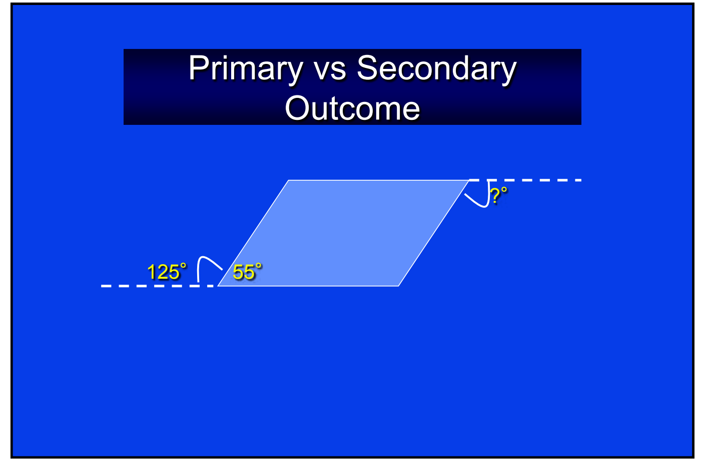
Abstract: Results (Intensive vs Standard)

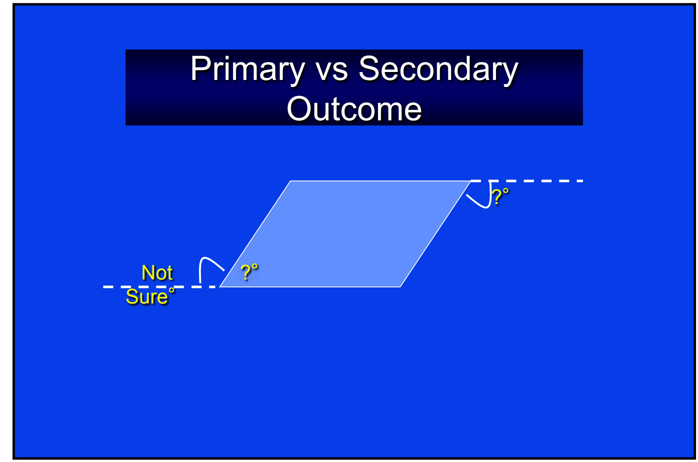
	Standard	Intensive	HR	p
SBP mm Hg	133.5	119.3		
1^0 Outcome (MACE %/yr)	2.09%	1.87%	0.88	0.20
2^0 Outcome (Stroke %/yr)	0.53%	0.32%	0.59	0.01
All-cause mortality	1.19%	1.28%	1.07	0.55
Serious AEs	1.3%	2.7%		<0.001

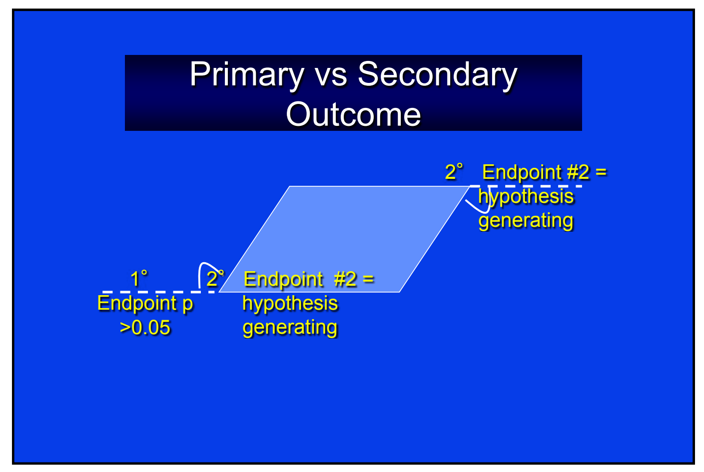
The ACCORD Study Group N Engl J Med 2010;362(17):1575-85

EBM: 2^0 Outcome(s) When 1^0 Outcome Fails

If a trial fails to achieve its primary outcome, otherwise 'positive' secondary outcomes must be instead considered 'hypothesis generating' (i.e., unconfirmed)







ACCORD: Methods

- Non-blinded PRCT (n=10,251) at 77 sites
- Randomization:
  - ALL subjects: ACCORD glycemia
  - ±HALF subjects (5, 518): ACCORD lipid
  - ±HALF subjects (4,733): ACCORD BP
- Sponsor: NHLBI

The ACCORD Study Group N Engl J Med 2010;362(17):1575-85

ACCORD Eligibility: Inclusions

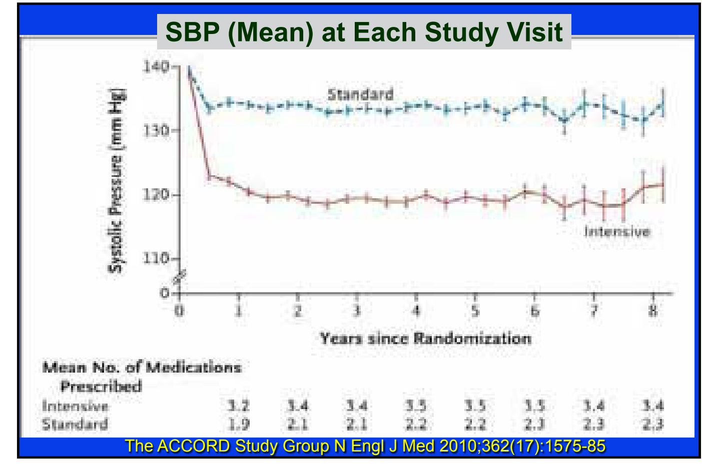
- DM2 with A1c ≥7.5%
- Age ≥ 40 + CVD or Age ≥ 55 with ≥ 1
  - Anatomical evidence atherosclerosis
  - Albuminuria
  - LVH
  - ≥2 CV RFs (lipids, HTN, Smoking, Obesity)
- SBP 130-180 mmHg on ≤3 meds + <1g/24 hr albuminuria

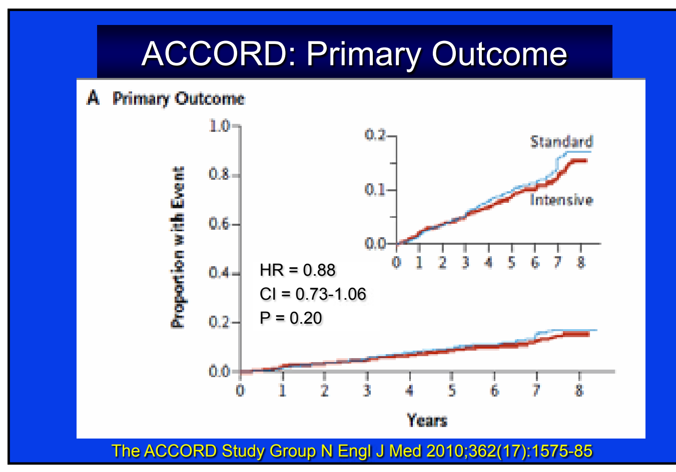
The ACCORD Study Group N Engl J Med 2010;362(17):1575-85

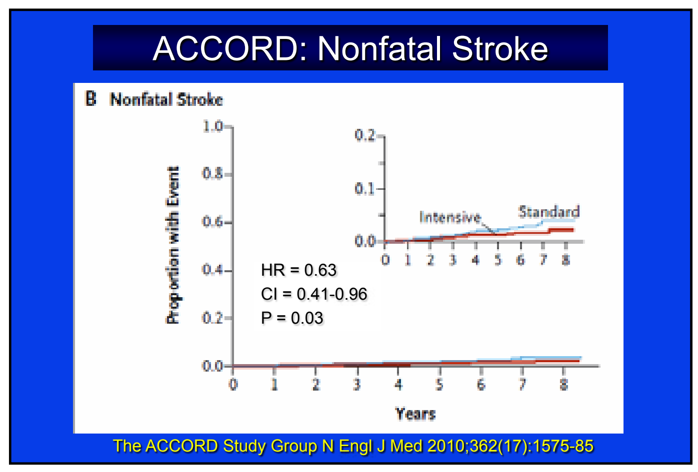
ACCORD Trial Procedures

- Intensive Rx: Goal SBP < 120 mmHg
- Standard Rx: Goal SBP < 140 mmHg
- Rx: as per provider preference
- Followup:
  - Intensive: Q1m X 4 then Q2m
  - Standard: month 1 and 4, then Q4m

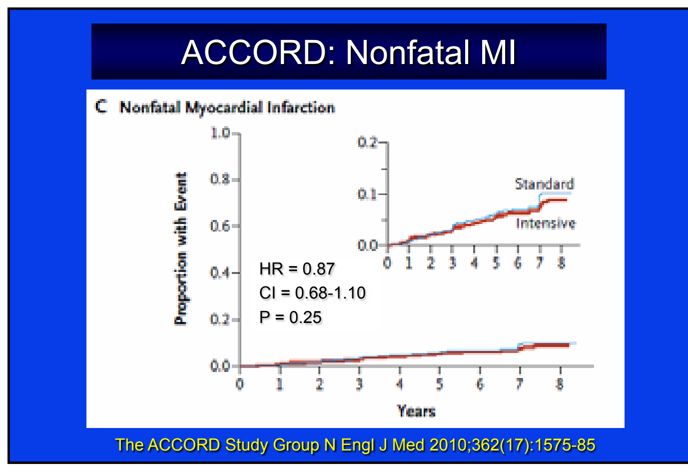
The ACCORD Study Group N Engl J Med 2010;362(17):1575-85





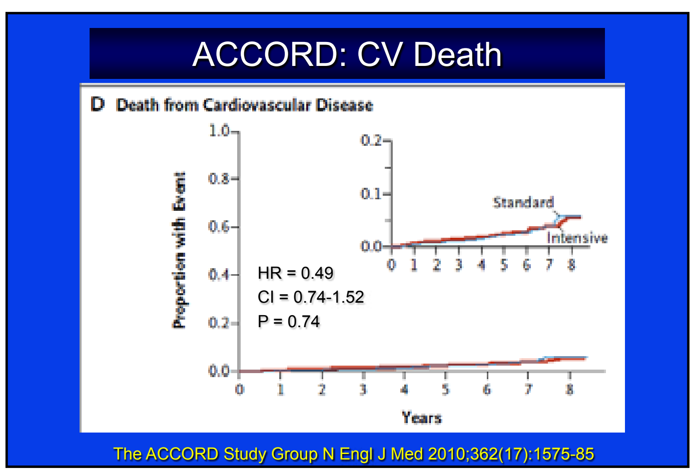


ACCORD: Nonfatal MI



The ACCORD Study Group N Engl J Med 2010;362(17):1575-85

ACCORD: CV Death



The ACCORD Study Group N Engl J Med 2010;362(17):1575-85

ACCORD: Outcomes

	Intensive	Standard	HR
Primary	208 (1.87)	237 (2.09)	0.88 (0.73-1.06)
Nonfatal MI	126 (1.14)	146 (1.28)	0.87 (0.68-1.10)
Total Stroke	36 (0.32)	62 (0.53)	0.59 (0.39-0.89)*
Nonfatal Stroke	34 (0.30)	55 (0.47)	0.63 (0.41-0.96)*
All-cause mortality	150 (1.28)	144 (1.19)	1.07 (0.85-1.35)
CV Death	60 (0.52)	58 (0.49)	1.06 (0.74-1.52)
ACS	253 (2.31)	270 (2.41)	0.94 (0.79-1.12)
Fatal/nonfatal HF	83 (0.73)	90 (0.78)	0.94 (0.70-1.26)

The ACCORD Study Group N Engl J Med 2010;362(17):1575-85

ACCORD: Adverse Events

* P <0.05 #(%)	Intensive Rx	Standard Rx
Hypotension	17 (0.7)	1 (0.04)*
Syncope	12 (0.5)	5 (0.21)
Bradycardia/arrhythmia	12 (0.5)	3 (0.13)*
Angioedema	6 (0.3)	4 (0.17)
Hyperkalemia	9 (0.4)	1 (0.04)*
Renal Failure	5 (0.2)	1 (0.04)
eGFR < 30	99 (4.6)	52 (2.3)*
Macroalbuminuria	143 (6.6)	192 (8.7)*
ESRD/dialysis	59 (2.5)	58 (2.4)

The ACCORD Study Group N Engl J Med 2010;362(17):1575-85

ACCORD: Discussion

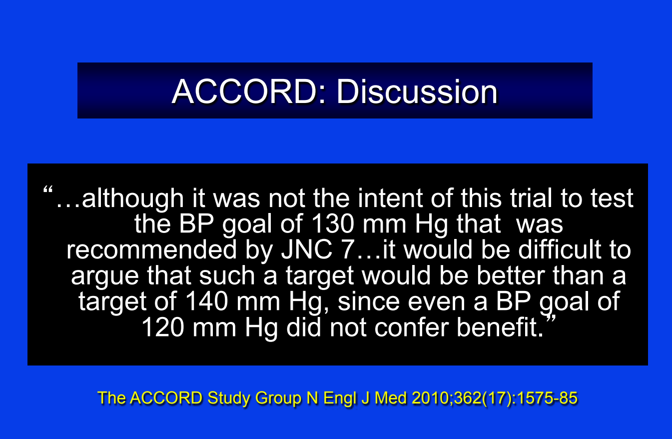
"Intensive antihypertensive therapy…did not significantly reduce the primary CV outcome or the rate of death from any cause, despite…a significant and sustained difference…in mean SBP."

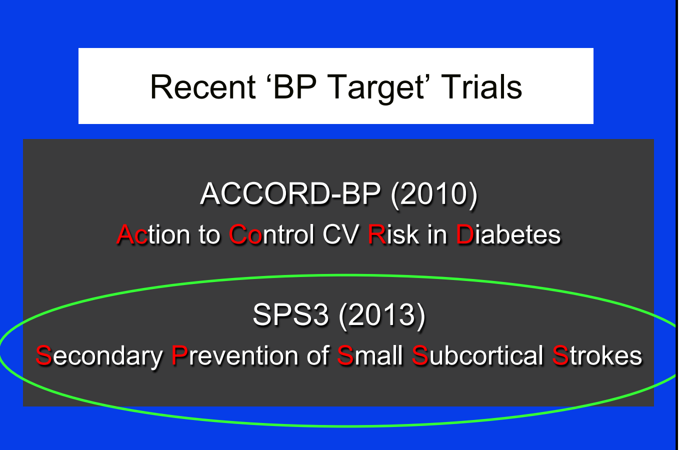
The ACCORD Study Group N Engl J Med 2010;362(17):1575-85

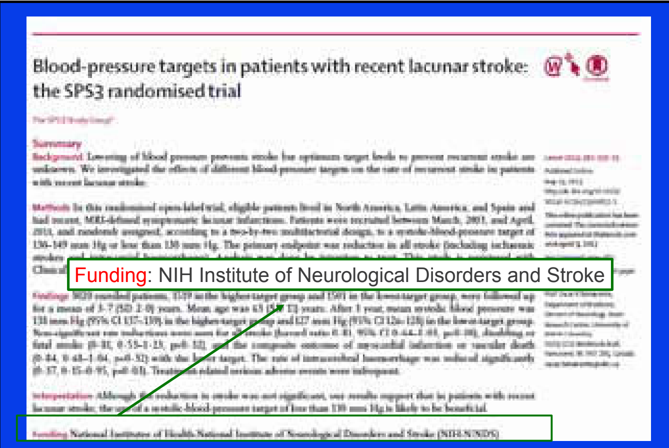
ACCORD: Discussion

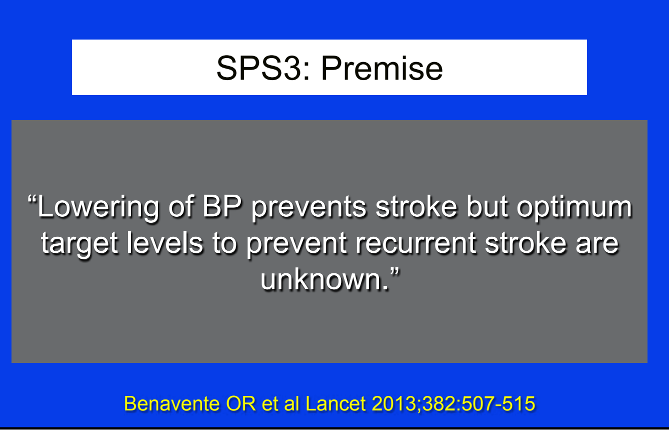
"There were some signals of possible harm…including a rate of serious adverse events that was significantly higher in the intensive therapy group…."

The ACCORD Study Group N Engl J Med 2010;362(17):1575-85






Blood-pressure targets in patients with recent lacunar stroke: the SPS3 randomised trial



SPS3: Purpose

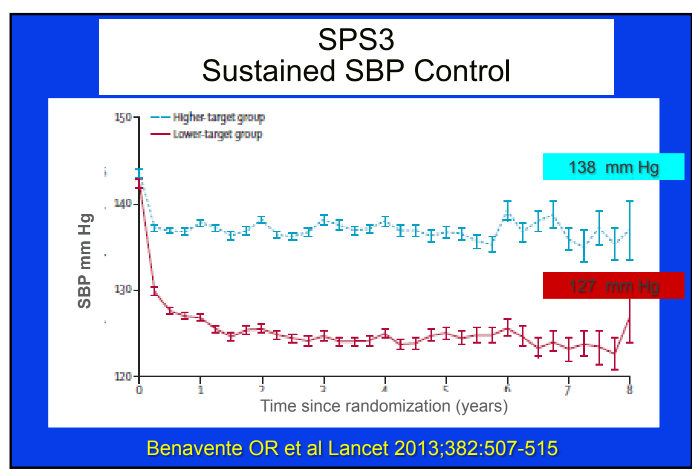
"We investigated the effects of different BP targets on the rate of recurrent stroke in patients with recent lacunar stroke."

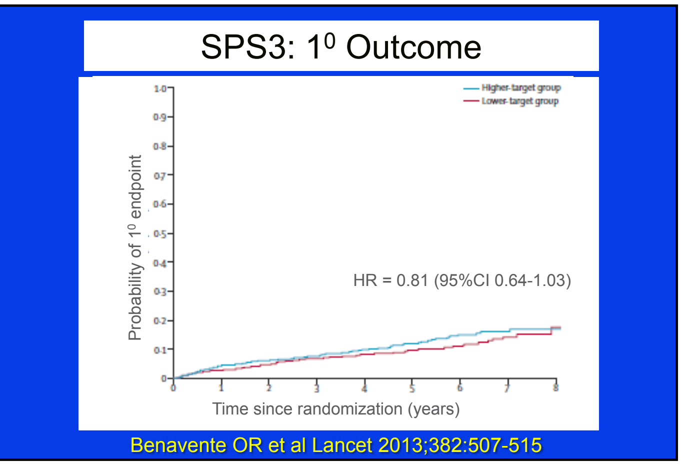
Benavente OR et al Lancet 2013;382:507-515

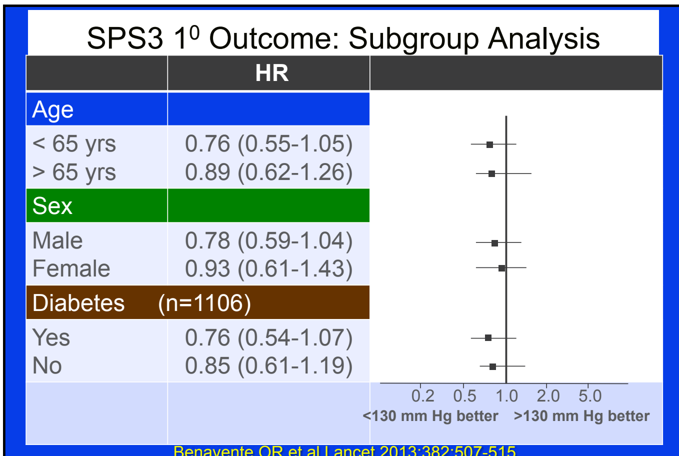
SPS3

- Study: PROL Trial (n=3,020)
- Inclusion:
  - HTN
  - Recent lacunar stroke (MRI)
- Rx arms: SBP <130 vs <140 mm Hg
- Rx as per clinician preference X 3.7 yrs
- Primary Outcome: New Stroke

Benavente OR et al Lancet 2013;382:507-515






SPS3 1⁰ Outcome: Subgroup Analysis

	HR
Age	
< 65 yrs	0.76 (0.55-1.05)
> 65 yrs	0.89 (0.62-1.26)
Sex	
Male	0.78 (0.59-1.04)
Female	0.93 (0.61-1.43)
Diabetes (n=1106)	
Yes	0.76 (0.54-1.07)
No	0.85 (0.61-1.19)

SPS3: Results
What it Said Instead

"Although the reduction in stroke was not significant, our results support that in patients with recent lacunar stroke, the use of a SBP target of <130 mm Hg is likely to be beneficial."

Benavente OR et al Lancet 2013;382:507-515

SPS3: Results
What it SHOULD Have Said

The reduction in stroke was not significant.

Benavente OR et al Lancet 2013;382:507-515

Bottom Line

- SPRINT: SBP < 120 better than <140 (NOT DM) but at a cost
- ACCORD: SBP <120 NOT better than <140 (DM)
- SPS3: SBP < 130 NOT better than <140 (DM & non-DM)

SPRINT: Issues Raised

- Currently ± 50% HTN <140/90 mm
- T2DM BP Goal? SPRINT vs SPS3 vs ACCORD
- SPRINT
  - 1^0 Outcome: absolute risk reduction = 0.54%
  - Serious AEs: absolute risk *increase* = 2.2%
  - No reduction in stroke (p= NS): why?
  - Generalizability: Younger HTN folks?

Wright JT et al The SPRINT Research Group NEMJ 2015;373(22):2103-2116

So, What Do I Advise Resident Physicians?

- Know and practice based on critical clinical trials and guidelines: whether successes or adverse events occur, your position is sound
- Non-DM: get to <120 mm Hg if it is possible with minimal burden
- DM: continue with <140 mm Hg. If <130 mm already attained, no reason to 'back off' if minimally burdensome
- Stay Tuned

SELF EVALUATION

The SPRINT Trial: Should it Change the Way You Practice?

1. The hypothesis tested in SPRINT was
   a. SBP <120 mm Hg provides better CV outcomes than SBP <140 mg Hg
   b. DBP < 80 mm Hg provides better outcomes than DBP <90 mm Hg
   c. Rapid control of HTN (within 3 months) is superior to standard (3-6 months)
   d. Home BP measurement is a better predictor of CV outcomes than office BP

2. Which of the following patient populations was EXCLUDED from the SPRINT trial
   a. Persons over 75 years of age
   b. Diabetics
   c. Women
   d. Smokers

3. The greatest relative risk reduction demonstrated in SPRINT was seen in reference to
   a. Carotid intima-media thickness
   b. CV mortality
   c. All-cause mortality
   d. Stroke

4. The treatments used to control BP in SPRINT were
   a. An ACE inhibitor + Calcium Channel Blocker
   b. A Beta Blocker + Diuretic
   c. An ARB + Diuretic
   d. Whichever agents investigators preferred

5. Serious adverse events were seen with
   a. Less frequency in the intensive treatment arm
   b. The same frequency in the intensive treatment arm as the comparator
   c. Greater frequency in the intensive treatment arm
   d. There were no serious adverse events

6. The results of SPRINT showed that lower BP was associated with
   a. A reduction in stroke that was not statistically significant
   b. A reduction in stroke that was highly significant reduction
   c. Worsening of ischemic stroke due to a "J-curve" effect
   d. An increase in hemorrhagic stroke

7. The results of the ACCORD-BP trial
   a. Confirm the SPRINT results that lower SBP is better for CV outcomes
   b. Conflict with SPRINT by suggesting that lower SBP may worsen CV outcomes
   c. Confirm stroke outcomes as seen in SPRINT
   d. Are not comparable because SPRINT used different meds to treat BP

8. The results of SPS3 trial
   a. Confirm that SBP <130 mm HG reduces stroke compared to < 140 mm Hg
   b. Found strong stroke risk reduction in the diabetic subgroup
   c. Found no stroke risk reduction in the diabetic subgroup
   d. Demonstrated the safety of nebivolol for hypertension

9. JNC 8 suggests that the goal BP for adults < 65 years with T2DM is
   a. SBP <120 mm Hg
   b. SBP < 130 mm Hg
   c. SBP < 140 mm Hg
   d. SBP < 150 mm Hg

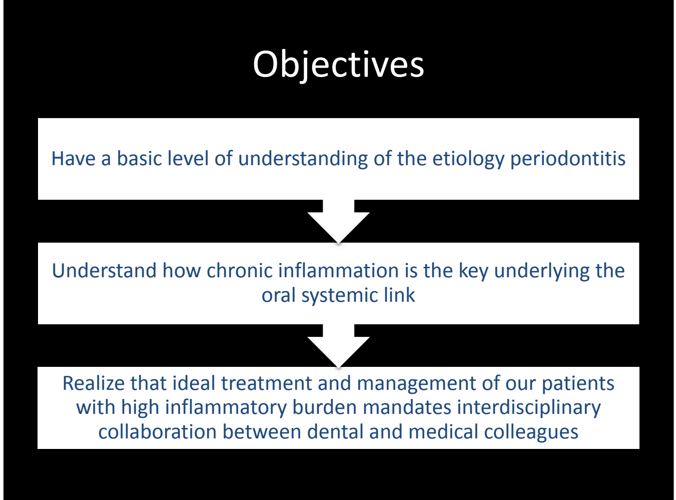
Answer Key: 1. A, 2. B, 3. C, 4. D, 5. C, 6. A, 7. B, 8. C, 9. C

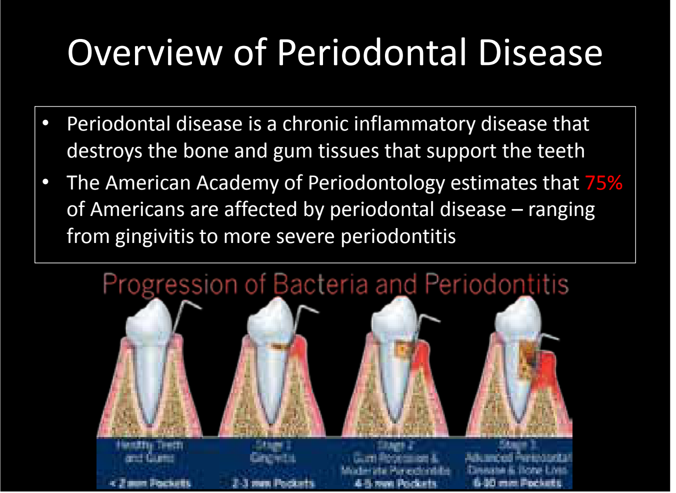
Whitney D. Weiner, DDS, MS

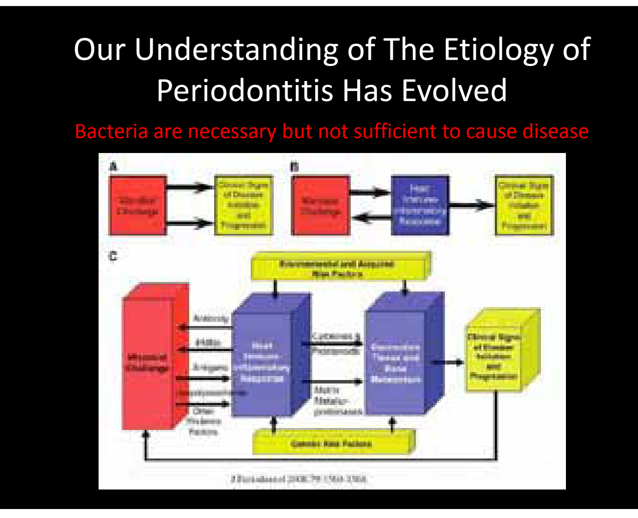
Whitney D. Weiner, DDS, MS, of Birmingham, Michigan, is a board certified periodontist and Diplomate of the American Board of Periodontology. Her master's research evaluating how inflammation and genetic susceptibility to disease contribute to overall periodontal risk has been recognized at the national level. Dr. Weiner runs a private periodontal and dental implant specialty practice and practices periodontics in the broadest sense; from treating gum disease and rebuilding lost gum and bone, to full mouth rehabilitation with dental implants utilizing the latest technologies available. She is licensed to practice in three countries and is a frequent presenter to both dentist and physician audiences. Dr. Weiner is also a speaker for Dentsply Friadent.

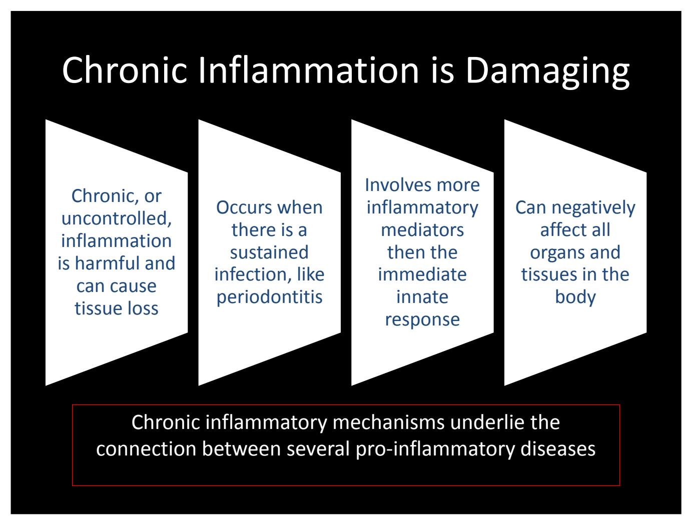
You may contact Dr. Weiner with your questions and comments at drweiner@pristineperioimplants.com.

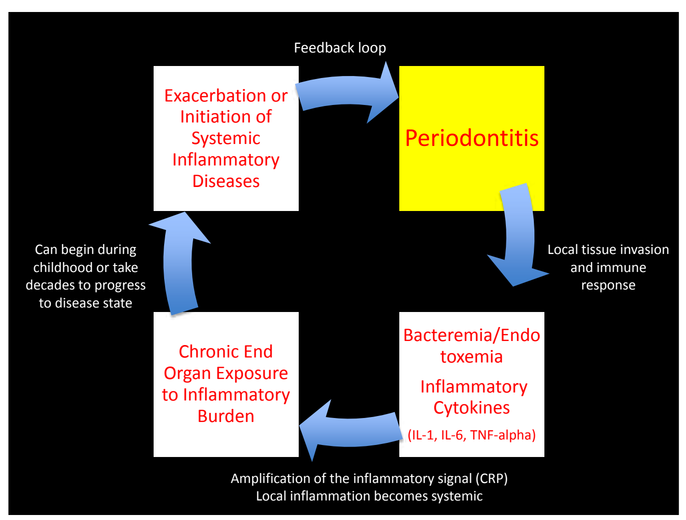
Understanding the Oral-Systemic Connection

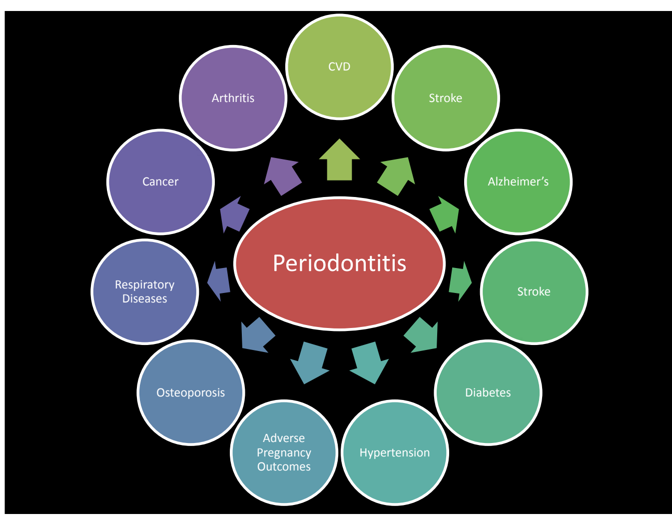


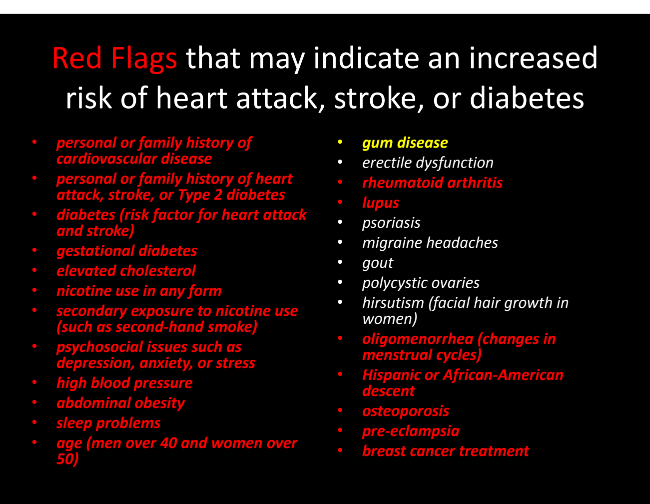




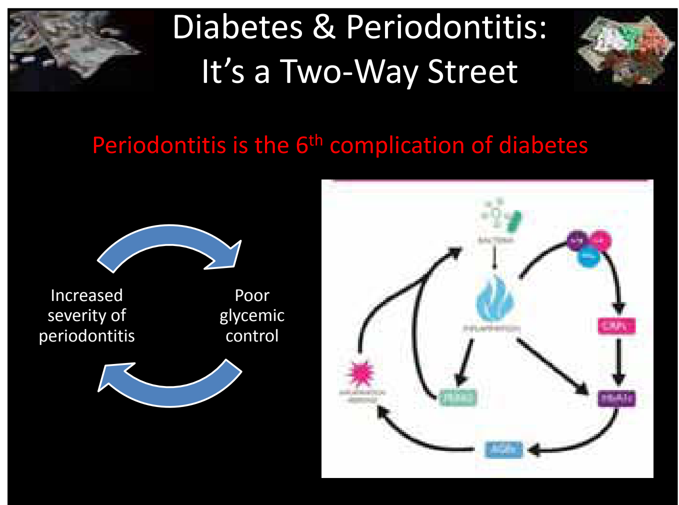


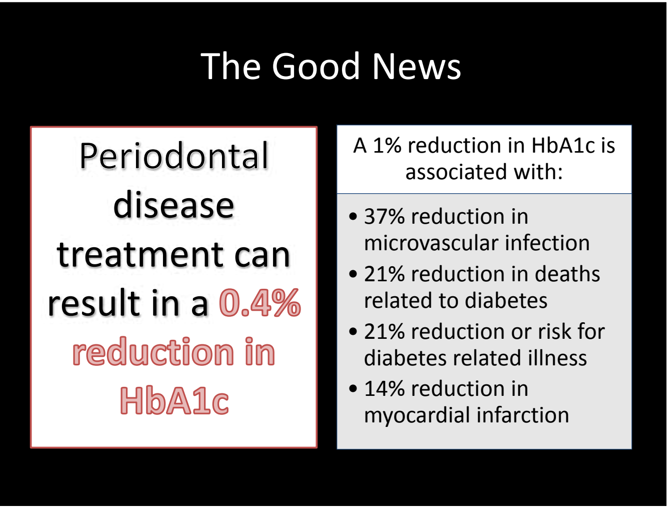

Feedback loop
Exacerbation or Initiation of Systemic Inflammatory Diseases
Periodontitis
Local tissue invasion and immune response
Can begin during childhood or take decades to progress to disease state
Chronic End Organ Exposure to Inflammatory Burden
Bacteremia/Endo toxemia
Inflammatory Cytokines
(IL-1, IL-6, TNF-alpha)
Amplification of the inflammatory signal (CRP)
Local inflammation becomes systemic

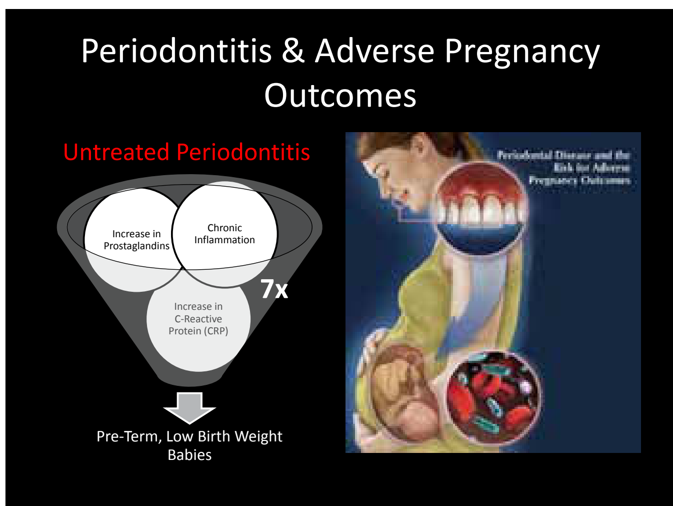

CVD
Arthritis
Stroke
Cancer
Alzheimer's
Periodontitis
Respiratory Diseases
Stroke
Osteoporosis
Diabetes
Adverse Pregnancy Outcomes
Hypertension

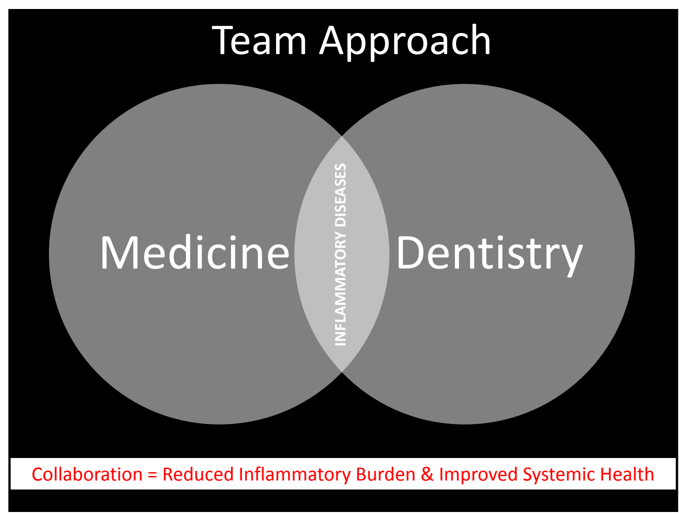

Red Flags that may indicate an increased risk of heart attack, stroke, or diabetes
personal or family history of cardiovascular disease
personal or family history of heart attack, stroke, or Type 2 diabetes
diabetes (risk factor for heart attack and stroke)
gestational diabetes
elevated cholesterol
nicotine use in any form
secondary exposure to nicotine use (such as second-hand smoke)
psychosocial issues such as depression, anxiety, or stress
high blood pressure
abdominal obesity
sleep problems
age (men over 40 and women over 50)
gum disease
erectile dysfunction
rheumatoid arthritis
lupus
psoriasis
migraine headaches
gout
polycystic ovaries
hirsutism (facial hair growth in women)
oligomenorrhea (changes in menstrual cycles)
Hispanic or African-American descent
osteoporosis
pre-eclampsia
breast cancer treatment

Diabetes & Periodontitis: It's a Two-Way Street
More money is spent in the USA caring for diabetic patients each year than is spent on all combined dental procedures
387 M
+205 MILLION
1/12 people with DIABETES
DO NOT KNOW
7 SECONDS
1 in 9
IS SPENT ON DIABETES


Diabetes & Periodontitis: It's a Two-Way Street
Periodontitis is the 6th complication of diabetes
Increased severity of periodontitis
Poor glycemic control


The Good News
Periodontal disease treatment can result in a 0.4% reduction in HbA1c
A 1% reduction in HbA1c is associated with:
37% reduction in microvascular infection
21% reduction in deaths related to diabetes
21% reduction or risk for diabetes related illness
14% reduction in myocardial infarction





SELF EVALUATION

Understanding the Oral-Systemic Connection

1. What appears to be the main factor underlying the oral-systemic link?
   a. Bacteria
   b. Race
   c. Age
   d. Inflammation

2. True/False - Periodontal disease is a chronic inflammatory disease that destroys the bone and gum tissues that support the teeth.

3. True/False - Inflammation is the body's delayed response to injury.

4. The main objectives of inflammation include:
   a. Provide an immediate response to an insult or injury
   b. Contain the injury to the local site
   c. Protect the body from further damage
   d. All of the above

5. True/False - Too much inflammation can be deleterious to the host and cause tissue destruction.

6. True/False - A significant body of research has linked peridontitis to several other systemic inflammatory diseases.

7. True/False - The American Heart Association has published Level A Evidence that a link exists between periodontitis and arterial disease.

8. True/False - Periodontitis is the 6th complication of diabetes.

9. True/False - Successful treatment of periodontal disease can directly improve diabetic control.

10. True/False - Interdisciplinary collaboration is essential to reducing the systemic inflammatory burden in our patients.

Answer Key: 1. D, 2. T, 3. F, 4. D, 5. T, 6. T, 7. T, 8. T, 9. T, 10. T

Rebecca Jaffe, MD, MPH, FAAFP, FACSM

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The Medical Response to Intimate Partner Abuse

Domestic violence- Learning objectives

- Participant will be able to

1. Cite statistics about domestic violence
2. Use a variety of screening tools to identify patients
3. Understand the public health cost of domestic violence.
4. Utilize national and community resources to aide those in need.

FACT:

More than 12 million adults in US experience intimate partner violence annually

What is Domestic Violence

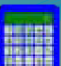
- Willful intimidation, assault, battery, other abusive behavior perpetrated by "known" person against another.
  - Physical
  - Sexual
  - Psychological/ emotional
  - Neglect
  - Stalking

GLOBAL- the "flat world"

-Female genital mutilation
-Non partner sexual assault
-Child marriage.

- **Intervention vs prevention**
  - Political climate
  - Community mobilization- social setting
  - Economic empowerment

DV Statistics



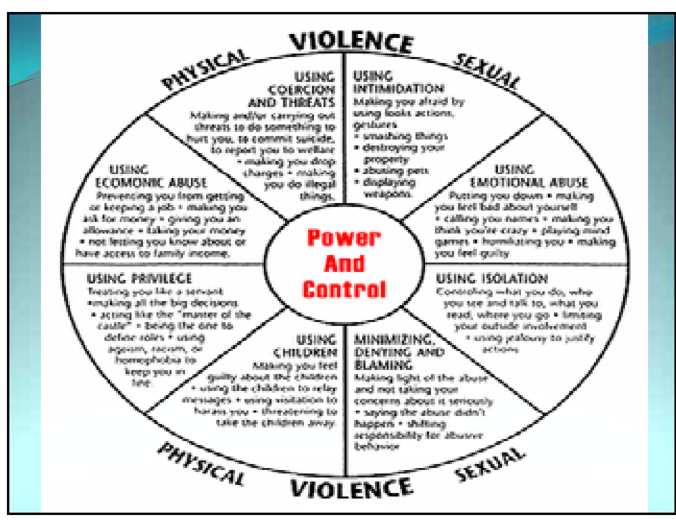
Every 9 seconds in US a woman is assaulted or beaten

- Health related costs exceed $5.8 billion each year.
- $4.1 billion are for direct medical and mental health care services.
- 72% of murder-suicides involve an intimate partner
- 94% of victims of these murder suicides are female

DV Statistics

1 in 5 women
& 1 in 71 men in US
has been raped
in their lifetime

almost half by an acquaintance



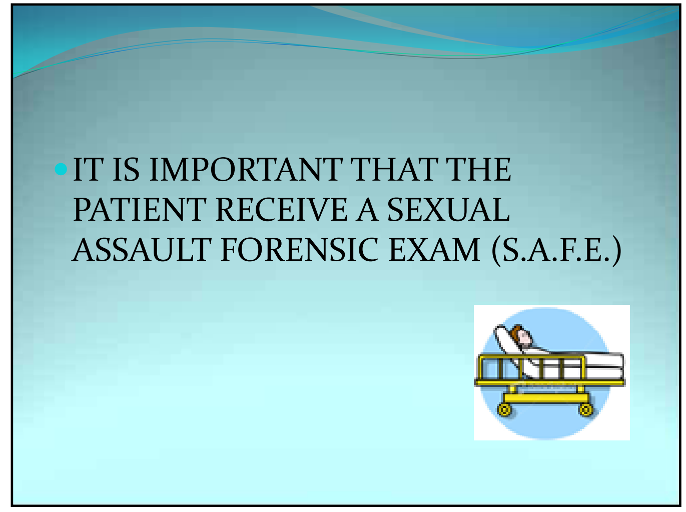
INTIMATE PARTNER VIOLENCE IS BLIND TO

- GENDER
- RACE
- AGE
- SOCIOECONOMIC STATUS
- RELIGION

- There is a strong association between alcohol use and violence—

Patient assessment

- Talk to patient alone , in a safe, private environment
- Ask simple, direct questions
- Look for clues
- Safety
- Always arrange for follow up



Screening tools

Intimate Partner Violence and Sexual Violence Victimization Assessment Instruments for Use in Healthcare Settings

www.cdc.gov/violenceprevention/pdf/ipv/ipvandsvscreening.pdf

HITS Screening Tool

- Physically **HURT** you?
- **INSULT** you or talk down to you?
- **THREATEN** you with physical harm?
- **SCREAM** or curse at you?

HARK tool – self admin, 4 items

- Humiliation,
- Afraid
- Rape
- Kick

STaT- self report, 3 item

- **Slapped**
- **Threatened and**
- **Throw**

SCREENING TO SAVE

- **SCREEN ALL YOUR PATIENTS**
- **ASK DIRECT QUESTIONS**
- **VALIDATE THEIR RESPONSES**
- **EVALUATE, EDUCATE AND REFER**

RADAR protocol

- **Routinely screen for IPV**
- **Ask direct questions**
- **Document findings**
- **Assess safety**
- **Respond, review options & refer**

Characteristics of Victims

Blames herself for the violence.

- Exhibits low self esteem (which is magnified by the batterer's confirmation that she is "worthless").
- Fears leaving or staying.
- Minimizes or denies that a problem exists.
- Often isolated from family, friends,& support systems.

- **AVOID USING THE WORDS "ABUSE" "BATTERED" "VICTIM", TRY MIRRORING THE PATIENT'S OWN WORDS DURING ANY AND ALL EXCHANGES.**
- Words like hurt, badly treated and suffer should be considered.

Sexual assault

- Underreported
- Perpetrator rarely prosecuted
- 32,000 pregnancies/ yr

SOS-DoC framework

- **S**- offer support and assess safety
- **O**- discuss options
- **S**- validate patient's strengths
- **Do**- document observations, assessments,& plans
- **C**- offer continuity

interventions

- Counseling
- Home visits
  - Safety plan, supportive care
  - Guided referral
- Information cards
- Referrals to community services
- Mentoring support

HEALTH CONSEQUENCES OF VIOLENCE

- Beyond physical injuries.....
  - STI
  - Mental health and behavioral disorders
    - Depression
    - PTSD
    - Personality and conduct disorders
    - Anxiety
    - Sleep and eating disorders,
    - Substance abuse
    - Suicide and suicide attempts.
  - Major noncommunical diseases- via alcohol, tobacco, physical inactivity and obesity

Public health push

- **PROMOTE HEALTHY RESPECTFUL RELATIONSHIPS AMONG YOUTH**
  - **RESPECTFUL** INTERACTIONS
  - OPEN **COMMUNICATIONS**
  - **NONVIOLENT** RESOLUTION SKILLS

  (starting at a very early age if possible)

ACCESS FOR SURVIVORS:

- HEALTHCARE
- LEGAL
- ECONOMIC
- HOUSING
- MENTAL HEALTH
- SAFE & CONFIDENTIAL COMMUNICATION

DV MUSTS

- **HOLD PERPETRATORS ACCOUNTABLE**
- **MORE RESEARCH**
- **MORE FUNDS**

Domestic violence resources

- **800-799-SAFE National Domestic Violence Hotline**
- 888-rx-ABUSE—National Health Resource Center on Domestic Violence
- **RAINN- RAPE, ABUSE AND INCEST NATIONAL NETWORK : WWW.RAINN.ORG 1.800.656.HOPE (4673)**
- Endabuse.org/health; thehotline.org; ncadv.org; dvrc-or.org
- **www.cdc.gov/ViolencePrevention/intimatepartnerviolence/resources.html**

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Breiding MJ, Smith SG, Basile KC et al. Prevalence and Characteristics of Sexual Violence, Stalking and Intimate Partner Violence Victimization- National Intimate Parner and Sexual Violence Survey, US 2011. MMWR Sept 5, 2014 63 (SS08) 1-18.

Nelson HD, Bougatsos C, Blazina I. Screening women for intimate partner violence: a systematic review to update the US Preventive Services Task Force recommendation. Ann Inter Med 156(11):798, 2012.

Tharp AT, DeGue S. Valle LA, Broodmeyer KA, Massetti GM, Matjasko JL. A systematic qualitative review of risk and protective factors for sexual violence perpetration. Trauma Violence Abuse 14(2):133-167, Apr 2013.

Florida Council Against Sexual Violence. How to Screen Your Patient for Sexual Assault: A Guide for Health Care Professionals. 2012.

National Protocol for Sexual Assault Medical Forensic Examinations: Adults/Adolescents, Second Edition, NIJ-Sponsored, OVW, April 2013, NCJ 228119. (145 pages). Accessed at https://www.ncjrs.gov/pdffiles1/ovw/241903.pdf on May 6, 2015.

SELF EVALUATION

The Medical Response to Intimate Partner Abuse

True/False

1. Domestic violence statistics are valid and verified.

2. As a health professional, you have a legal obligation to report domestic/intimate partner violence in the United States.

3. When you learn that someone is a victim of domestic abuse, you invite a friend or neighbor to accompany the patient.

4. If someone claims to have been sexually assaulted, you bring them to an emergency room for further evaluation.

5. There are no validated tools for patient interviews in partner violence.

6. Intimate partner violence is unique to the Western Hemisphere.

7. Most cases of intimate partner violence are sexual.

8. There are many health consequences to individuals who suffer from intimate partner violence.

Answer Key: 1. F, 2. F, 3. F, 4. T, 5. F, 6. F, 7. F, 8. T

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Rachel V. Rose, JD, MBA, of Houston, Texas, is principal of her own law firm specializing in healthcare and securities law. Her practice areas include anti-kickback and Stark laws, the HIPAA and HITECH acts, the medical device industry, physician reimbursement issues and more. Previously Ms. Rose worked on Wall Street, for one of the major consulting firms, as head of business development and assistant general counsel for a healthcare advisory company and as a judicial clerk.

Ms. Rose is chair of the Federal Bar Association's Corporate and Associations Counsel Division, past vice-chair of Distance Learning for the American Bar Association's Health Law Division, and teaches bioethics at Baylor College of Medicine's Center for Health Policy and Medical Ethics.

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Healthcare Practice Cybersecurity: Threats, Standards and Safeguards

Disclaimer

THE INFORMATION PRESENTED IS NOT MEANT TO CONSTITUTE LEGAL ADVICE. CONSULT YOUR ATTORNEY FOR ADVICE ON A SPECIFIC SITUATION.

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Overview

- The purpose of this program is to provide the participants with the following knowledge:
- How the recent DOJ guidance on compliance programs impacts cybersecurity;
- Requirements of cybersecurity compliance across a variety of sectors;
- Enforcement action and breach examples; and
- Ways to mitigate the damage in the event of a breach.

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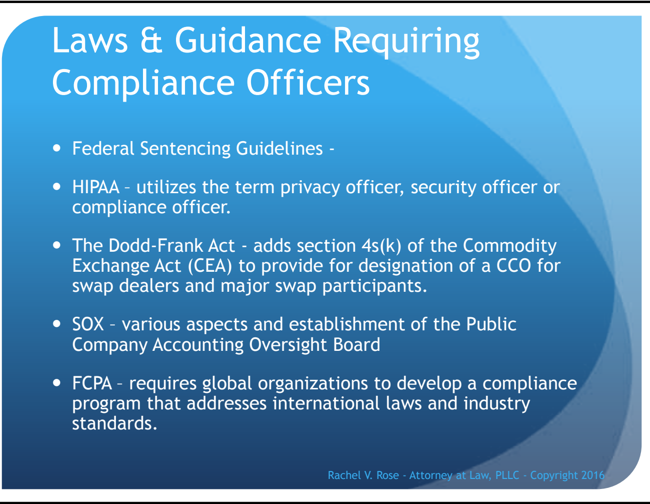

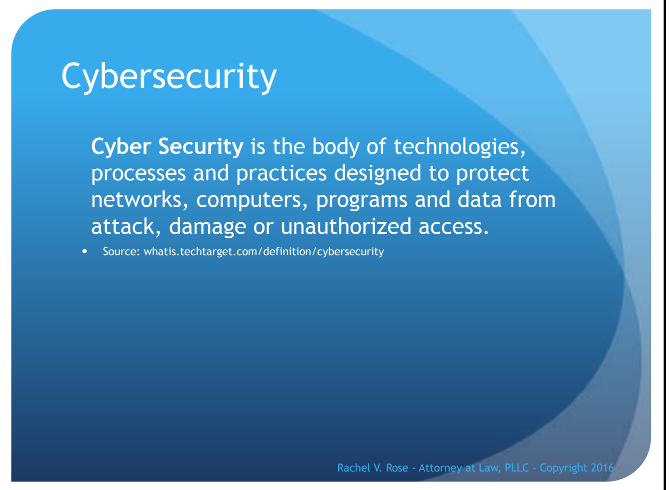

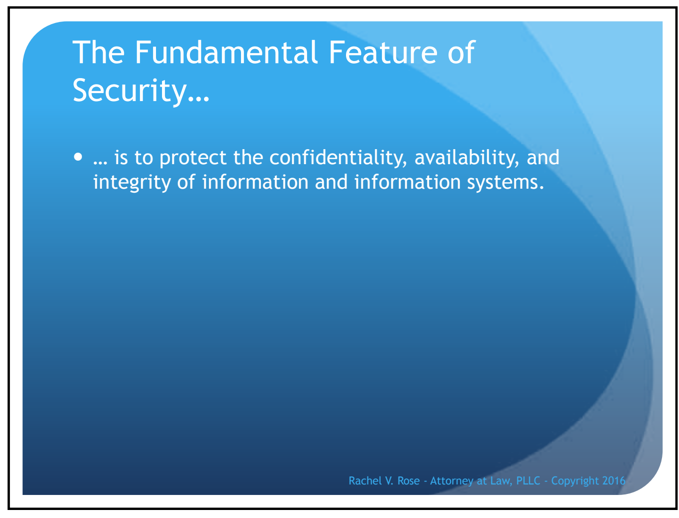

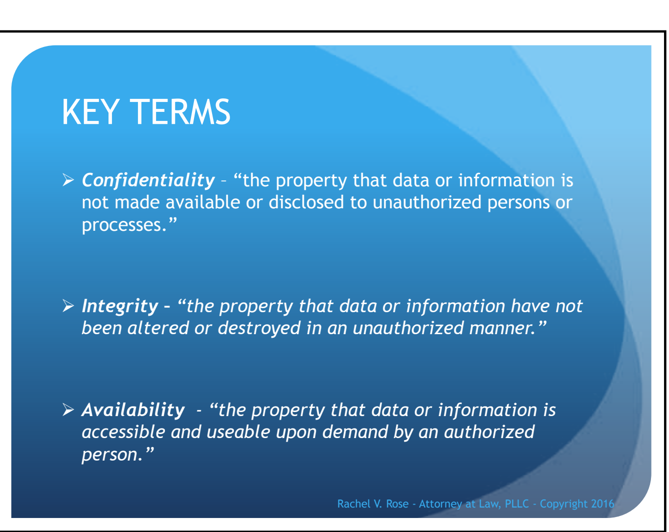

Texas License **(713) 907-7442** **rvrose@rvrose.com**

Who Puts Data at Risk?

There are four types of employees who put the workplace at risk:

- The **security softie**, who knows very little about security and poses a threat by using their work computer at home or letting family members use it.
- The **gadget geek**, who comes to work armed with a variety of devices that get plugged into their PC.
- The **squatter**, who uses company IT resources in ways they shouldn't.
- The **saboteur**, who will hack into areas to which they don't have access or infect the network on purpose.

  American Bar Association Article (Apr. 2014)

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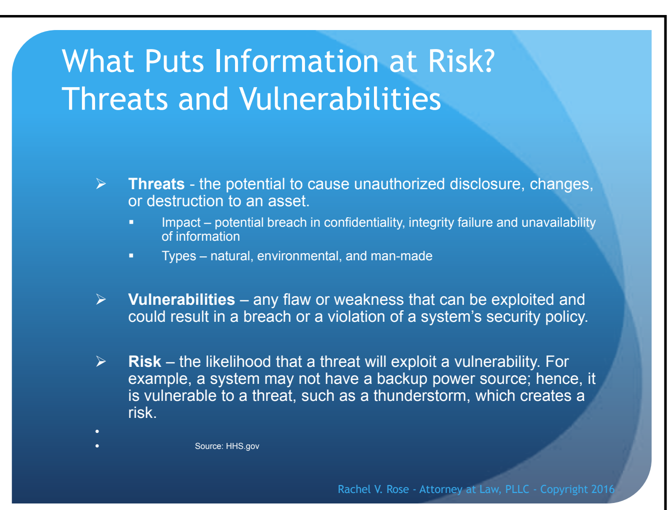

Risk Assessment Components

- Due Diligence by assessing PHI through the continuum of care and billing.
- "Define and confine the circumstances where PHI may be used or disclosed by covered entities, business associates and subcontractors."
- National Institute of Technology Standards
  - Have you identified the ePHI within your organization?
  - What are the external sources of PHI/ePHI?
- OCR's Guidance on HIPAA Risk Analysis Requirements

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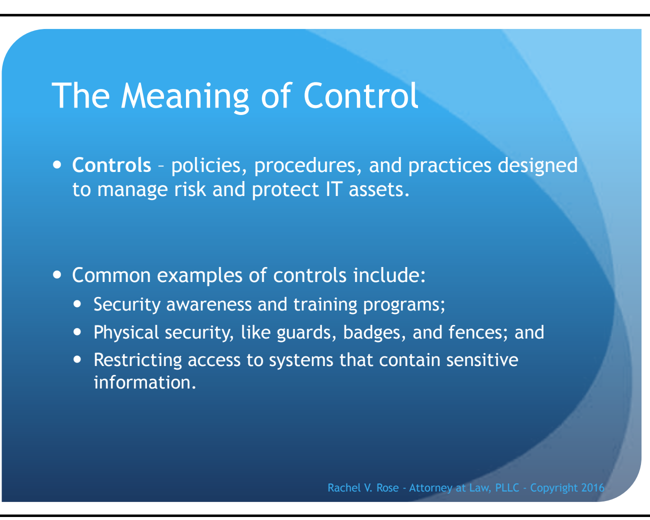

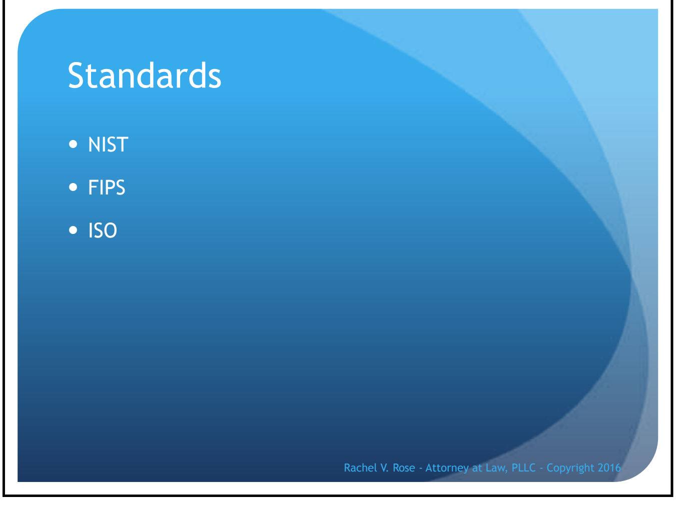

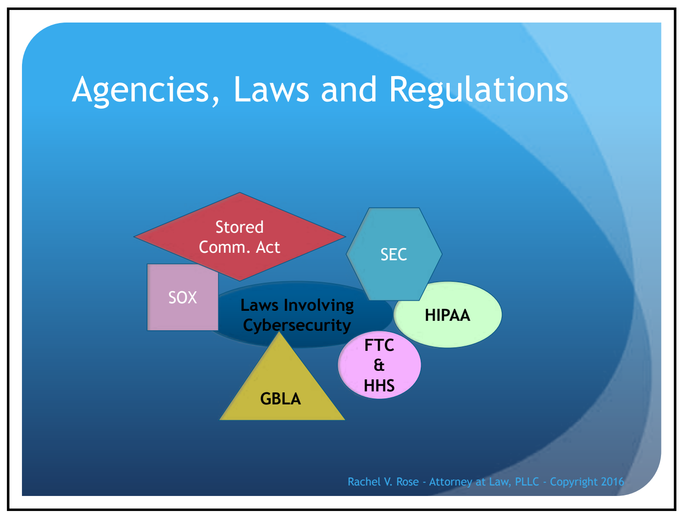

Legislative History

- 1996 -HIPAA (Public Law 104-191) - need for consistent framework for transactions and other administrative items.
- 2002 - The Privacy Rule (Aug. 14, 2002)
- 2003 - The Security Rule (Feb. 20, 2003)
- 2009 - Health Information Technology for Economic and Clinical Health (“HITECH”) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Feb. 17, 2009)
- 2009 - The Breach Notification Rule (Aug. 24, 2009)
- 2010 - Privacy and Security Proposed Regulations (Feb. 17, 2010)
- 2013 - Omnibus Rule (Effective March 26, 2013, Compliance Sept. 23, 2013).

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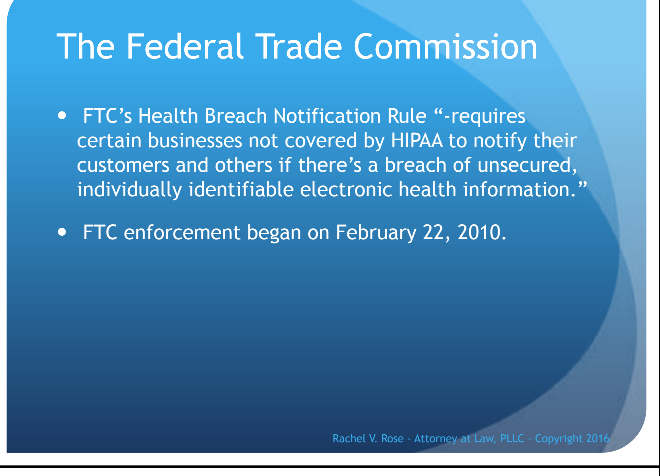

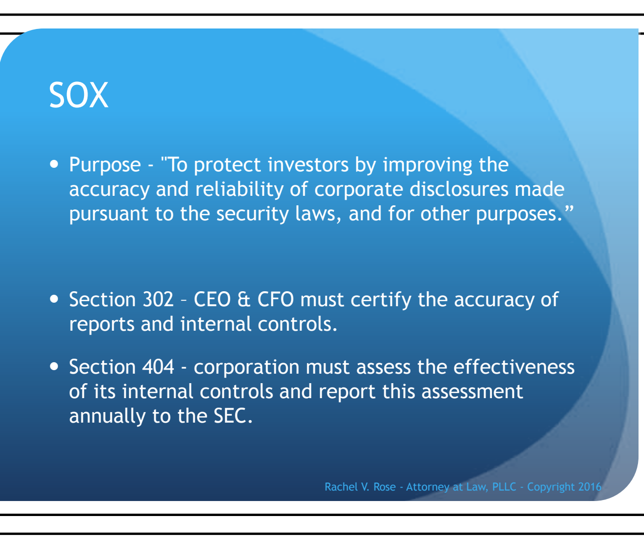

Graham Leach Bliley Act

- Title V, §501

(a) PRIVACY OBLIGATION POLICY.—It is the policy of the Congress that each financial institution has an affirmative and continuing obligation to respect the privacy of its customers and to protect the security and confidentiality of those customers’ nonpublic personal information.

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SEC Disclosure Guidance (Oct. 13, 2011)

- Look at the individual facts and circumstances.
- When was a cyber incident discovered?
  - After the balance sheet date but before the issuance of financial statements?
  - If so, registrants should consider whether disclosure of a recognized or nonrecognized subsequent event is necessary.
- If it is a material nonrecognized subsequent event, then…
  - Financial statements should disclose the nature of the incident and an estimate of its financial effect, or
  - A statement that such an estimate cannot be made.

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Major Breaches

- Adobe (38 million customer accounts),
- Target (40 million customers),
- Snapchat (4.6 million users),
- U.S. banks (websites offline),
- HIPAA Violations (CHS, Anthem Bluecross/Blueshield, Tenet ($32.6 million) and
- Securities exchanges (infrastructure attacks).

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HIPAA VIOLATIONS

Enforcement Item	Reason	Settlement	FCA Liability Penalty/Treble
Hospice of N. Idaho (Jan. 2013)	Unencrypted Laptop Stolen = Security Rule Breach (< 500)	$50,000	$2,425,500 to $4,851,000/ **$7,276,500 to $14,553,000**
Phoenix Cardiac Surgery (Apr.2012)	Violations of HIPAA & Regs (1,000)	$100,000	$5,500,000 to 11,000,000/ **$16,500,000 to $33,000,000**
Accretive (July 2012)	Unencrypted Laptop Stolen = Security Rule Breach (28,000)	$2.5 million	$154,000,000 to $308,000,000/ **$462,000,000 to $924,000,000**

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The Federal Trade Commission - I

- Henry Schein Practice Solutions, Inc. (“Schein”), a dental practice software company
  - $250,000 fine
  - prohibition on “misleading customers about the extent to which its products use industry-standard encryption or how its products are used to ensure regulatory compliance”

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Federal Trade Commission - II

- Rite Aid - $1 million fine
- CVS - $ 2.25 million (2009 – FTC and OCR)
- LabMD - "Contrary to LabMD's contention, Congress has never enacted any legislation that, expressly or by implication, forecloses the Commission from challenging data security measures that it has reason to believe are 'unfair ... acts or practices'"

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Ways to Mitigate Risk

- Disclose!
- Have a comprehensive Risk Analysis and Risk Assessment performed.
- Do you due diligence before entering into agreements and partnerships with entities you may be subcontracting with or joint venturing/purchasing.
- Understand the what is required of management and the fiduciary duties.
- Make Cybersecurity a priority.

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SELF EVALUATION

Healthcare Practice Cybersecurity: Threats, Standards and Safeguards

1. When were most of the requirements of the HIPAA Omnibus Rule required to be implemented?

a. January 25, 2013
b. March 30, 2015
c. September 25, 2013
d. None of the Above.

2. What are the three main areas to consider in relation to HIPAA Security Rule compliance?

a. Technical
b. Administrative
c. Physical
d. All of the Above.

3. What parties need to execute a Business Associate Agreement ("BAA")?

a. Covered Entity
b. Business Associate
c. Subcontractor
d. It depends on the type of relationship and the services being performed.

4. True/False - In general, a BAA is required when the parties are creating, receiving, transmitting or maintaining PHI.

5. Who should be notified in the event of a breach of 500 persons or greater?

a. The patients whose information was compromised.
b. The media.
c. The federal Secretary of Health and Human Services.
d. All of the above.

6. True/False - Patients are required to be given a notice of privacy practices.

7. True/False - HHS is the ONLY government agency with jurisdiction to enforce HIPAA and cybersecurity issues.

Answer Key: 1. C, 2. D, 3. D, 4. T, 5. D, 6. T, 7. F

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The Contentious Role of Vitamin D Supplementation

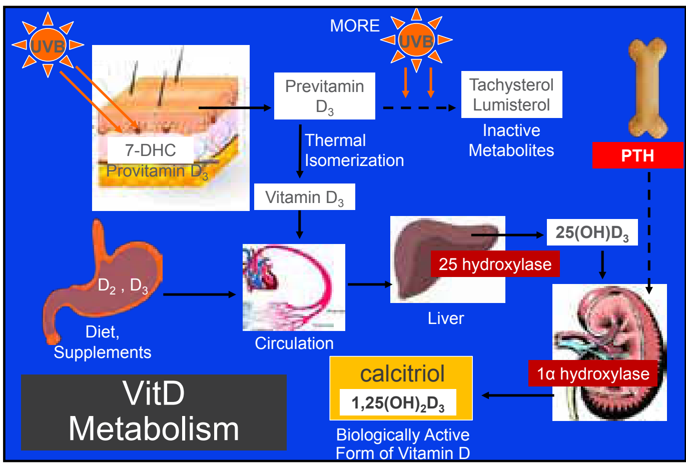
Vitamin D: Maybe it does EVERYTHING?

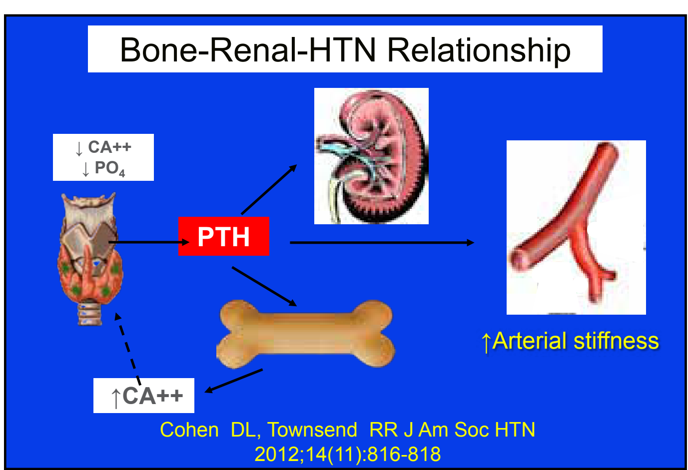
"Vitamin D deficiency has been linked with HTN, MI, stroke….atherosclerosis and endothelial dysfunction. There is also increasing evidence that vitamin D plays a role in RAS regulation, may directly affect cardiac muscle and regulates the immune system."

Cohen DL, Townsend RR J Am Soc HTN 2012;14(11):816-818

WARNING! WARNING! WARNING!

Much of the enthusiasm for VitD supplementation has been based upon *observational* data sets. You may be disappointed to learn the fairly stark limitations, and even potential toxicity of VitD supplementation





VitD: Should We Screen?

"The question of whether to screen for vitamin D deficiency…is one of the most vexing issues in clinical practice."

Manson J Medpage Today 2015 (October 15)

SCREENING for VitD Deficiency: NOT

- Most organizations do NOT recommend
  - Endocrine Society
  - American Geriatrics Society
  - American Academy of Pediatrics
  - ACOG
- USPSTF: "I" recommendation (2014)

- Vitamin D supplement sales: $108 million (2007) → $713 million (2013)

Taylor CL Am J Med 2015;128:1167-1170

Why 25(OH) Vitamin D?
Since 1,25(OH) is the Biologically Active Form

- Reflects total available vit D from
  - diet/supplements
  - cutaneously derived
  - adipose stores
- Longest vit D t ½ (2-3 weeks)[1]
- Correlates with disease states[1]
- Not affected by CKD [as is 1,25(OH)D

Rosen C NEJM 2011;364(3):248-254
[1] Wolpowitz D et al J am Acad Dermatol 2006;54:301-17

25(OH)D: So What are the 'issues'?

- Test methods vary (immunoassay, competitive protein binding, high-performance liquid chromatography, mass spectrometry, etc)
- Sensitivity and specificity of methods varies (intra- and inter-method)
- No nationally recognized reference standard
- Inflammation/acute illness may →↓25(OH)D
- No accommodation for ethnicity

Taylor CL Am J Med 2015;128:1167-1170

Why Do Seniors Have Lower Vitamin D?

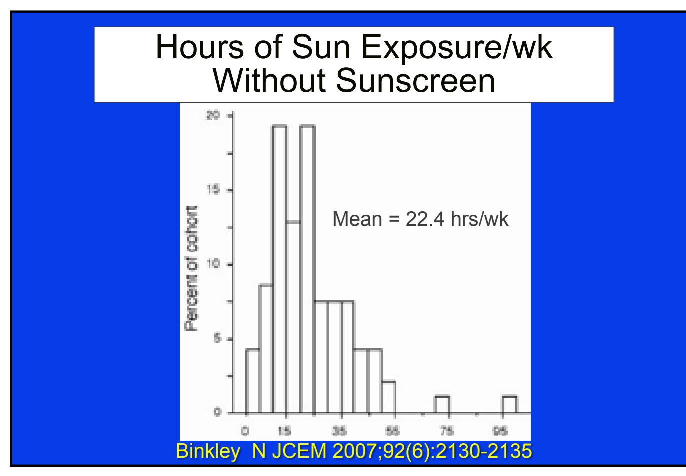
- They are more likely to
  - Stay indoors at peak sun hours
  - Wear sunscreen
  - Cover a greater % of skin with clothing
- D_3 levels in response to UVB > 4X lower at age 62-80 than at age 20-30

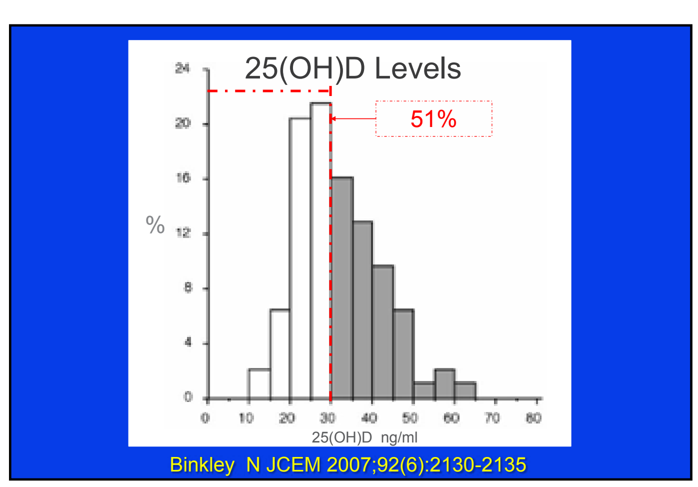
Heaney RP Journal of Nutrition 2006;136:1123-1125

Not Enuf Sun in Hawaii?!

- Study: Adults (n=93) recruited from University of Hawaii and A'Ala Park Board Shop (skateboards)
- Inclusion: ≥3 hrs/d for ≥5d/wk for ≥3 months
- Metric: 25(OH)D levels
  - low 25(OH)D defined as <30 ng/ml

Binkley N JCEM 2007;92(6):2130-2135





Not Enuf Sun in Hawaii?! Discussion

"…regardless of the amount of sun exposure, the serum 25(OH)D concentration does not increase to more than approximately 60 ng/mL."

"An apparent physiological ceiling does not support attempts to achieve higher values by pharmacological intervention."

Binkley N JCEM 2007;92(6):2130-2135

Serum 25(OH)D vs Actual Bone Health

"…total serum 25(OH)D levels are systematically *lower* in African Americans, yet they experience *notably better bone* health."

emphasis added

Taylor CL Am J Med 2015;128:1167-1170

WHY Might AA Enjoy Better Bone Health?

"…African Americans have levels of *free* 25(OH)D similar to Caucasians."

emphasis added

Taylor CL Am J Med 2015;128:1167-1170

Vitamin D: Dementia The Case

"Recent meta-analyses confirm that low serum vitamin D concentrations are associated with prevalent Alzheimer disease (AD), dementia, and cognitive impairment. This is cause for concern given the high rates of vitamin D deficiency in older adults and continued uncertainty about the causes of AD and other forms of dementia."

Littlejohns TJ et al Neurology 2014;83:1-0

Vitamin D: Dementia The Case: Physiologic Underpinnings

- 1,25-$(OH)_2$-vitamin D3 receptors located throughout CNS
- 1-alpha-hydroxylase (synthesizes bioactive vitamin D) found throughout CNS
- In vitro: vitamin D clears amyloid plaques
- Vitamin D deficiency ≈ ischemic stroke risk

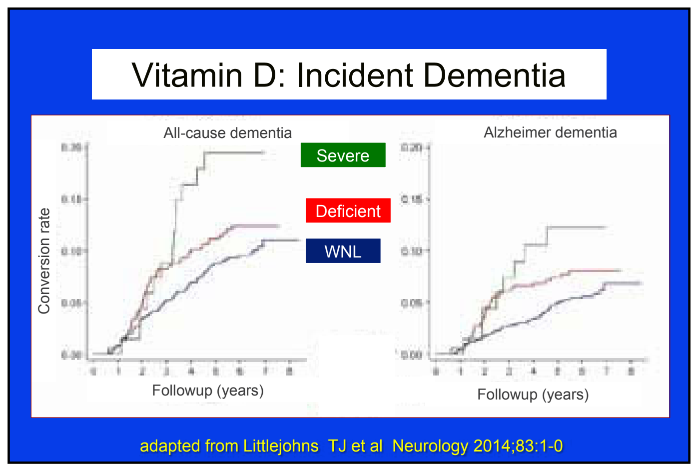
Littlejohns TJ et al Neurology 2014;83:1-0

Vitamin D: Dementia

- Study: US CV Health Study subjects (n=1,658)
- Ambulatory Adults, mean age: 74
- Free of dementia & CVD at baseline
- Metrics
  - 25(OH)D:
    - WNL = > 50 nmol/L
    - Deficient = 25-50 nmol/L
    - Severely Deficient = <25 nmol/L
  - Annual cognitive assessment
- Outcome: Incident dementia 1992 -1999

Littlejohns TJ et al Neurology 2014;83:1-0

Vitamin D: Incident Dementia



adapted from Littlejohns TJ et al Neurology 2014;83:1-0

Vitamin D Status: Dementia HR

	25(OH)D status nmol/L			
	WNL (> 50)	Deficient (>25 to <50)	Severe Deficiency (<25)	p for trend
All-cause dementia				
Model A	1	1.51	2.22	.002
Model B	1	1.53	2.25	.002
Alzheimer Disease				
Model A	1	1.67	2.27	.006
Model B	1	1.69	2.22	.008

HR: compared to REFERENCE of WNL (=1)

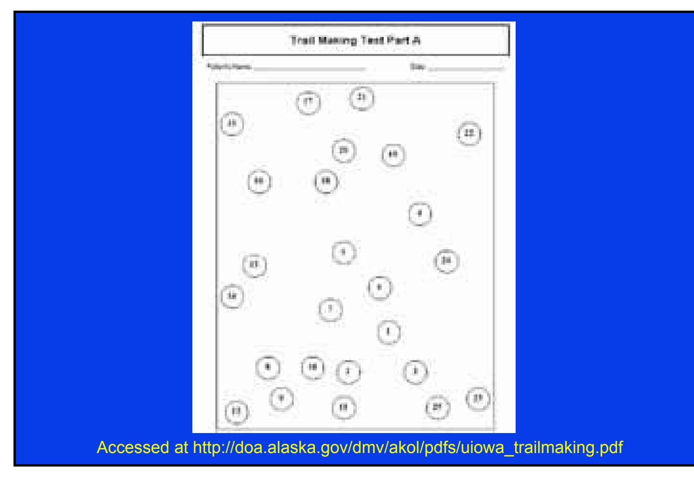
Model A: adj for age and season of vitamin D collection
Model B: adj for education, sex, BMI, smoking, ETOH, depression

adapted from Littlejohns TJ et al Neurology 2014;83:1-0

VitD & Cognitive Decline in Elderly

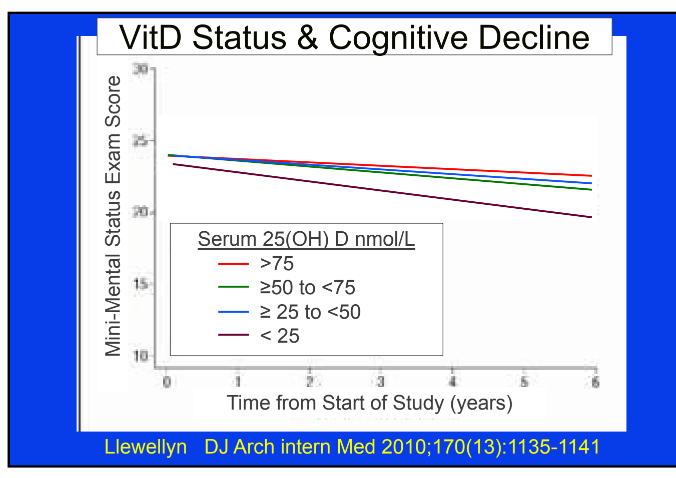
- Study: Adults > 65yrs in Italy (n=858)
- Metric: 25(OH)D
- Outcomes
  - MMSE
  - Trail-Making Tests A/B
- Substantial decline over 6 yrs defined as
  - 3 points ↓MMSE
  - lowest 10th percentile: Trail-Making

Llewellyn DJ Arch intern Med 2010;170(13):1135-1141

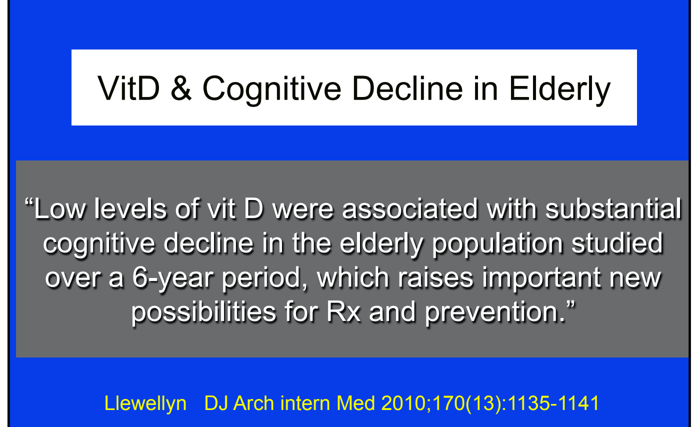


Accessed at http://doa.alaska.gov/dmv/akol/pdfs/uiowa_trailmaking.pdf

VitD Status & Cognitive Decline



Llewellyn DJ Arch intern Med 2010;170(13):1135-1141



Vitamin D and Colon CA: So Much Supportive Evidence it HAS to Work

- In vitro: inhibits proliferation, inhibits angiogenesis, promotes apoptosis in epithelial tissues
- INVERSE relationship
  - Vit D intake : colon CA/adenomas
  - Serum 25(OH) vit D : colon CA/adenoma
- High dose vit D inhibits experimental carcinogenesis even in vitamin-replete animals

Baron JA et N Engl J Med 2015;373(1):1519-1530

OK…it HAS to Work. Does it?

- Study: Recently excised adenoma pts (n = 2,259)
- Rx: Vit D_3 1000 IU/d vs $CaCO_3$ 1200 mg/d vs both vs placebo x 3-5 yrs*
- Outcome: new lesions on repeat colonoscopy
- Results: "Daily supplementation with vitD, Ca++ or both…did not significantly reduce the risk…"

Baron JA et N Engl J Med 2015;373(1):1519-1530

VitD & Falls: Meta-Analysis

- Study: Meta-analysis of trials evaluating falls & Vit D in seniors > 60 yrs
- Exclusions: Unstable health status
- Data set: 5 RDBCT (n=1,237)
- Results (Vit D vs CA++ or Placebo)
- Corrected Odds Ratio = 0.78 ($p < 0.05$)

Bischoff-Ferrari HA et al JAMA 2004;291(16):1999-2006

VitD & Falls: Meta-Analysis Conclusions

"VitD supplementation appears to reduce the risk of falls among ambulatory or institutionalized older individuals with stable health by more than 20%."

Bischoff-Ferrari HA et al JAMA 2004;291(16):1999-2006

Vit D supplementation by M.o.W. Pilot Study on Falls

FOUNDATION

"More than ⅓ of community–dwelling adults aged 65 and older fall annually, with approximately one in 10 falls resulting in serious injury."

Houston DK et al J Am Geriatr Soc 2015;63:1861-1867

Vit D supplementation by M.o.W. Pilot Study on Falls

- Study: Community-dwelling homebound adults, age 65-102 years (n=68)
- Rx: Vitamin D_3 100K IU/once monthly vs placebo X 5 months
- Outcomes
  - Falls
  - 25(OH) Vit D Levels

Houston DK et al J Am Geriatr Soc 2015;63:1861-1867

Vit D supplementation by M.o.W. Pilot Study on Falls: Results

	Baseline	Endpoint	
		Rx	Placebo
25(OH)D (mean)	20.9 ng/mL	22.5 ng/mL	18.9 ng/mL
25(OH)D <20 ng/mL	57%	3%	72%
Falls	61%*	33%**	46%
			**Adjusted HR = 0.42, p < 0.05

*in past year

Houston DK et al J Am Geriatr Soc 2015;63:1861-1867

VitD + Ca++ Reduces Fx in Elderly Women

- Study: 'Mobile' Women mean age 84 years living in nursing homes (n=2,303)
- Rx: Vit D 800 IU/d + Ca^{++} 1.2 g/d vs placebo X 3 years
- Outcome: Fx

Chapuy M BMJ 1994;308(April):1081-1082

VitD + Ca++ Reduces Fx in Elderly Women

	Placebo	VitD/Ca++	RR	p
Hip Fx	184	138	25%	< 0.02
>1 Hip Fx	178	137	23%	< 0.02
Any Fx	368	301	18.2%	< 0.02
>1 Fx	308	255	17.2%	< 0.02

...but was it the Ca^{++}, the vit D, or both?

Chapuy M BMJ 1994;308(April):1081-1082

VitD & Bone Health

"RCT of VitD supplementation have addressed its effects on skeletal outcomes, but most of these trials involved supplementation with both VitD and CA++, making it impossible to separate out the effects attributable specifically to VitD"

Rosen C NEJM 2011;364(3):248-254

VitD & Bone Health
A 2009 Cochrane Analysis of 10 Trials

- VitD supplementation alone: no Fx↓
- VitD/CA++:
  - 'marginally effective' in older persons
  - O.R. = 0.89 (CI = 0.80-0.99)

Rosen C NEJM 2011;364(3):248-254

Vit D & Bone Health

- Falls & Fx: inconsistent results
- WHI: No hip Fx ↓ with VitD 700 IU + 2000mg Ca^{++} vs placebo
  - Subgroup analysis: age > 60 + good compliance (>80%) showed hip Fx reduction

Rosen C NEJM 2011;364(3):248-254

Annual High Dose VitD for Community-Dwelling Older Women

BACKGROUND

"Some meta-analyses conclude that 700-800 IU of vitamin D daily reduces fracture risk by 13%-26%, whereas others conclude that vitamin D is ineffective."

Sanders KM JAMA 2010;303(18):1815-1822

Annual High Dose VitD for Community-Dwelling Older Women

BACKGROUND

"A Cochrane analysis and the Vitamin D Individual Patient Analysis of Randomized Trials (DIPART) group, published after this study commenced, showed a nonstatisticallly significant increase in hip fracture risk associated with vitamin D supplementation."

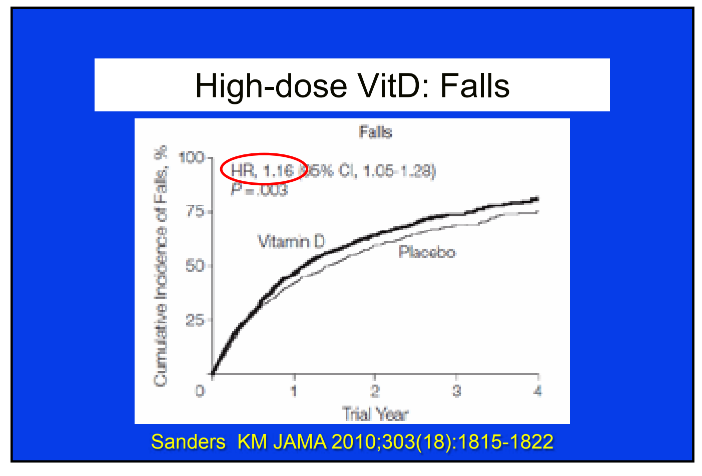
Sanders KM JAMA 2010;303(18):1815-1822

High Dose VitD: Community-Dwelling Older Women

- Study: DBPCT women >70 yrs (n=2,256)
- Rx: VitD 500,000 IU PO annually X 4 yrs
- Outcomes: Incident falls/fractures
- Results: "Among older community-dwelling women, annual oral administration of high-dose cholecalciferol resulted in an ↑risk of falls and Fxs"

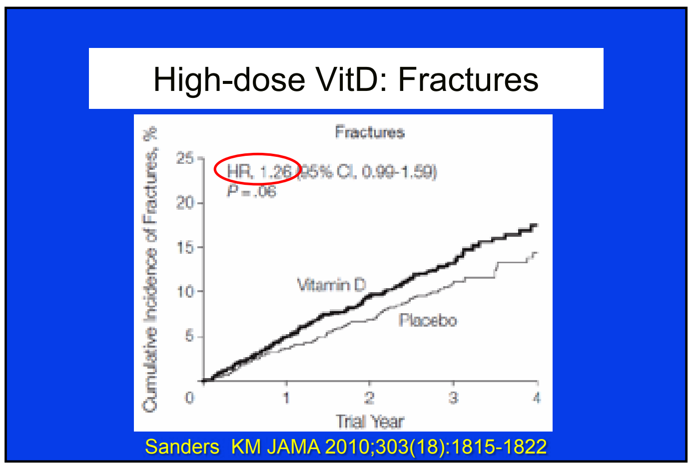
Sanders KM JAMA 2010;303(18):1815-1822

High-dose VitD: Falls



Sanders KM JAMA 2010;303(18):1815-1822

High-dose VitD: Fractures



Sanders KM JAMA 2010;303(18):1815-1822

Annual High Dose VitD for Community-Dwelling Older Women

COMMENT

"Contrary to our hypothesis, participants receiving annual high-dose oral cholecalciferol experienced 15% more falls and 26% more fractures than the placebo group."

Sanders KM JAMA 2010;303(18):1815-1822

Vit D: Insulin Resistance & β-cell Function

- Study: X-sect analysis of Canadian adults over age 30 "at high risk for T2DM and/or metabolic syndrome" (n =712)
- Inclusion: Normal OGTT, no diabetes
- Measured: Insulin sensitivity, β-cell function

Kayaniyil S et al Diabetes Care 2010;33(6):1379-1381

Vit D: Insulin Resistance & β-cell Function

"25(OH)D concentration was independently associated with both insulin sensitivity and β cell function among individuals at risk of T2DM"

Kayaniyil S et al Diabetes Care 2010;33(6):1379-1381

Vit D: A1c

- Study: NHANES 2003-2006 adults with diabetes (n = 9,773)
- Measured: A1c, 25(OH)D
- Outcome: A1c to 25(OH)D relationship

Kositsawat J et al Diabetes Care 2010;33(6):1236-1238

Vit D & A1c: Results

"Serum 25(OH)D levels were inversely associated with A1c levels in subjects age 35-74 years…. Screening people with elevated A1c levels for vitamin D insufficiency should be considered."

Kositsawat J et al Diabetes Care 2010;33(6):1236-1238

The Far Reaches of VitD: Psoriasis

- Study: psoriasis patients (n=43) vs age-matched controls (n=43)
- Outcome: relative 25(OH) VitD levels
- Results 25(OH)VitD:
  - psoriasis = 24.4 ng/ml
  - control = 29.9 ng/ml

p = 0.007

Orgaz-Molina J J Am Acad Dermatol 2012;67:931-8

Can't I Just Fix This With MILK?

A Study of Health Young Adults (n=307)

"Dietary intake of milk was not associated with higher 25(OH)D. This is not unexpected since the VitD content in milk is highly variable….even if the milk contained 400IU of VitD/qt, 1.6 glasses of milk would be = 160 IU of VitD, which is below the recommended daily intake."

Tangpricha V Am J Med 2002;112:559-562

Where *Should* We Get Vit D? Mother Nature's Apparent Plan

"…it has become clear that metabolic utilization of vitamin D is on the order of a few thousand IU/d and that, because oral intake is typically only about one tenth of that amount, the principal source of vitamin D for most of the population must be cutaneous synthesis."

Heaney RP Journal of Nutrition 2006;136:1123-1125

Vit D: How Much Sun?

"Just 10-15 minutes of exposure to sunlight on face, hands, and arms each day, 2-3 days/week is required to synthesize sufficient amounts of vitamin D."

Powell HS, Greenberg D "Tackling vitamin D Deficiency" Postgrad Med 2006;119(1):25-30

Vit D: How Much Sun?

"As little as 10-15 minutes of direct sunlight can generate 10,000-20,000 IU of vitamin D."

Casey CF, et al Am Fam Phys 2010;81(6):745-748

Well, It's So Darn Safe…What's the Harm?

"Emerging observational data suggest that *adverse outcomes* may occur at…levels…as [low as] the 50-75 ng/mL range."

emphasis added

Taylor CL Am J Med 2015;128:1167-1170

"Excessive Vitamin D Intake May Elevate A Fib Risk"

- Study: non-AF patients with 25(OH) vit D measured during clinical care (n =132,000)
- Results in relation to 25(OH) vit D levels:
  - ≥100 ng/dL → AF HR ↑2.5
  - <20 ng/dL: p = NS

Smith MB Circulation; 2011;124: Abstract 14699

VitD TOXICITY: IOM Statement

"There is evidence that higher levels of serum VitD at ± 40 ng/ml are associated with all-cause mortality, fractures, pancreatic cancer, and prostate cancer."

Slomski A "IOM Endorses VitD, Ca^{++} Only for Bone Health, Dispels Deficiency Claims" JAMA 2011;305(5)453-455

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If I Do Want to Rx Vit D Deficit

- ergocalciferol ($VitD_2$) 50,00 IU/wk PO
  - Weekly X 6-8 then maintenance (≥800 IU/d)

Powell HS, Greenberg D "Tackling vitamin D Deficiency" Postgrad Med 2006;119(1):25-30

Vit D Supplementation: How Much Cluck for Your Buck?

↑25(OH) Vit D/ IU D_3/d	
Vitamin D Replete	Vitamin D Deficient
0.7 nmol/L (0.6-1.2)	2-2.5 nmol/L

Heaney RP Journal of Nutrition 2006;136:1123-1125

What to DO Then?

"…clinicians have limited time to spend…and there are likely other health matters more pressing than vitamin D, so the best course of action would be not to bring up the issue of vitamin D unless the patient asks or there is a clinical reason to do so."

Taylor CL Am J Med 2015;128:1167-1170

Overzealous Vit D Testing: New Zealand to the Rescue

"In 2011, in the face of a total annual laboratory cost of about NZ$1million for vitamin D testing alone, a decision was made to restrict direct access to the test to a limited range of clinicians or for the investigations of metabolic bone disease or hypocalcaemia….resulting in a rapid and substantial reduction…."

Grey A Lancet 2012;379:1699-1701

Where Might This Leave Us?

- Screening for VitD Deficiency: Not
- At-risk groups (osteoporosis): literature has essentially always used VitD + Ca++, so EBM says we should. Monitor for toxicity
- We may not be measuring the right thing
- Observational trials ++; RCT ±
- VitD, like HRT, appears to have been oversold

SELF EVALUATION

The Contentious Role of Vitamin D Supplementation

1. Previtamin D_3 is created in the skin from ultraviolet light conversion of 7-dihyrodcholesterol. The reason people do not get toxic levels from vitamin D conversion in the skin is

a. The conversion pathway becomes saturated and additional UV light products are metabolites are converted to inactive metabolites
b. We do not spend sufficient time exposed to the sun to become Vit D toxic
c. Sun-induced vitamin D toxicity does occur, but requires years to become manifest
d. The type of vitamin D created by UV light is inherently non-toxic

2. The United States Preventive Services Task Force has addressed screening for Vitamin D and says

a. Screening for vitamin D deficiency should be performed in adults
b. Women of childbearing age should be screened for vitamin D deficiency
c. Smoking males should be screened for vitamin D deficiency
d. There is insufficient evidence to recommend for or against vitamin D screening

3. If measurement of vitamin D status is done, the recommended metric is

a. 25(OH) vitamin D level
b. 1,25 (OH) vitamin D level
c. Free vitamin D level
d. Albumin-bound vitamin D

4. PTH levels begin to rise as 25(OH)vitamin D levels drop below 31 ng/ml. In a study of highly sun—exposed young adults in Hawaii (mean 22 hours/week), measured 25(OH) vitamin D levels showed

a. More than 90% of subjects were over 50 ng/mL
b. Most subjects had very high 25(OH) vitamin D levels (> 70 ng/mL)
c. More than half of subjects had levels below 31 ng/mL
d. Young adults appear to have different vitamin D responses compared to seniors

5. Total 25(OH)vitamin D levels are lower in African Americans than Caucasians

a. That is why African Americans suffer greater risk for osteoporosis
b. This is because African Americans spend less time in the sun than Caucasians
c. This reflects socioeconomic differences in diet
d. While this is true, *free* 25(OH) vitamin D levels are similar in both races

6. Observational studies have shown that vitamin D deficiency

a. Is associated with an increased risk of incident dementia
b. Is not associated with risk for incident dementia
c. Is associated with risk for cerebellar degeneration and subsequent falls
d. When reversed, produces measureable improvements in cognitive function

7. A clinical trial of high dose vitamin D (500,000 IU once yearly) in community dwelling seniors found

a. A reduction in falls of about 20%
b. No change in falls
c. an increase in falls and fractures
d. a decrease in falls but an increase in serious fracture risk

Answer Key: 1. A, 2. D, 3. A, C, 4. C, 5. D, 6. A, 7. C

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Common Outpatient Neurologic Conditions

Mononeuropathis
Mechanisms of Analyzing

- Detailed knowledge of PNS anatomy vs.
- Common patterns of focal complaints
  - Motor: loss of function
  - Sensory: loss and/or "gain" of function
- Basic epidemiology of mononeuropathy lesions (typically compressive)
- Brief differential diagnosis

Complaints

- Motor symptoms and functional impairment:
  - Weakness & other terms (? heaviness)
  - Functional limitations
  - Atrophy, ? cramps
- Sensory changes and functional impairment:
  - Numbness
  - Injuries
  - Neuropathic pain, including hot/cold discrimination, itching
  - Autonomic/trophic – more for PN

Screening Questions

- What bothers you the most?
- For any limb complaint:
  - Are there similar issues in other limbs?
  - Is there loss of sensation?
  - Are there excess or unpleasant sensations – describe
  - Is there weakness? – examples of task limitations
  - Is there loss of focal bulk
  - Bowel/bladder involvement
- For upper extremity complaint:
  - Bulbar, other CN sx
  - CNS sx
- For trunk: dermatomal, level, hemi-body changes

Nociceptive vs Neuropathic Pain States

Nociceptive vs **Neuropathic**

Nociceptive:
- Pain that arises from a stimulus that is outside of the nervous system
- Proportionate to the stimulation of the receptor
- When acute serves a protective function

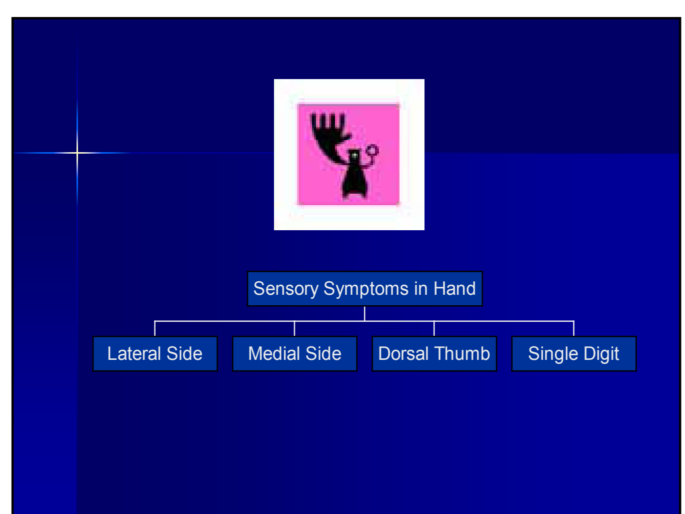
Neuropathic:
- Pain initiated or caused by a primary lesion or dysfunction in the nervous system
- No nociceptive stimulation required
- Disproportionate to the stimulation of receptor
- Other evidence of nerve damage
- PHN is classified as neuropathic pain

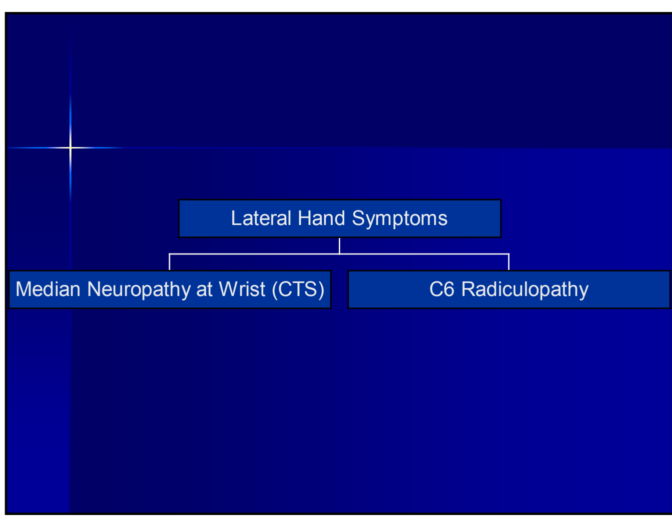
Neuropathic Pain Terms

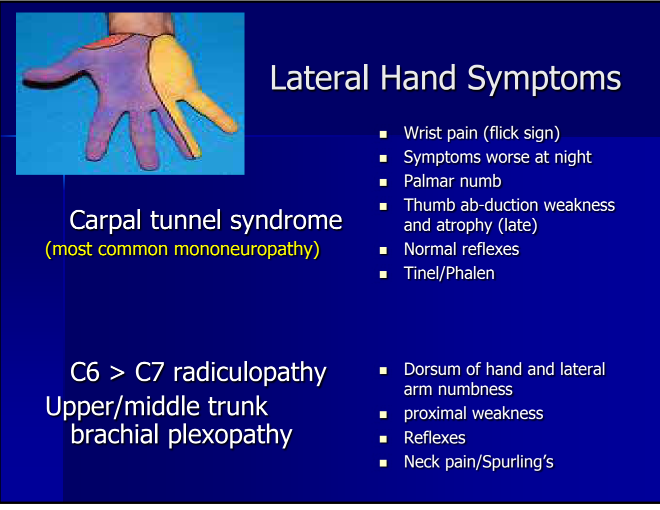
- Symptoms: prickling, burning, rocks in shoes …
- Functional Complaints: e.g. bedsheets
- Paresthesia: an unpleasant sensation arising spontaneously
- Dysesthesia: an abnormal sensation in response to an ordinary stimulus
- Allodynia: an ordinary, painless stimulus perceived as unpleasant and painful
- If I had a magic pill that took all your pain away, would you be ok?

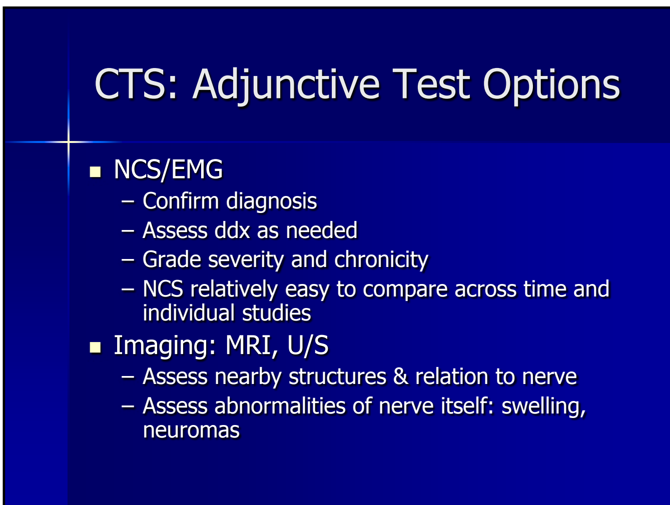
Neurologic Examination

- Mental Status
- Cranial Nerves: as needed
- Motor: bulk, power
- Sensory: vibration, focal/dermatomal pin
- Reflexes: r/o UMN, focal loss
- Coordination
- Gait: for lower extremity motor complaints









CTS - Rx Options

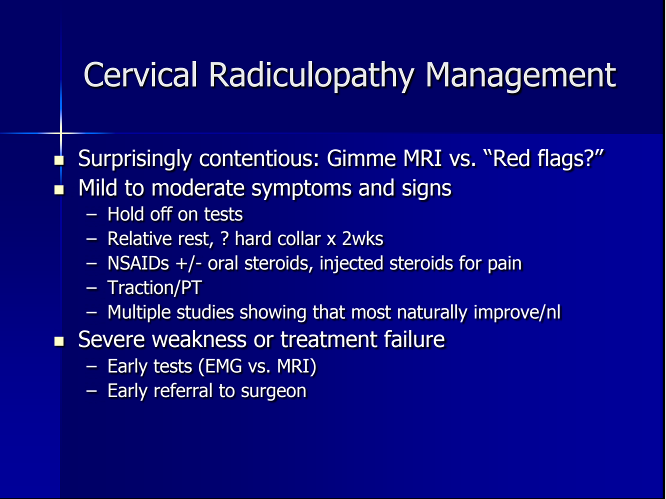
- Splints
- NSAIDs
- Oral neuropathic pain agents
- Injected steroids
- Surgery
  - Decompression/exploration

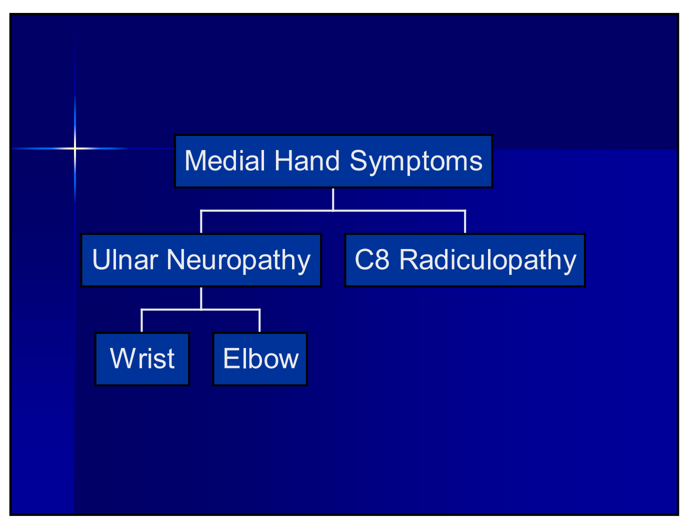
CTS Management: AAN 1993 guidelines

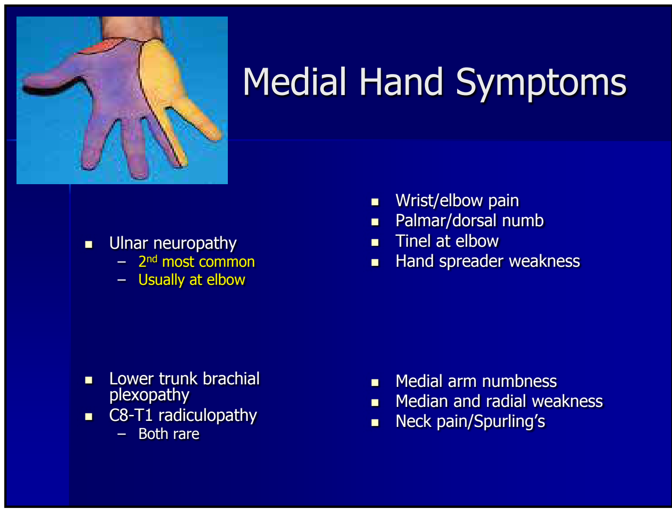
- Mild to moderate
  - Hold off on adjunctive tests
  - Trial of splints, oral agents
  - Improved at 2weeks
    - Continue for 6 m
    - 90% return to normal
  - Trial of injected steroids (qm x 3)
- Severe (or rx failure)
  - Consider adjunctive tests and surgery

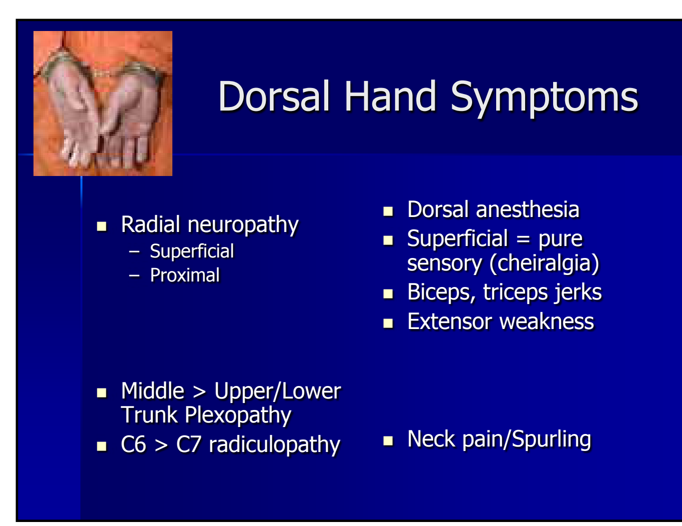
C6-7 Radiculopathy: Adjuctive Test Options

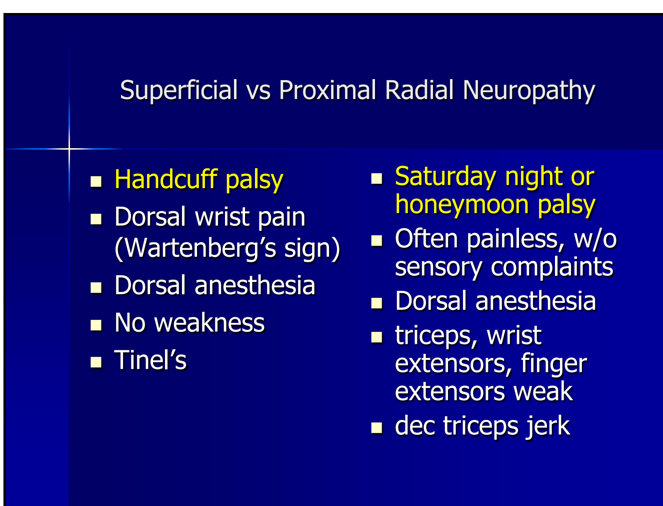
- NCS/EMG
  - False negatives occur
  - Can be painful, min invasive
- Imaging studies:
  - MRI: false positives, mult minor findings
  - CT myelogram: painful, invasive, risks

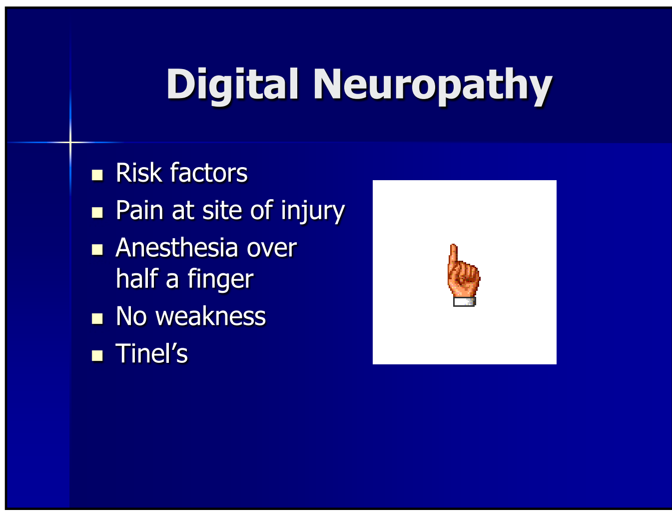


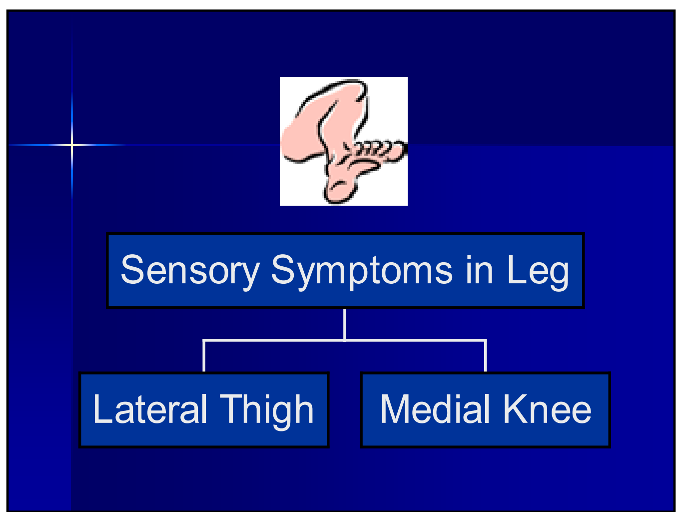






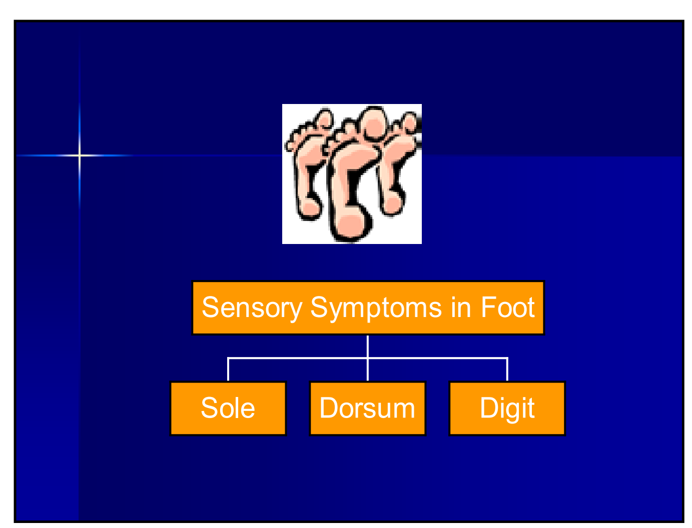


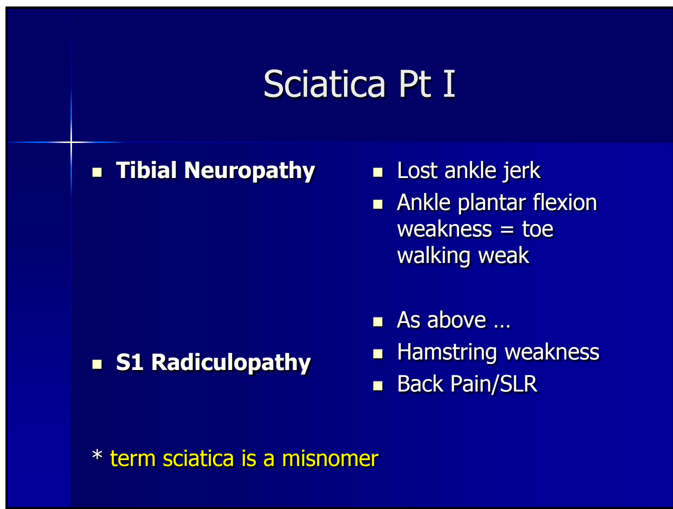


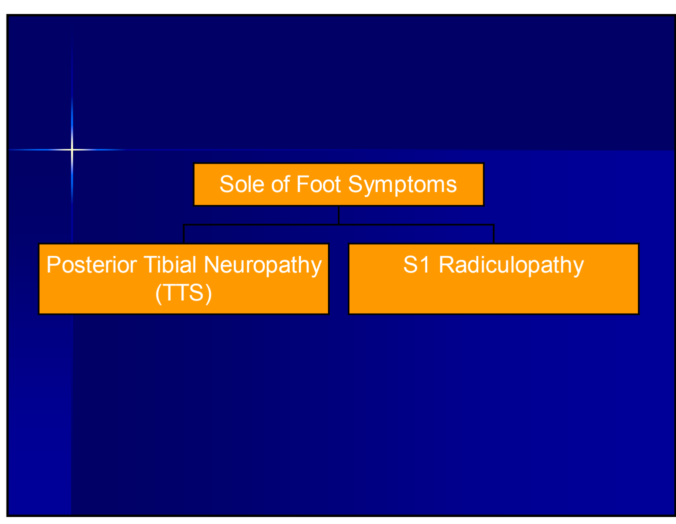


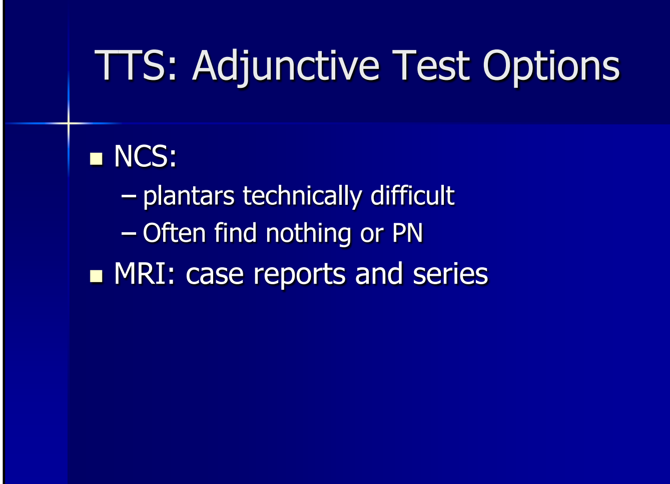
LFCN: Adjunctive Tests and Treatment

- Clinical diagnosis
- NCS: technically difficult
- EMG: rule out plexopathy/radic
- Imaging: retrospective case series
- Surgical exploration/decompression



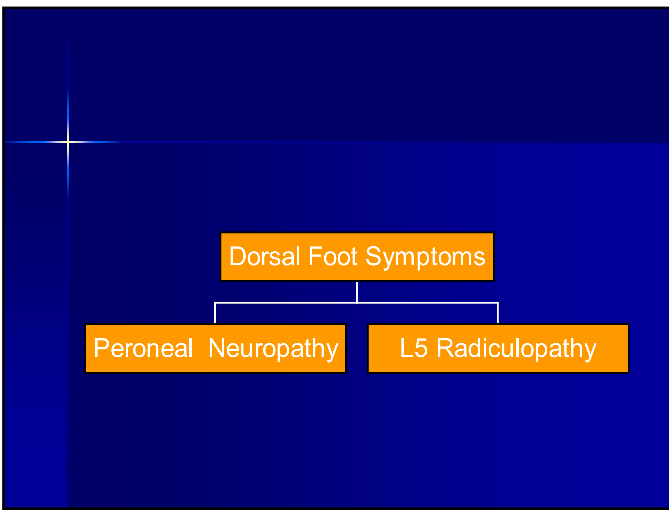


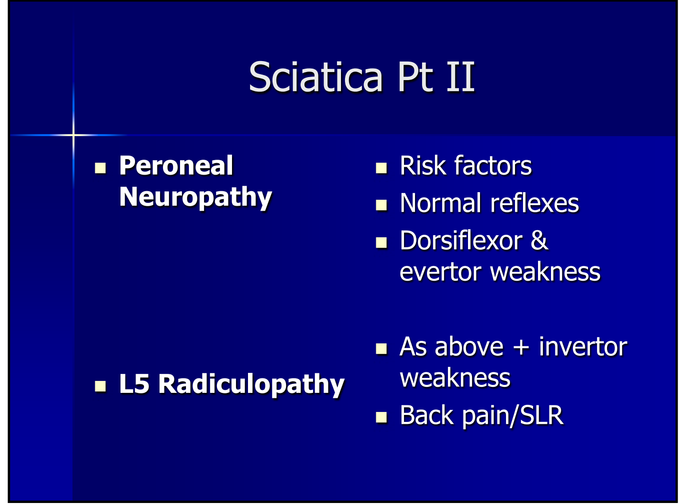




TTS: Adjunctive Test Options

- NCS:
  - plantars technically difficult
  - Often find nothing or PN
- MRI: case reports and series





NCS/EMG
Caveats and Limitations

- Operator driven
- Technical flaws
- Beware of data to interpretation mismatch
  - Technical summary
  - Clinical correlate
- Incidental findings
- Laundry lists
- I don't believe in EMG consults!!
- You can't be more normal than perfect
- You can't normalize dead nerves
- PAIN IS PAINFUL
  - pure sensory radiculopathy
  - Small fiber/autonomic neuropathy
  - NOT neurologic

Conclusions

- Focal sensory (and motor) symptoms are common and in certain patterns suggest PNS disease
- History and exam are usually adequate to localize and grade severity of problem
- Management of identified problems is usually conservative treatment

Seizures and Epilepsy
Overview

- Seizures and epilepsy are common
  - ED/hosp/ICU: stroke/TIA, sz, AMS
  - Neuro: protean manifestations, "one stroke at a time"
- Definition and classification scheme
  - It's not all generalized tonic clonic (GTC)
  - Variety of presentations and mimics
- Risk factors and history taking
- Impact of disease on patient
- Workup:
  - the MRI is NOT the end all be all
  - brief overview of EEG
- When to start an anti epileptic medication

Misnomers That Earn No Respect

- "Seizure" as a label without semiology
  - Bland terms: spell, event (fit)
  - No ICD9/10 code for pseudosz: 780.39
- 19th century sz descriptions:
  - GTC = grand mal VS.
  - Absence = petit mal
- "Post ictal" state
  - A sudden event; a beat/pulsation
  - Differentiate from inter or peri ictal

Definitions:
they signify CNS dysfunction with an episodic phenotype

- Seizure: abnormal synchronization of cortical neurons resulting in a **clinical** change in perception or behavior
  - Leoao theory of cortical spreading depression
  - Thalamocortical connections for IGE
- Epilepsy: **recurrent seizures** caused by an inherent brain abnormality (i.e. unprovoked)
  - Epilepsy trait on EEG requires a clinical context
- Epileptic syndrome: classification scheme involving seizure type(s), EEG pattern, age at onset, family history and prognosis, including response rates to certain AEDs/classes

Epidemiology On A Global Scale: Why Do Seizures Matter?

- 7-10% pop will have a sz during their life
  - Incidence highest in infantile/early childhood and geriatrics (> 60; more rapid inc > 70)
  - 4-5% children will have a febrile sz
- Common reason for ED visit/hospitalization and for neuro consultation
- 0.5-1% pop have epilepsy
  - Classified by clinical and EEG characteristics
  - Medical and social ramifications
  - Require chronic neurologic care
    - One of top 5 most diagnoses neurologists dread to give
    - Dilantin one of top 4 most frequently prescribed drugs by a neurologist (along with aspirin, amitryptyline)

Medical Ramifications

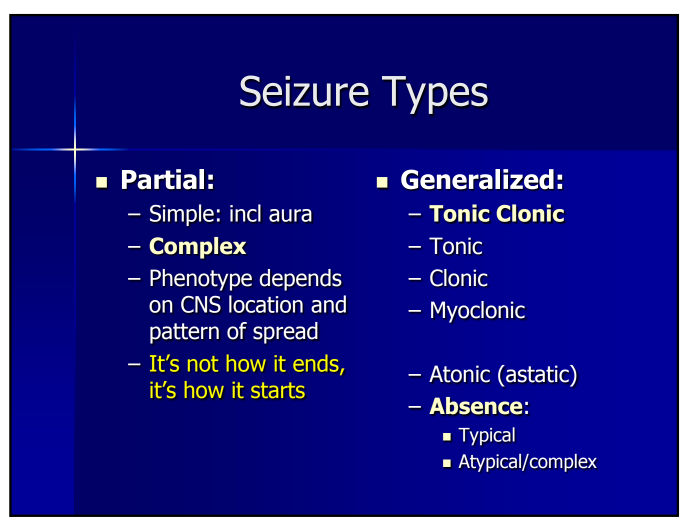
- Somatic comorbidities
  - Seizures as a static/reactive vs dynamic phenomenon
  - Trauma– oral/dentition, fractures, internal, asp PNA
    - Posterior shoulder dislocation
  - Drowning
  - Memory loss and cognitive dysfunction
  - SUDEP (sudden unexplained death in epilepsy)
- Psychiatric comorbidities
  - Substance abuse
  - High rates of depression
  - suicidality (especially temporal lobe epilepsy)
    - Forced normalization

Social Ramifications

- Stigmatized diagnosis
- Caregiver burden and psychosocial implications
- Low socioeconomic achievement
  - Education level
  - High rates of unemployment
- Social and work environment limitations
  - Construction, carpentry, roofing, cooking …
  - Bathing/swimming, incl supervising others
- Workplace discrimination
  - Sen Coelho and Americans w/ Disabilities Act
- Driving Restrictions…

Social Issues: Driving Privileges

- Rules vary state by state
- DMV renewal mentions multiple etiologies of loss of consciousness states
- For CPS and gen sz, recs usually for 6-12 mos sz freedom prior to resuming driving
  - Based on studies examining rates of sz recurrence at various time points
- Pts w/ isolated and well documented simple partial or nocturnal seizures may be exempt



Seizure Classification

	Partial	Generalized
Genetic	▪ Childhood – BECTS, benign occipital epilepsy	▪ **IGE** - CAE - JAE/**JME** - GTC am
Acquired	▪ **Structural lesions** ▪ Adults > peds ▪ May be **multifocal**	▪ Toxic (EtOH, drugs) ▪ Metabolic (hypoglycemia, hypoxia, organ failure) ▪ Degenerative (CJD)

What Is Plan B ? Treatment Options

Partial	▪ Approved AEDs ▪ Clinical Trials ▪ Stimulators: VNS, NeuroPace ▪ **Surgery: Resection vs. radiofrequency**
Generalized	▪ Approved AEDs ▪ Clinical Trials ▪ Stimulators: VNS

Predisposing Factors By All Ages

- Genetic - ?: 2/3 idiopathic/cryptogenic
- Developmental/Congenital – 8%
- Trauma: closed/open head injury – 6%
- Vascular: perinatal, adult onset – 12%
- Neoplastic & Rx Related – resection, chemo, post XRT with necrosis – 4%
- Infectious – 1-2%
- Degenerative: i.e. **2ary to atrophy-** 3%

Partial Seizure Epidemiology by Lobe

- Frontal – 30+% - tumor, ACA, **trauma**
- Temporal – 50+% - tumor, **MCA, trauma, hypoxia/ischemia, prior sz**
  - CA-1 sector of hippocampus
  - Sz begets sz/kindling
- Parietal - <10% - tumor, MCA
- Occipital - <10% - genetic; PCA

Partial Onset Seizure Semiology

- Variable: more narrow seizure focus with limited spread produces more narrow clinical phenotype
- Partial motor spread: Jacksonian march
- **Frontal** – hyperkinetic, incl fencing, bicycling or pedaling, versive eye/head mvmts
  - Eyes towards lesion = destructive vs away = sz
- **Temporal** – GI, olfactory, deja/jamais vu, orofacial or limb automatisms, insular
  - Epileptic rage/violence rare; overplayed in media/courts
- Parietal - sensory disturbance, apraxia
- Occipital - can be positive (flashers, hallucinations, formed images) or negative (scotoma)

Complex Partial Seizure

- Might have warning/aura
- Abnormal responsiveness to environment
- Amnesia for some/all of event
- Post ictal period (may be hard to sort clinically from seizure itself)
- Can progress into generalized event

Differential Diagnosis

Peds

- All of the above, plus:
- Rage attacks
- Breath holding spells
- Sandifer syndrome
- Parasomnias
- Etc…

Adults

- **Stroke**
- **Syncope**
- **Complex migraine**
- **Arrhythmia**
- PNEA (“pseudosz”)
  - Conversion/malinger
  - Panic/other psych
- Movement disorder
- Narcolepsy
- TGA

Psychogenic Events

- Represent 20% referral to tertiary epilepsy centers
- Clues:
  - Unusual motor movements: eyes held shut or sustained muscle contractions, pelvic thrusting, opisthotonus, poorly coordinated thrashing, avoidance maneuvers
  - On-off pattern
  - No post ictal state
  - Khishchenko ism: the more attention they attract …
  - No metabolic derangements despite long generalized spell
    - Prolactin not reliable; may also inc w/ syncope
- Importance of diagnosis:
  - Impacts prognosis, ED visits
  - Get appropriate psychotherapy
  - Avoid or wean off AEDs w/ side effects
  - Avoid acute med mgmt & complications (psychogenic SE)
  - 1/3 may have both PNEA and epilepsy

Work Up

- HISTORY:
  - spell description (including witnesses/bystanders)
  - risk factors
  - **Sz/epilepsy is a clinical diagnosis**
- Neurologic Examination:
  - usually non localizing
  - syndromic findings: e.g. phakomatoses
- EEG
- Imaging: acute CNS injury; suspect focal sz
  - Sz protocol study: temporal thin cuts
  - sometimes fronto polar thin cuts as well
- Other: metabolic, CSF, genetic testing

Risk Factors (Seizure History)

- **Standard PMH**, with focus on CNS and systemic disorders
- **Developmental:**
  - Pregnancy complications
  - Birth weight and gestational age
  - Motor and intellectual milestones
  - CNS structural insults: stroke, infection, surgery, trauma (open vs CHI)
  - Febrile seizures: prolonged, multiple, focal, temp
- **Family history of unprovoked sz/epilepsy/rx**
- **Psych/social:**
  - Comorbid psych disorders
  - History of substance abuse
  - History of being victim of abuse
  - Disability/secondary gain

Factors That Lower Seizure Threshold

- Drugs:
  - Prescribed:
    - Toxic levels: PCN, INH, lithium
    - Lower sz threshold: TCAs, neuroleptics
  - Legal: Alcohol (overuse and withdrawal)
    - Withdrawal sz usually 12-48hrs post abstinence
    - Can be up to > 7days out, a/w DTs
    - Benzo taper; AEDs don't work unless 2ary cause
  - Illegal: cocaine, amphetamines
- Sleep deprivation
- Medication noncompliance

Electroencephalogram: What Is It?

- Neurophysiologic tool for assessing electrical activity of brain in real time
- Standard electrode placement, provocative maneuvers and (sort of) reporting
- multiple montage options
- Tech dependent: acquisition and interpretation typically separate functions
- IT revolution: acquisition, storage, video

EEG As a Tool

- epileptiform abn'l
- Spell characterization
- Prolonged monitoring
- Structural lesions
- AMS workup: degenerative, delirium
- Sleep disorders
- Coma & prognosis
  - ECI: ancillary tool for brain death
- Live Monitoring:
  - PSG (ltd montage)
  - Tilt table
  - Intra Op: e.g. CEA, BIS
- NeuroPace
- Pre Operative workup
  - Special Leads
  - Intracranial Recording
  - Combine with functional neuroimaging

EEG: What To Order

- Routine vs sleep deprived
- Provocative maneuvers: photic stim, HV
- 24hr ambulatory studies
- Workup may require serial studies
- Sedation:
  - Don't use in adults; can be reoriented
  - Chloral hydrate sometimes used in peds
  - Benzos might minimize relevant findings

Yield of EEG: Think a little bit like a cardiologist

- Single EEG: 30-40% interictal abnl
  - "normal EEG does not r/o epilepsy"
- Multiple routine EEGs inc yield to 60-90%
- Ambulatory recording for frequent spells and increased yield of interictal abnormalities
- Growing emerging body of evidence for continuous monitoring for SCSE or NCSE in ICU pts and selected brain injury pts
  - Limited by pragmatic issues: machines, techs, electrodes interfering w/ imaging studies
  - Real time acquisition is NOT real time interpretation
    - NOT like cardiac telemetry: EEG reading skills in most hospitals highly concentrated, even w/ detection software

When To Initiate AED? (Probability of Future Recurrence)

- First ever seizure, normal EEG: 20-30%
  - Two sz w/in 24hrs, w/ return of consciousness in between, carries no worse prognosis for recurrence than one sz
  - MESS trial: early vs delayed AED start did not change long term prognosis or 2yr sz freedom rate
- Two seizures or one seizure with abnormal EEG: 50-60%
- Three seizures: 75-80%
- increased risk of recurrence with:
  - Status epilepticus as presenting seizure
  - Focal sz onset/neuro deficits/structural CNS lesion
    - Focal sz w/ nl EEG: 40-60%; w/ abnl EEG: 60-80%
  - mental retardation/global CNS dysfunction
- Even pts w/ mult acute sx sz only do NOT need AED
- AED prophylaxis for brain tumors, stroke/bleed, TBI, neurosurgical procedures is largely expert opinion driven
  - Some data in TBI that prophylaxis dec early but NOT late sz risk

SELF EVALUATION

Common Outpatient Neurologic Conditions

1. True/False - Carpal tunnel syndrome is the most common nerve disorder

2. True/False - The most common location for ulnar nerve entrapment is at the wrist

3. The differential diagnosis of medial hand (pinky) symptoms includes all of the following EXCEPT

a. ulnar neuropathy
b. axillary neuropathy
c. lower trunk brachial plexopathy
d. C8 radiculopathy

4. Radial neuropathy is also known as:

a. Saturday night palsy
b. honeymoon palsy
c. handcuff palsy
d. all of the above

5. The most common cause of lateral thigh numbness is:

a. Brain tumor
b. Lumbar radiculopathy
c. Lateral femoral cutaneous neuropathy aka meralgia paresthetica
d. Cord compression

6. Sensory symptoms of the lateral aspect of the foot are due to compression at what root level:

a. C7
b. T5
c. L4
d. S1

7. The prevalence of a single non febrile seizure is:

a. 1%
b. 7-10%
c. 30%
d. 50%

8. The differential diagnosis of seizure includes:

a. stroke
b. migraine
c. syncope
d. all of the above

9. Factors that lower the seizure threshold include:

a. sleep deprivation
b. Use of illicit substances
c. Medication noncompliance
d. All of the above

Answer Key: 1. T, 2. F, 3. B, 4. D, 5. C, 6. D, 7. B, 8. D, 9. D

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Medical Errors Prevention: Parts I & II

Florida Board of Medicine: Five Most Misdiagnosed Conditions

1. Cancer
2. Neurological Conditions
3. Cardiac-related issues
4. Timely diagnosis of surgical conditions
5. Urological-related issues

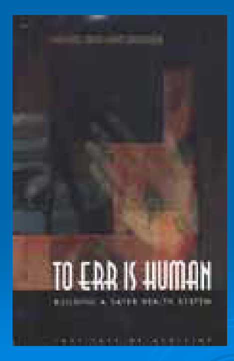
MEDICAL ERRORS PREVENTION: FLORIDA LAW (Florida Statute 395.0197)

- Adverse (sentinel) events must be reported to organization leadership.
- Licensed facilities (hospitals) must have a risk management program and an incident reporting system.
- Incident reports submitted within 3 business days; some →AHCA (Agency for Health Care Administration) within 15 d.

What's different from last year?

- Proactive recognition of adverse events.
- Encourage comments, critique and suggestions.
- Provide learning experience and tools to incorporate into your daily practice.

IOM – November, 1999



3.7% error rate

14% death rate

98,000 deaths annually (more die each year than the entire Vietnam War, or motor vehicle accidents or breast cancer).

Lucian Leape, MD

IOM Report

- " More people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516) "

To Err Is Human: Building a Safer Health System (2000, 312 pp.)
Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, Editors; Committee on Quality of Health Care in America, Institute of Medicine

Leading Cause of Death 1999

1. Heart disease — 725,192
1. Cancer — 549,83
2. Chronic Respiratory Disease - 142,181
3. Medical errors >98,000 ⇦
5. Injuries — 97,820
6. Diabetes — 68,399
7. Influenza & Pneumonia 63,700
8. Alzheimer's Disease 44,356
9. Nephritis 35,525

Sources: *http://www.cdc.gov/ncipc/pub-res/research_agenda/chart.htm 13sep02*

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Can You Believe The Numbers?

- Assuming 6000 acute-care hospitals in US the IOM estimates imply 7-10 fatal medical errors/year/hospital.
- NOT including similar deaths at skilled nursing, long term care, or outpatient facilities.
- Equivalent to one jumbo jet crashing every day.

Crossing the Quality Chasm

- GOAL:

To arrive at health care that was high quality that is, safe, effective, patient-centered, efficient, delivered on a timely basis, and devoid of disparities based on race or ethnicity—would require a herculean effort to move the field across the abyss

Focus On Quality

- "Quality healthcare means doing the right thing at the right time in the right way for the right person and having the best results possible."
  - Agency for Healthcare research and Quality, National Quality Report 2003.

IOM Report Impact

- Leapfrog Group, a coalition representing large health care purchasers that has advocated "safety leaps" through the use of computerized order entry, evidence-based hospital referrals, and physician staffing in the intensive care unit.
- In surveys, 24 percent of responding hospitals said they had intensive care units staffed by intensivists in 2003, as compared with 12 percent in 2001, and the use of computerized physician order entry had increased from 2 percent to 5 percent

IOM Report Impact

- American Board of Medical Specialties has expanded the requirements for maintenance of board certification to include demonstrated competence in providing safe, high-quality care.

Joint Commission Medical Error Prevention Policy

- To have a positive impact in improving patient care, treatment, and services and in preventing unintended harm
- To focus the attention of a hospital that has experienced a sentinel event on understanding the factors that contributed to the event (such as underlying causes, latent conditions and active failures in defense systems, or hospital culture), and on changing the hospital's culture, systems, and processes to reduce the probability of such an event in the future.
- To increase the general knowledge about patient safety events, their contributing factors, and strategies for prevention
- To maintain the confidence of the public, clinicians, and hospitals that patient safety is a priority in accredited hospitals

What Has Changed Since the IOM Report in 1999?

Painful Realization

- Medical error—the third leading cause of death in the US
  - BMJ 2016; 353 doi: http://dx.doi.org/10.1136/bmj.i2139 (Published 03 May 2016)

Study Results

- 10 percent of all U.S. deaths are now due to medical error.
- Third highest cause of death in the U.S. is medical error.
- Medical errors are an under-recognized cause of death.

Analyzing medical death rate data over an eight-year period, Johns Hopkins patient safety experts have calculated that more than 250,000 deaths per year are due to medical error in the U.S

Study

- In their study, the researchers examined four separate studies that analyzed medical death rate data from 2000 to 2008, including one by the U.S. Department of Health and Human Services' Office of the Inspector General and the Agency for Healthcare Research and Quality.
- Using hospital admission rates from 2013, they extrapolated that based on a total of 35,416,020 hospitalizations, 251,454 deaths stemmed from a medical error, which the researchers say now translates to 9.5 percent of all deaths each year in the U.S.

Conclusions

The researchers caution that most of medical errors aren't due to inherently bad doctors, and that reporting these errors shouldn't be addressed by punishment or legal action.

Conclusion

Most errors represent systemic problems, including poorly coordinated care, fragmented insurance networks, the absence or underuse of safety nets, and other protocols, in addition to unwarranted variation in physician practice patterns that lack accountability.

What Is A Sentinel Event?

- A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.
- Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.
- Such events are called "sentinel" because they signal the need for immediate investigation and response.

JOINT COMMISSION: NINE YEAR REVIEW OF SENTINEL EVENTS (2004-2012)

MAJOR CAUSES OF 6994 SENTINEL EVENTS AFFECTING 7061 PATIENTS:

1. Wrong patient, wrong site, wrong surgical procedure
2. Delays in treatment
3. Operative and postoperative complications
4. Patient suicide
5. Patient falls
6. Medication errors

Medical Error

- A failure of a planned action to be completed as intended (error of execution) or the use of a wrong plan to achieve an aim (error of planning)
- Anything that happened that should not have happened and was not anticipated.
- A commission or omission with potentially negative consequences for the patient

Error Terminology

- Error of Commission (doing something wrong) as a result of an action taken.
  - ordering a medication for a patient with a documented allergy
  - Surgery performed on wrong site
  - Transfusion with blood cross matched for another patient
- Error of Omission (failing to do the right thing) as a result of an action not taken.
  - Failing to prescribe a proven medication with major benefits for an eligible patient (eg, low-dose unfractionated heparin as venous thromboembolism prophylaxis for a patient after hip replacement surgery)
  - Delay in doing an indicated C-Section resulting in fetal death

Error Terminology

Errors of omission are more difficult to recognize than errors of commission but likely represent a larger problem.

Adverse Medical Events

- Adverse medical events (also known as iatrogenic events) are injuries and deaths that are caused by something other than the medical condition for which the patient is seeking care.
- They are typically divided into three categories, as follows: preventable and negligent; preventable but not negligent; and other adverse events

Preventable And Negligent

- Also called malpractice errors, are injuries or deaths resulting from medical misconduct or lack of adherence to basic minimum standards of care.
- Examples are performing surgery on the wrong site, or leaving a sponge in a patient after an operation.

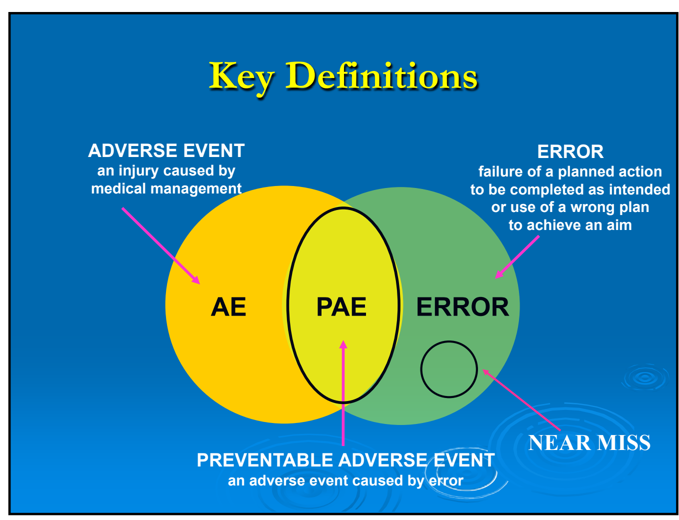
Preventable But Not Negligent

- Considered avoidable, although they are not the result of negligence.
- Some hospital-acquired infections are examples of this sort of medical error

Other Adverse Events

- Events that we do not know how to prevent with our current knowledge and technology.
- There is no obvious way of avoiding them YET!

Key Definitions



Root cause analysis …

. . . a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event.

Organizing to Conduct a Root Cause Analysis

- Commitment and participation of leaders
  - Administration, nursing, medical staff
- "Hands-on" care-givers (all disciplines)
- QI & RM professionals; legal counsel
- Getting started:
  - Facts of the case (Who? What? Where? When?)
  - Describe the process(es):
    - As designed
    - As usually performed
    - As performed in this case

Goal of a RCA

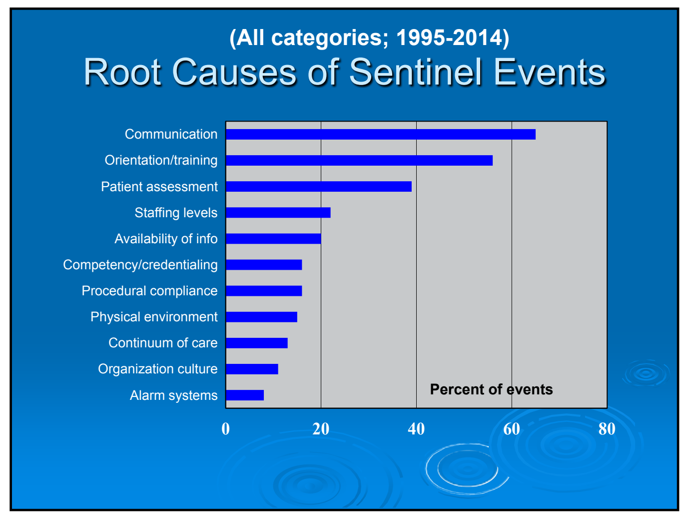
- Determine WHAT happened
- Determine WHY did it happen
- Determine HOW TO PREVENT it from happening again
- All within the CULTURE OF SAFETY
- Safety is the CORNERSTONE OF QUALITY

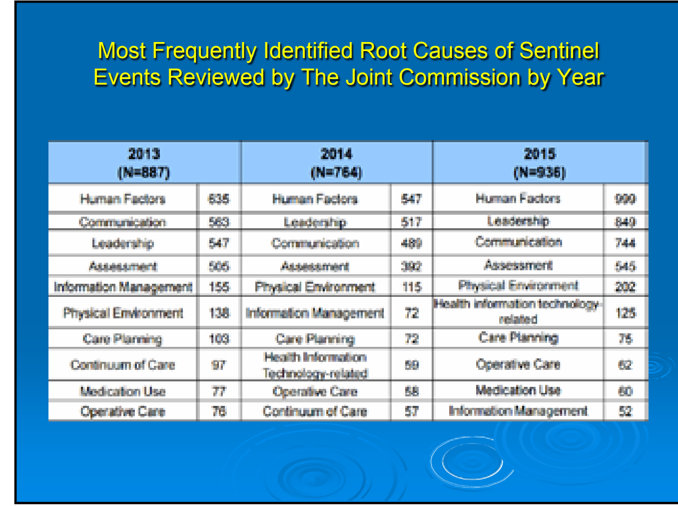
To Be A Credible RCA

- Include participation by the leadership of the organization
- Be internally consistent
- Include consideration of ALL relevant information.

RCA: Flow Chart Method

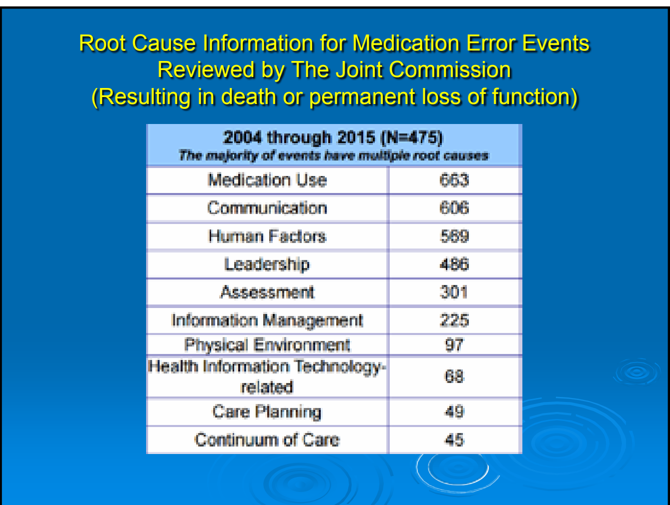
- Detailed sequence of what happened
- Sequence of what should have happened
- Compare the two charts
- If identical and outcome was adverse, then there is a flaw in the system
- If different, then it may be possible to identify the deviation and find why it occurred
- Always search for the flaw and the "why"





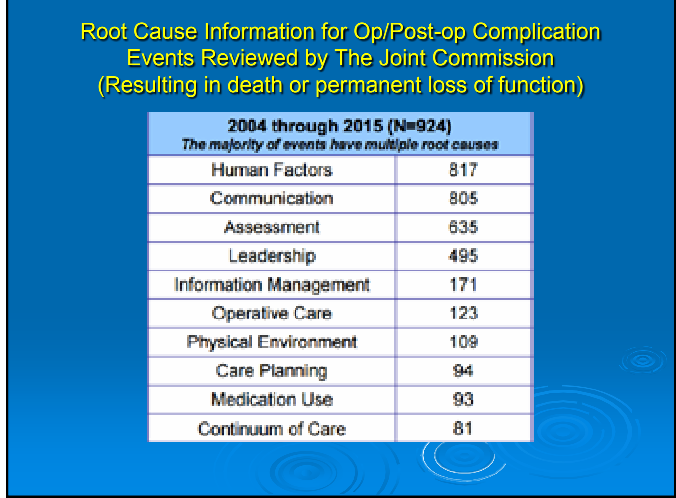
Most Frequently Identified Root Causes of Sentinel Events Reviewed by The Joint Commission by Year

2013 (N=887)		2014 (N=764)		2015 (N=936)	
Human Factors	635	Human Factors	547	Human Factors	999
Communication	563	Leadership	517	Leadership	849
Leadership	547	Communication	489	Communication	744
Assessment	505	Assessment	392	Assessment	545
Information Management	155	Physical Environment	115	Physical Environment	202
Physical Environment	138	Information Management	72	Health information technology-related	125
Care Planning	103	Care Planning	72	Care Planning	75
Continuum of Care	97	Health Information Technology-related	59	Operative Care	62
Medication Use	77	Operative Care	58	Medication Use	60
Operative Care	76	Continuum of Care	57	Information Management	52



Root Cause Information for Medication Error Events Reviewed by The Joint Commission (Resulting in death or permanent loss of function)

2004 through 2015 (N=475) *The majority of events have multiple root causes*	
Medication Use	663
Communication	606
Human Factors	569
Leadership	486
Assessment	301
Information Management	225
Physical Environment	97
Health Information Technology-related	68
Care Planning	49
Continuum of Care	45



Root Cause Information for Op/Post-op Complication Events Reviewed by The Joint Commission (Resulting in death or permanent loss of function)

2004 through 2015 (N=924) *The majority of events have multiple root causes*	
Human Factors	817
Communication	805
Assessment	635
Leadership	495
Information Management	171
Operative Care	123
Physical Environment	109
Care Planning	94
Medication Use	93
Continuum of Care	81

The Patient Safety and Quality Improvement Act of 2005

- This law sets up a voluntary system under which doctors, hospitals, and other healthcare providers can report medical errors.
- Create a network of patient safety organizations (PSOs), both public and private, under the auspices of the Department of Health and Human Services.
- Doctors will voluntarily report medical errors to these PSOs, which will then analyze the incident reports and enter non-identifiable information into central databases
- HHS analysts will then access these databases to produce recommendations on how patient safety can be improved on a national level.

The Patient Safety and Quality Improvement Act of 2005

- Reports on errors and near misses remain confidential and cannot be used in any criminal, civil, or administrative actions, in most circumstances.
- If a court determines that a report contains evidence of a criminal act, that this evidence is material to the case, and that the same evidence isn't reasonably available from any other source, a voluntary report, under these restrictive circumstances, could be used in a legal proceedings.
- Information gained from sources other than a voluntary report (patient records or billing records, for example) remains open to discovery.
- The law doesn't preempt existing mandatory state reporting laws.

Patient Safety and Quality Improvement Act

- SHARE information about events so you can learn from them.Facilitate learning about best practices from your peers
- LEARN from data aggregation, in-depth patient safety analytics and Advisories, statewide and national comparisons
- PROTECT patients from harm through evidence-based solutions

Serious Reportable Events

- Surgical Events
- Product or Device Events
- Patient Protection Events
- Care Management Events
- Environmental Events
- Criminal Events

Surgical Events

- Surgery performed on the wrong body part
- Surgery performed on the wrong patient
- Wrong surgical procedure performed on a patient
- Unintended retention of a foreign object in a patient after surgery or other procedure
- Intraoperative or immediately postoperative death in an ASA Class I patient

Product or Device Event

- Patient death or serious disability associated with the use of contaminated drugs, devices or biologics provided by the healthcare facility
- Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended
- Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility

Patient Protection Events

- Infant discharged to the wrong person
- Patient death or serious disability associated with patient leaving the facility without permission
- Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility

Care Management Events

- Medication Errors
- Hemolytic reaction
- Patient death associated with hypoglycemia
- Stage 3 or 4 pressure ulcer
- Maternal death during labor or delivery
- Artificial insemination with wrong donor

Environmental Events

- Patient death or serious disability associated with an electric shock.
- Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.
- Patient death or serious disability associated with a burn incurred from any source.
- Patient death or serious disability associated with a fall while being cared for in a healthcare facility.
- Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility.

Criminal Events

- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
- Abduction of a patient of any age
- Sexual assault on a patient within or on the grounds of a healthcare facility
- Death or significant injury of a patient or staff member resulting form a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility

Adverse Events Medicare Patient

Report of the OIG – November 2010

- 780 Medicare Charts – Oct 2008
  - NQF Never Events, CMS Hospital Acquired Events
- 13.5% adverse events led to patient harm
- 1.5% contributed to death
- 44% preventable
- 200,000 preventable deaths annually
- $4,400,000,000 additional costs
- **http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf**

To Err is Human – To Delay is Deadly

Consumer Reports, SafePatientProject.org 2009

"Despite a decade of work, we have no reliable evidence that we are any better of today. More than 100,000 patients still needlessly die every year… We have failed to make the systemic changes in health care needed to end preventable medical harm."

Jim Guest, President
Consumers Union

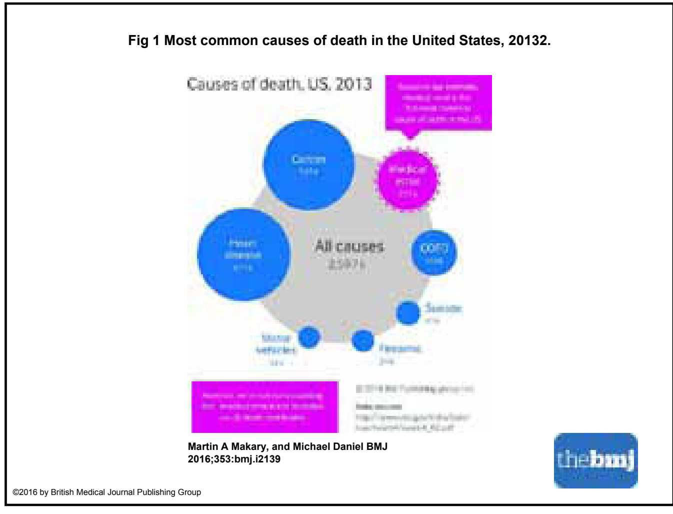


Fig 1 Most common causes of death in the United States, 20132.

What is the Problem?

- A major obstacle is the absence of a consensus on what specific efforts should be the focus of safety improvement, including how best to collect and report information on the quality and safety of hospitals and health care professionals.
- Gap between the steps identified as important by patient-safety experts and the views of health care professionals.

Medical Error Reporting

- Physicians often oppose public reporting of information on medical errors
- But 71 percent of the public believes that public reporting of medical errors by government agencies would be very effective in reducing errors.
- 7 in 10 persons say that such reports would tell them "a lot" about the quality of a hospital or a health care professional.

Need For Change

- The principal obstacle to broader action is therefore not Congress or money but a lack of consensus among policy makers and the public, and especially among health professionals themselves, on which events should be publicly reported and what systemwide steps are needed to prevent avoidable harm.

Patient Safety

- Achieving high reliability of health care delivery determined primarily by establishing and maintaining rates of failure that are near ZERO on important measures of quality across ALL clinical services provided by the organization.

Requirements

- Strong Leadership
- Reliable Safety Culture
- Robust process improvement

IMPORTANT!

- Term high reliability describes consistent performance at high levels of safety over long periods of time.
- Collective mindfulness means that everyone who works in these organizations, both individually and together, is acutely aware that even small failures in safety protocols or processes can lead to catastrophic adverse outcomes.

Safety Culture - Aircraft Carriers

Karlene Roberts

- Raise expectations
- Explicit Priority
- Change in command and control
- "Stop the Line"
- Teams

Ritz Carlton Credo

- …create a work environment of teamwork…to meet the needs of our guests and each other
- …when a guest has a problem you should …address and resolve the issue
- Whoever receives a complaint will own it, resolve it to the guests satisfaction and record it
- Think safety first. Each employee is responsible for creating a safe environment…

Common Organizational Features

- They eliminate deficiencies in safety processes through the use of powerful tools to improve their processes.
- Rely on a particular organizational culture to ensure the performance of improved safety processes over long periods of time and to remain constantly aware of the possibility of failure.

Prevalence and Characteristics of Physicians Prone to Malpractice Claims

- Approximately 1% of all physicians accounted for 32% of paid claims.
- Among physicians with paid claims, 84% incurred only one during the study period (accounting for 68% of all paid claims), 16% had at least two paid claims (accounting for 32% of the claims), and 4% had at least three paid claims (accounting for 12% of the claims).
- In adjusted analyses, the risk of recurrence increased with the number of previous paid claims.
- **Prevalence and Characteristics of Physicians Prone to Malpractice Claims.David M. Studdert, L.L.B., Sc.D., Marie M. Bismark, M.B., Ch.B., L.L.B., Michelle M. Mello, J.D., Ph.D., Harnam Singh, Ph.D., and Matthew J. Spittal, Ph.D.N Engl J Med 2016; 374:354-362January 28, 2016**

What Are The Challenges?

- The available evidence suggests that the risk of harmful error in health care may be increasing.
- As new devices, equipment, procedures, and drugs are added to our therapeutic arsenal, the complexity of delivering effective care increases.
- Complexity greatly increases the likelihood of error, especially in systems that perform at low levels of reliability.

IMPORTANT!

- We face the intersection of two interrelated trends:
- Hospitals house patients who are increasingly vulnerable to harm due to error, and the complexity of the care hospitals now provide increases the likelihood of those errors.

The 5 R's of Medical Errors

- R ely only on your memory
- R ely only on your self
- R ely on a blank piece of paper
- R eminders and Audits anger you
- R etraining is an insult to your intelligence

REASONS FOR ERRORS

- HUMAN FALLIBILITY
- COMPLEXITY OF MEDICINE
- SYSTEM DEFICIENCES
- VUNERABILITY OF DEFENSE BARRIERS

Medical Errors and Humans

- Many medical errors are attributable to characteristics of the human condition, and their risk is predictable.
- We can not change the human condition, but we can change the conditions under which humans work.

To Err is Human

- Punishment makes reducing error much more difficult by providing strong incentives for people to hide their mistakes, thus preventing recognition, analysis, and correction of underlying diseases.
- Error analysis has focused on individuals.
- Focus should be on system and safety.

Why Do Errors Happen?

- Most errors occur because caring professionals are forced to work in "imperfect" situations:
  - High stress environments
  - Long work hours
  - Complexity and subjectivity of medicine
  - Medical and healthcare culture
  - Information Overload and Deficit

Medical Errors Blame The Person

- Person approach isolates the acts from the system.
- Errors happen to good people in bad systems.
- Mishaps are not random and usually fall into recurrent patterns.
- Same circumstances can provoke similar errors, regardless of the people involved.

"…modern health care is the most complex activity ever undertaken by human beings." *Ken Kizer*

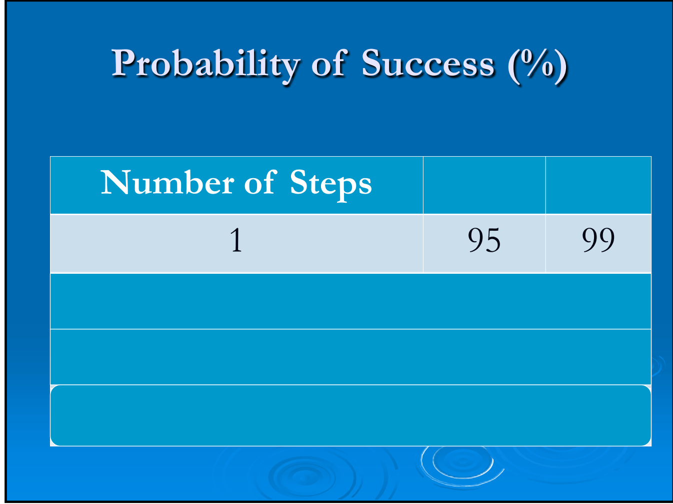
- Highly complicated technologies
- Panopoly of powerful drugs
- Widely differing professional backgrounds
- Unclear lines of authority
- Highly variable physical settings
- Unique combinations of diverse patients
- Communication barriers
- Care processes widely vary
- Time pressured environment

Medication Process – Hospital

Prescribing | Transcribing | Dispensing | Administering | Monitoring

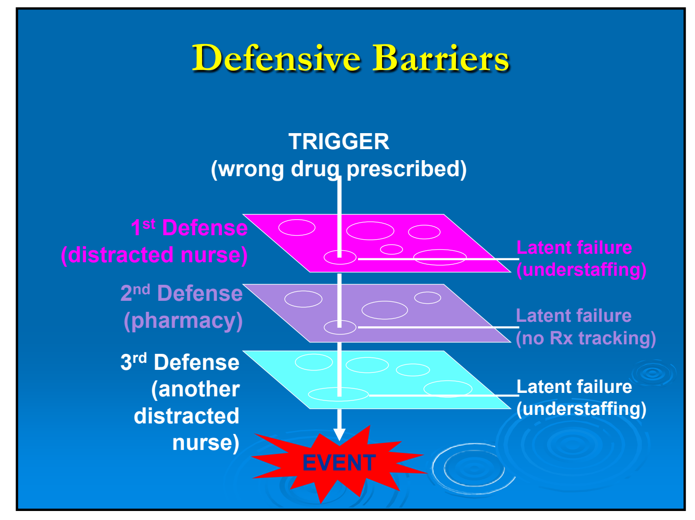
25 Steps

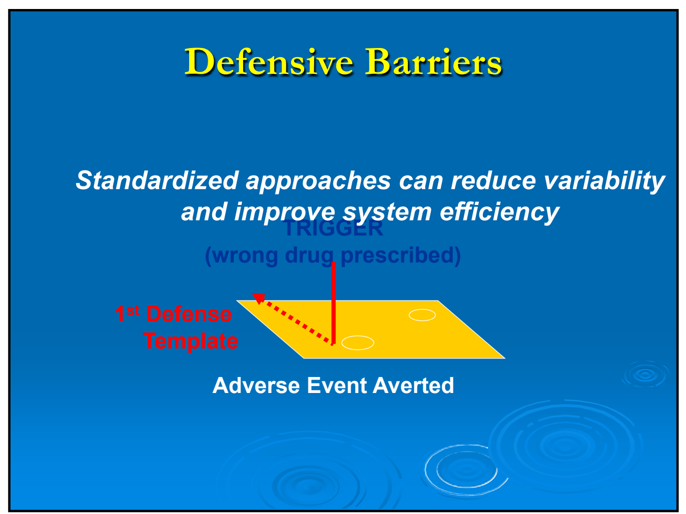
Quality Improvement Activities

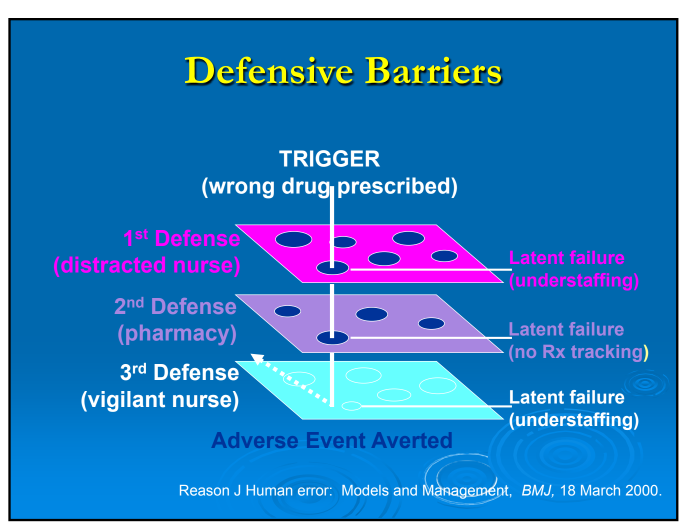


Probability of Success (%)

Number of Steps		
1	95	99







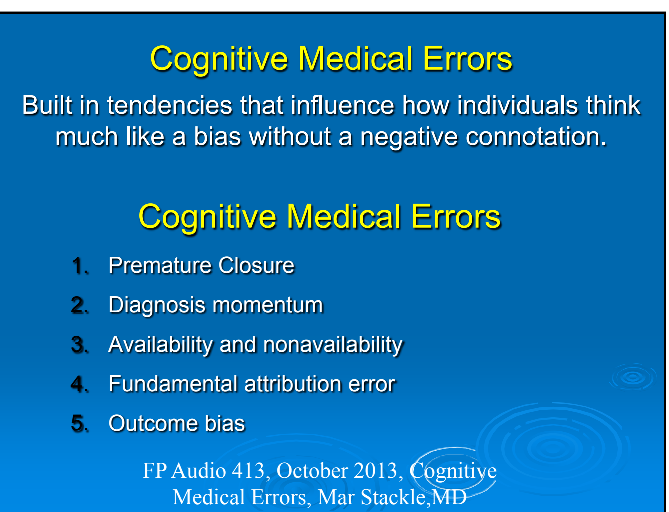
Defense Barriers

- Professional Communication
- Training
- Quality Management
- Knowledge
- Information technology
- Credentialing
- Peer review
- Protocols, pathways, policies
- Redundancy
- Forcing functions

ASK "WHAT HAPPENED" *NOT* "WHO DID IT"

"Adverse outcomes are *system deficiencies*, not human error. Most medical errors are not committed by incompetent or negligent practitioners."

David Shapiro, MD, JD



Premature Bias

Tendency to settle on a firm diagnosis before completing the evaluation.

Diagnostic momentum

The tendency of a diagnosis to "stick" with the patient throughout the healthcare delivery process.

Availability

Tendency to think a diagnosis is likely if it readily comes to mind.

Influenced by recent experience.

Nonavailability

Tendency not to make a correct diagnosis if the physician has not seen the condition recently or has not been exposed to it.

Fundamental attribution error

The tendency to blame the patient for the illness. Occurs often in marginalized groups (homeless, psychiatric, SUD, minorities)

Outcome Bias

Tendency to make a diagnosis based on the physicians relationship with or feeling towards the patient.

What's the Solution?

1. Develop insight and awareness that cognitive errors exists. Talk and educate.
2. Awareness of internal and external factors that distract or influence you.
3. Consider the context in which the diagnosis was made.
4. Consider the prevalence of the condition.
5. Consider the data and how it is interpreted.
6. Trust but verify conclusions.

Management of Patients At Risk For Opioid Abuse

Inappropriate prescribing of opioids in patients in whom there have been misdiagnosis or failure to diagnose addiction, psychiatric conditions and diversion

Epidemic

- Deaths from prescription painkillers have quadrupled since 1999, killing more than 16,000 people in the U.S. in 2013.
- Nearly two million Americans, aged 12 or older, either abused or were dependent on opioids in 2013.
- Overdose rate for adults aged 55–64 increased more than seven-fold during this same time period.

Epidemic Continues ….

- More persons died from drug overdoses in the United States in 2014 than during any previous year on record.
- From 2000 to 2014 nearly half a million persons in the United States have died from drug overdoses.
- In 2014, there were approximately one and a half times more drug overdose deaths in the United States than deaths from motor vehicle crashes
- Opioids, primarily prescription pain relievers and heroin, are the main drugs associated with overdose deaths.
- In 2014, opioids were involved in 28,647 deaths, or 61% of all drug overdose deaths; the rate of opioid overdoses has tripled since 2000.
- The 2014 data demonstrate that the United States' opioid overdose epidemic includes two distinct but interrelated trends:
  - a 15-year increase in overdose deaths involving prescription opioid pain relievers
  - and a recent surge in illicit opioid overdose deaths, driven largely by heroin.

Setting the Ground Rules

- Managing expectations with a new patient:
  - Informed consent, treatment agreement
  - Refill frequency, office visit frequency
  - Urine drug testing

Chou R, et al. *J Pain*. 2009;10:147-159.
FSMB. Model Policy for the Use of Controlled Substances for the Treatment of Pain. Accessed March 9, 2009 at: www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf

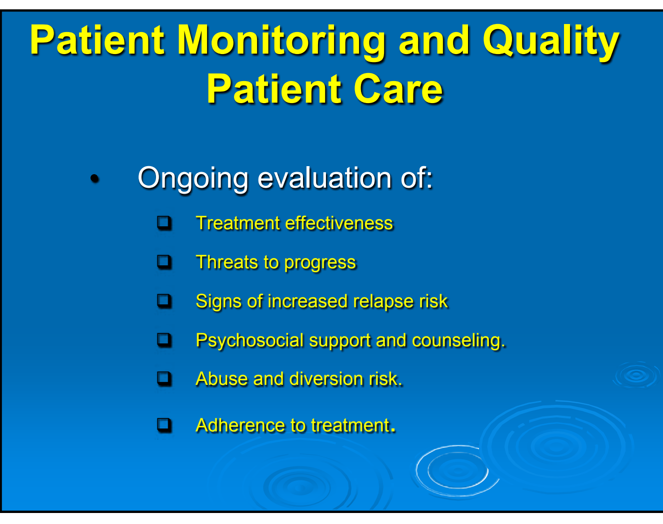
Compliance Monitoring

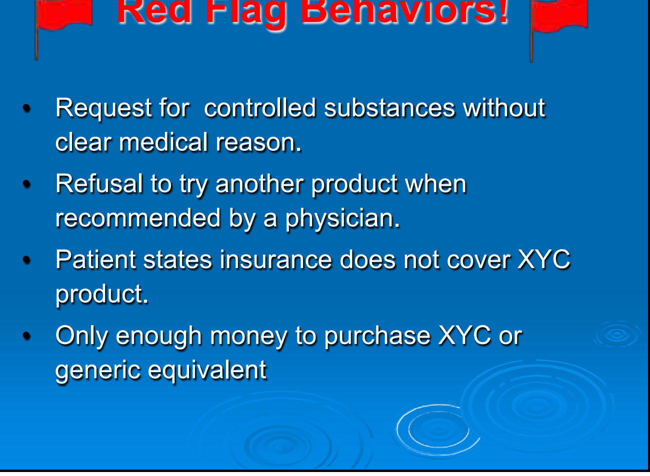
- Written documentation
- Frequent visits and small quantities (month's supply- your choice) every 3 months appt at minimum
- One pharmacy; One prescriber; pill counts; no replacements or early scripts
- Urine drug screen
- Complete medical records (informed consent & treatment plan)
- Required contact with other treating clinicians
- Required Consider consultation with other specialists if needed
- Prescription Drug Monitoring Program

Fine P, Portenoy RK. *Opioid Analgesia.* New York: McGraw Hill; 2004.
Portenoy RK, et al. Acute and chronic pain. In: Lowinson JH, et al, eds. *Comprehensive Textbook of Substance Abuse.* 4th ed. Baltimore: Williams and Wilkins; 2005:863-903.

Visit Frequency and Quality Practice Care

- Tailor visit frequency to individual patients to ensure:
  - Adequate monitoring.
  - Detection of patients at risk for relapse.
  - Limited prescription volume to reduce diversion risk
  - Utilization of urine drug screening.





The 4 C's
(Screen for Possible Substance Use Disorder)

- Loss of **C**ontrol
- **C**ompulsivity
- **C**ontinued Use Despite Adverse Consequences
- **C**raving

State Attempts to Curb Rx Abuse

- **Monitoring**
  - state's prescription drug monitoring
  - Treatment agreement/Informed consent
  - Urine drug screen every 3-6 months
- **Education**
  - special training before can prescribe certain potent or long-acting opioids
  - Educate patients
- **Proper Disposal**
  - Per instructions
  - National Prescription Drug Take-Back Day

Food and Drug Administration. Safe Disposal of Medicines. Accessed February 13, 2014

Urine Drug Screening

- An important monitoring tool to show evidence of:
  - Therapeutic compliance with prescribed medication
  - Use *or* non-use of illicit drugs
- Likely to result in a higher yield in patients with risk factors for drug abuse or diversion, but should be done in all patients to avoid missing some proportion of patients
- Recommended at initial visit and then 3-6 month (random)
- Random testing may be more informative than scheduled testing

United States Department of Health and Human Services, Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs notice. November 25, 2008. http://edocket.access.gpo.gov/2008/pdf/e8-26726.pdf (Accessed February 5, 2014).
Moeller KE, Lee KC, Kissack JC. Urine drug screening: practical guide for clinicians. *Mayo Clin Proc* 2008;83:66-76.

Utilize Prescription Drug Monitoring Program (PDMP)

- Support access to legitimate medical use of controlled substances
- Help identify and deter or prevent drug abuse and diversion
- Facilitate and encourage the identification, intervention with and treatment of persons addicted to prescription drugs by health care practitioners
- Help inform public health and safety initiatives through the outlining of use and abuse trends of controlled prescription drugs
- Help educate individuals about PDMPs and the use, abuse and diversion of and addiction to controlled prescription drugs

Using Opioids in the Management of Chronic Pain Patients: Challenges and Future Options, An *American Family Physician* Outsert/Special Booklet, Dawn A Marcus M.D., Penny Tenzer M.D., 2010

Overdose Risk Factors

Demographics
- Men
- 35-54 year olds
- Whites
- American Indians/Alaska Natives

Socioeconomics and Geography
- Medicaid
- Rural

Clinical Characteristics
- Chronic pain
- Substance abuse
- Mental health
- Nonmedical use
- Multiple prescriptions
- Multiple prescribers
- High daily dosage

Overdose Prevention Guidelines

- Follow best practices for responsible painkiller prescribing, including:
- Prescribing the lowest effective dose and only the quantity needed for the expected duration of pain.
- Planning with your patients on how to stop opioids when their treatment is done.
- Providing your patients with information on how to use, store, and dispose of opioids.
- Avoiding combinations of prescription opioids and sedatives unless there is a specific medical indication.

OPIOID PRESCRIPTION AND OVERDOSE

According to a recent study of pharmacy claims 91% of patients continued to receive opioid prescriptions after their overdose.

Ann Intern Med. 2016;164(1):1-9.
doi:10.7326/M15-0038

Cancer

Estimated 12% of cancer is misdiagnosed, and the missed or delayed diagnoses account for a large number of medical malpractice claims

1. Atypical or ambiguous presentations;
2. Not considered because of the patient's young age;
3. A low index of suspicion;
4. Diagnosis considered unlikely because of the absence of risk factors.

Avoiding Errors in Clinical Decision-Making

- Consider diseases you cannot afford to miss
- Supplement diagnostic skills using a bayesian approach or established algorithms
- Consider tests that will help rule in an alternative diagnosis rather than pursue a test for a diagnosis already in doubt
- Be aware of common cognitive biases—avoid "premature closure" by re-examining the facts
- Ask yourself, "What else could this be?"

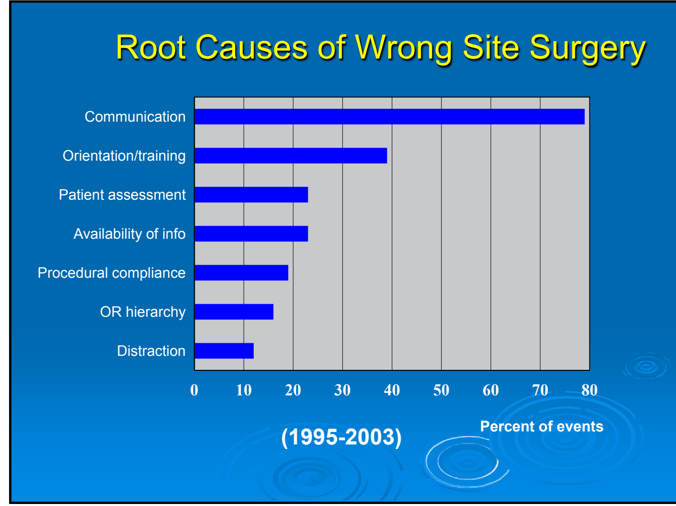
Testing Process Errors

- In a typical family medicine office with approximately 5,200 patient visits per year, significant test processing errors with adverse patient outcome would occur in 260 patient visits per year.

Preventing Test Processing Orders

- Implement a formal tracking system
- Notify EVERY patient of EVERY result
- Use the patient as a double checker and safety advocate
- FP Essentials 327, Quality and Patient Safety in the Physicians Office, 2006

Root Causes of Wrong Site Surgery



WRONG SITE SURGERY

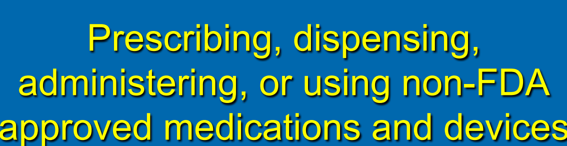
- Surgeon error
- Incorrect site preparation by staff
- Wrong information provided by patient
- Errors in Consent Form and medical records
- X-ray interpretation and report language errors

Barriers to the Elimination of Wrong Site Surgery

- Physician buy-in
- Time & efficiency pressures
- Patient acceptance
- Concerns about infection, tattooing
- Inconsistent approach among practitioners and facilities

Case Report

- July, 2013; Orlando,Florida: A surgeon performed a vascular procedure on the wrong leg. Apparently, a nurse anesthetist noticed the error during the case and spoke up, but the surgeon didn't stop. He finished the wrong leg and then did the correct leg too.
- When the patient awoke, the surgeon asked her to sign a consent form for the wrong leg and told her that she had needed that surgery anyway.
- The hospital failed to report the error for two weeks.
- In the Orlando Sentinel article, a hospital spokesman said, "We have policies in place, and training in place, but the system broke down because of the human element." I think he was admitting that the incorrect procedure was the result of a human error, but I'm not sure.



Prescribing, dispensing, administering, or using non-FDA approved medications and devices

- Off-label use is the use of pharmaceutical drugs for an unapproved indication or in an unapproved age group, unapproved dosage, or unapproved form of administration
- Off-label use is generally legal unless it violates specific ethical guidelines or safety regulations, but it does carry health risks and differences in legal liability

Prescribing, dispensing, administering, or using non-FDA approved medications and devices

- The FDA approves a drug for prescription use, and continues to regulate the pharmaceutical industry's promotional practices for that drug through the work of the Office of Prescription Drug Promotion (OPDP, formerly the Division for Drug Marketing, Advertisement and Communication (DDMAC).
- The FDA does not have the legal authority to regulate the practice of the medicine, and the physician may prescribe a drug off-label.
- It is legal in the United States and in many other countries to use drugs off-label, including controlled substances such as opiates.

It is Legal BUT……….

- If you are going to use a product in an off-label manner, it is your responsibility to your patient to make sure your plan is satisfactorily supported by evidence of safety and potential efficacy.
- Educate, Document, Disclose, Obtain Informed Consent and DOCUMENT!

Its Is Legal But ………….

- You are allowed to use products that are approved by the Food and Drug Administration (FDA) for one indication for a different indication. That is off-label use.
- Using any devices or off-label products is prohibited if your primary objective is to test a hypothesis or obtain general knowledge.
- Those situations require that you conduct a study under Human Subjects Protection, Institutional Review Board, or other oversight,

Medication Errors

- Medications are a cornerstone of the management of most chronic conditions. A 2010 report showed that approximately 70 percent of physician office visits for patients older than age forty-five years resulted in medications' being prescribed or continued.
- This represents a 10 percent increase over a ten-year time frame.
  - Cherry D, Lucas C, Decker SL. Population aging and the use of office-based physician services [Internet]. Hyattsville (MD): National Center for Health Statistics; 2010 Aug [cited 2011 Mar 3]. (NCHS Data Brief, no 41). Available from:

Medication Errors

- > 7000 deaths/year in US
- 30% due to deficient drug knowledge
- 20% due to limited patient knowledge
- 50% due to poor labeling or name confusion
- 25% occur during administration of drug

IOM 1999-2000

Medication Errors: Root Cause Analysis

Most medication errors are attributed to:

- faulty prescribing, monitoring or refilling practices

- improper documentation

- inadequate communication

- inappropriate formularies

System Errors = Medication Errors

- > 33,000 trademarked medication names
- > 9000 generic medication names in the US
- 15% of all reported drug errors due to name confusion

"Medication Errors on Rise" Miami Herald, 07/19/2009

- Medication errors harm at least 1,5 Million people annually (IOM)
- 3 Billion Prescription filled annually.
- Name confusion accounts for 25% of all errors.

COMMON CAUSES OF ERRORS

- Transcription
- Verbal Orders
- Staffing
- Multiple prescriber/single patient
- Allergies not recorded
- Inadequate drug history taken

COMMON PRESCRIBING ERRORS

- Wrong dose
- Wrong dosage form
- Route
- Frequency
- Contraindicated

ALLERGY IDENTIFICATION

- **Review incoming hospital summaries or consultation reports**
- **Update the patient history**
- **Periodically ask patients about their medications or food allergies – document their responses**
- **Document allergies or denials in brightly colored ink or labels**
- **Determine medications prescribed by other doctors**
- **Retake an allergy history when prescribing new drugs**

PRESCRIBING POLICIES

- **Do not casually delegate refill authority**
- **Increase telephone communication to prevent misunderstandings**
- **Do not refill or re-prescribe drugs prescribed by another physician without verification**
- **Conduct a medical exam before prescribing controlled drugs**

DANGEROUS ABBREVIATIONS

- **"Q.D." vs. "QID"**
- **"units" abbreviated as "U" mistaken for "0" or "4"**
- **Failure to include a leading zero preceding a decimal "0.5"**
- **Using trailing zero after a decimal 5.0 as "50" mgs**

IMPORTANT CONSIDERATIONS

- Implement and electronic prescribing system
- Use sample drugs with care
  - Pharmacists make 150 million callbacks annually to clarify prescriptions.
- Empower the patient to serve as safety double checkers
- Develop a system of continuous quality improvement

FLORIDA STATUTE 456.42 - PRESCRIPTIONS

Effective 7/1/03 all written prescriptions *must* be legibly printed or typed and *must* be signed by the prescribing practitioner on the date issued and *must* contain:

- Name of prescribing practitioner;
- Name and strength of the drug;
- Quantity of the drug in both textual and numerical formats;
- Directions for use; and
- Date of prescription with month written in textual letters.

Case Report

- 17 year old treated by psychiatrist with Zyprexa 2.5mg daily. Care transferred to FP, because parents cannot afford psychiatric care. FP accepted care and continued prescribing.
- After having issued six prescriptions for Zyprexa 2.5mg pharmacy called requesting refill AGAIN.
- Receptionist informed nurse, nurse recalled that " he always gets 5mg Zyprexa". Pharmacy faxes 5mg refill request for verifcation. Doctor signs.

Case Report

- Mother does not check bottle, because she assumed its "O.K.".
- Patient receives 5mg Zyprexa and after a few days gets agitated, dizzy, aggressive.
- Mother checks bottle with old script and noticed difference in dose.
- Mother contacts doctor, doctor gets defensive, offers her to be transferred to another doctor " if she doesn't like the care". Blames the pharmacist for mistake.

Tips To Prevent Medical Errors

Fam Pract Manag. 2002 Jul-Aug;9(7):49-50.

1.The single most important way you can help to prevent errors is to be an active member of your health care team.

2. Make sure that all of your doctors know about everything you are taking.

3. Make sure your doctor knows about any allergies and adverse reactions you have had to medicines.

4. When your doctor writes you a prescription, make sure you can read it.

5. Ask for information about your medicines in terms you can understand – both when your medicines are prescribed and when you receive them.

Tips To Prevent Medical Errors

Fam Pract Manag. 2002 Jul-Aug;9(7):49-50.

6. When you pick up your medicine from the pharmacy, ask whether it is the medicine that your doctor prescribed.

7. If you have any questions about the directions on your medicine labels, ask.

8. Ask your pharmacist for the best device to measure your liquid medicine. Also, ask questions if you're not sure how to use it.

9. Ask for written information about the side effects your medicine could cause.

10. If you have a choice, choose a hospital at which many patients have the procedure or surgery you need.

Tips To Prevent Medical Errors

Fam Pract Manag. 2002 Jul-Aug;9(7):49-50.

11. If you are in a hospital, consider asking all health care workers who have direct contact with you whether they have washed their hands.

12. When you are being discharged from the hospital, ask your doctor to explain the treatment plan you will use at home.

13. If you are having surgery, make sure that you, your doctor and your surgeon all agree and are clear on exactly what will be done.

14. Speak up if you have questions or concerns.

15. Make sure that someone, such as your personal doctor, is in charge of your care.

Tips To Prevent Medical Errors

Fam Pract Manag. 2002 Jul-Aug;9(7):49-50.

16. Make sure that all health professionals involved in your care have important health information about you.

17. Ask a family member or friend to be there with you and to be your advocate (someone who can help get things done and speak up for you if you can't).

18. Know that "more" is not always better.

19. If you have a test, don't assume that no news is good news.

20. Learn about your condition and treatments by asking your doctor and nurse and by using other reliable sources.

Tactics of Error Reduction

- Reduce Complexity
- Optimize information processing
- Automate wisely
- Use Constraints
- Mitigate the unwanted side effects of change

Reduce Complexity

- Complexity is measured by steps in task numbers of choices, duration of execution, amount of information and distracting tasks.
- Delays, missing information, unable to locate equipment contribute to complexity.
- Reducing or eliminating the above helps reduce complexity.

Automate Wisely

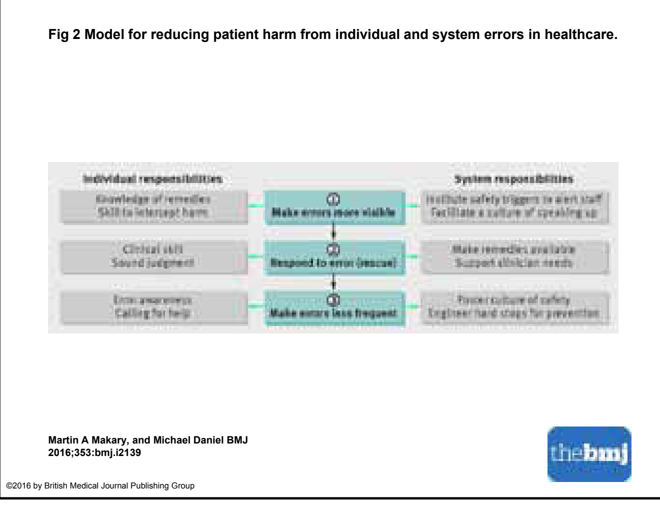
- Medication order entry (reduce scribbles)
- Disease entry, computerized reminder system and electronic medical records.
- These automated systems support but do not replace the human operator.
- Focus on system improvement not just automation.

Mitigate Side Effects

- Mitigate the effect of error with contingency plans and training.
- First try change on a small scale.
- Develop a culture where monitoring and testing is the norm.

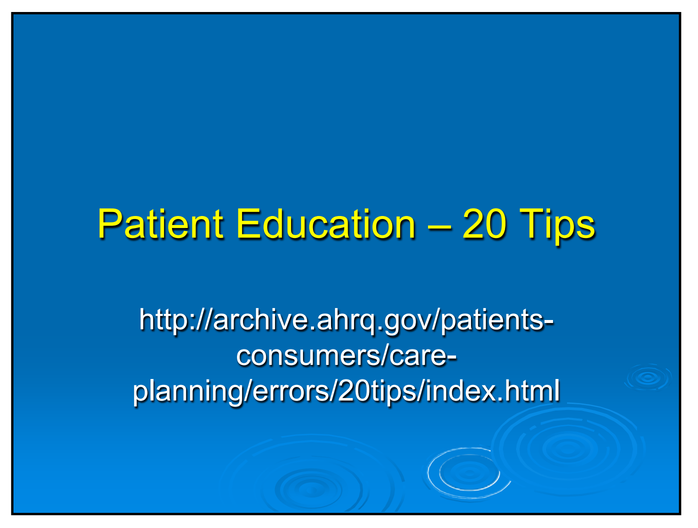
The **5 R's** of Error Reduction

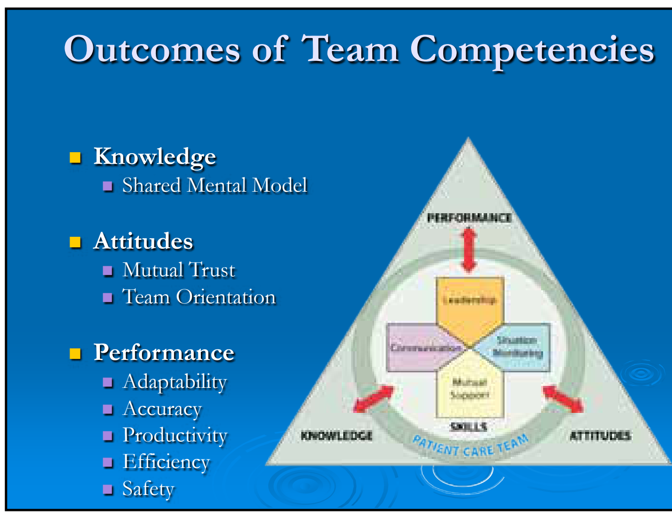
- **R** ely on more than your memory
- **R** ely on more than your self
- **R** ely on more than a blank piece of paper
- **R** eminder and audits help you
- **R** etraining is an aid to your intelligence



Disclosing Medical Errors

- Under Florida Statute 456.0575 it is the physician's duty to inform the patient of a medical error.
- Practitioner must inform the patient, or the patient's legal representative, in person about adverse incidents that result in serious harm to the patient.
- Notification of outcomes of care that result in harm to the patient governed by the disclosure statute shall not constitute an acknowledgment of admission of liability, nor can such notification be introduced as evidence.





SELF EVALUATION

Medical Errors Prevention: Parts I & II

1. According to a recent study by Johns Hopkins patient safety experts how many deaths per year are due to medical error in the U.S ?

a. 50,000
b. 100,000
c. 95,000
d. 250,000

2. True/False - Most errors represent systemic problems, including poorly coordinated care, fragmented insurance networks, the absence or underuse of safety nets, and other protocols.

3. True/False - A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.

4. True/False - Errors of omission are more difficult to recognize than errors of commission but likely represent a larger problem.

5. True/False - A root cause analysis describes a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event.

6. Reportable adverse surgical events include:

a. Surgery performed on the wrong body part
b. Surgery performed on the wrong patient
c. Wrong surgical procedure performed on a patient
d. Unintended retention of a foreign object in a patient after surgery or other procedure
e. Intraoperative or immediately postoperative death
f. All of the above

SELF EVALUATION

Medical Errors Prevention: Parts I & II (continued)

7. The most frequently identified root causes of sentinel events reviewed by the Joint Commission include:

a. Human factor
b. Communication
c. Leadership
d. Medication Use
e. Information Management
f. All of the above

8. The occurrence of wrong site surgery is avoided by:

a. Marking surgical sites
b. Having all caregivers reaffirm patient identity
c. Having a time out immediately before incision
d. All of the above

9. True/False - High reliability organizations eliminate deficiencies in safety processes through the use of powerful tools to improve their processes.

10. Most medication errors are the result of:

a. Patients not knowing what medications they are taking
b. Physicians in different practices not knowing what other physicians are prescribing
c. Similar sounding medication names
d. Faulty prescribing, monitoring or refilling practices
e. All of the above

11. Defense Barriers to prevent medical errors include:

a. Professional Communication
b. Training
c. Quality Management
d. Knowledge
e. Information technology
f. All of the above

12. True/False - Urine drug screening is an important monitoring tool to show evidence of adherence to prescribed medication and to ascertain the use or non-use of illicit drugs.

13. True/False - Patients who repeatedly present to the emergency room with vague symptoms should be reassessed to ascertain if the initial diagnose(s) are correct.

14. Tactics of medical error prevention include:

a. Reduce Complexity
b. Optimize information processing
c. Automate wisely
d. Mitigate the unwanted side effects of change
e. All of the above

Answer Key: 1. D, 2. T, 3. T, 4. T, 5. T, 6. F, 7. F, 8. D, 9. T, 10. E, 11. F, 12. T, 13. T, 14. E

Identifying and Managing Practice Employment Risks

The recurring risk of employment-related lawsuits can be substantially mitigated by following some simple steps. As previously mentioned, a good asset protection plan has multiple layers including the management of predictable and recurring risks.

According to a recent **EEOC** press release the agency **levied nearly $400 million in fines against employers in 2013 alone**. This number is the largest collection year in the history of the EEOC, which receives close to 100,000 complaints a year.

What Are All These Lawsuits Actually About?

The EEOC lists the causes of these complaints, in order, as:

1. *Retaliation* claims under all the statutes (roughly 40 percent);
2. *Racial discrimination* (roughly 33 percent);
3. Sex discrimination, including sexual harassment and pregnancy discrimination (roughly 27 percent); and
4. Disability based discrimination (about 25 percent). Both race and disability discrimination claims have *increased* as a percentage of all charges filed.

There are two layers of distinct financial exposure to be aware of with employment related lawsuits. **First, the awards themselves can be financially devastating,** with sexual harassment *verdicts*, as one common example, regularly reaching hundreds of thousands of dollars, the national average sexual harassment is estimated to be as high as $530,000.

Second, the *costs of legal defense* alone could put many medical practices out of business. The costs for competent legal defense regularly reach six figures without including the potential dollar value of any award that may be obtained against the physician.

The First Layer of Defense: A Professionally Drafted and ENFORCED Employment Manual

Despite this well-known exposure we are surprised to find that many, if not most medical practices fall in to one of three basic categories.

1. They have NO formal manuals.
2. They have generic form manuals of questionable legality and fit that are not specific to the practice and how it operates, often obtained free from the internet or from a doctor friend in another state.
3. They have a custom manual but have not implemented it, distributed it to the staff in a

formal way, or consistently enforced it. **Just *having* it is not enough.**

What Does Having an Employment Manual and Policy Guide Do for me?

Your employment manual is a vital first line of defense and a compliance guidebook for both management and employees and prescribes the policies and procedures for the vast majority of employment-related issues at your practice. According to Paul Edwards, CEO of *CEDR Solutions*, an employment law resource that specializes in medical practices:

"An employee handbook is also your first defensive tool in deterring and fighting employment lawsuits. Policies that are well-written and in compliance with all state and federal laws can prevent 90 percent of legal exposures because an employee or manager was not aware of or did not understand a rule or regulation. A strong handbook will also often deter aggressive contingency fee attorneys who know it is much more difficult to fight and win when a medical practice has implemented written, legally compliant policies."

Understanding Why Your Manual Needs to Be Custom Drafted

Four key legal areas require custom drafting in an employment manual:

It should comply with and cite laws of your state. Employment laws vary from state to state. New York and California, as just two specific examples, are more onerous for employers than others. Citing the wrong laws can make your practice non-compliant or subject you to rules that are more onerous than they would have been under the correct choice of law. Remember, if it's in your manual you are required to follow it, even if the manual is harsher than the actual law.

It should be specific to the number of employees you have. Your compliance burdens and legal obligations change with the number of employees you have, so the difference between 49 employees vs. 50 employees or even 14 employees vs. 15 employees very significant from a legal standpoint.

It should be specific to the needs and realties of a *medical practice*. In addition to all the general business law issues you have many additional, unique compliance burdens as a *medical employer* and significantly extended liability for the actions of your employees on issues like HIPPA compliance, credentialing, and many other issues should be specifically and carefully addressed.

Your manual should reflect the actual and desired "culture" of your practice. Every practice and its needs and expectations are different, your manual and polices should match how your practice actually runs and help conform behavior to your ideals.

EMPLOYMENT PRACTICES LIABILITY (EPLI) INSURANCE

The second layer of employment risk liability management you must have in place is commonly referred to as *employment practices liability insurance or EPLI*.

What is EPLI insurance?
EPLI insurance is specialty property and casualty (P&C) coverage that can help protect you against both the risks of employee lawsuits against your practice and liability you may bear for the vicarious liability of your employees under the legal theory of *respondeat superior*, or *let the master answer*. One unique feature of the better polices (they are not all the same) is that some of them even cover certain “intentional acts,” an important gap in most insurance coverage you must understand and manage.

You Have More Than One Level of Liability as an Employer
It’s easy to think of employment liability with tunnel vision and to assume that we are only about an employee *suing you*. As great as that risk is, you are also liable for a variety of acts and omissions, or failures to act, committed by your employees including:

- How they interact with patients and other third parties including in the delivery of care, through social media, etc;
- How they interact with each other (again, the employment manual is a key control on this issue that can set polices on language, dress codes, harassment and many other issues);
- Actions they take while on the job including while driving, treating patients, creating risky physical conditions on the property through acts or omissions (i.e. the wet, slippery floor they ignored or created);
- Anything else that a plaintiff’s lawyer can think of to link the claim your deep pocket instead of what is likely your employee’s substantially smaller one.

Some Unfortunate and Very Real Examples:

1. *Mid-west Doctor sued when long time trusted employee and L.M.T. molests 17 year-old girl while performing physician-ordered massage therapy;*
2. *Florida Doctor sued for employee’s auto accident involving fatality when employee is sent to pick up lunch for office birthday party;*
3. *And perhaps the most shocking example, doctor sued for discriminatory conduct of office manager faces $500K demand from EEOC. It was filed by the discriminating employee, that’s right the bad guy, when the physician practice-owner learned of his actions and fired him. That employee then went to the EEOC and made a large number of false claims with the help of another disgruntled employee that had also been properly and legally terminated for cause.*

Aren’t these issues covered by my other existing insurance policies?

In most cases no. My personal experience with practices across the country is that most don’t provide any coverage at all. Those that do offer EPLI through special riders or bundled programs don’t have high enough limits to cover the costs typically involved. **Your EPLI coverage should be $1 million as a minimum, ideally more, not the $50,000 or $100,000 we might find in a base policy, if at all.** Six figures in legal defense expenses and six figure awards are now both routine, and that assumes you face only a single plaintiff. The exposure on a class action suit or one with multiple plaintiffs is a multiple of those figures.

EPLI insurance addresses specific risks and financial and legal gaps that are not adequately covered by the three basic polices we assume you've had counsel in properly implementing already:

1. A medical malpractice insurance policy of *at least* $1 million per occurrence.
2. A worker's comp policy (aka: employee hurt on the job coverage);
3. A general liability policy (covers slip and fall and other injuries or non-medical liability related to general function of your business);

What kinds of employment claims are covered, and perhaps more importantly, are excluded?

This is a **policy-specific question**, so the insurance agent you work with must be knowledgeable about the all options available in this area, and should give you a very specific list of what is covered and what is not, **in writing.**

Always keep in mind that even the best EPLI is not a license to sin and break labor laws and that following the law and the policies in your manual is always the best defense.

Violations that are repeated, *implemented by* and *known to* the organization itself are often explicitly excluded from your EPLI carrier's liability. There is an important distinction if the harm complained of is by an employee or manager that is outside the scope of the organization's policies (like the ones found in the manual) and was **unknown** to the employer. In other words, if this is a result of an individual employee or manager generating liability for your practice by not following the rules, it probably will help. Issues commonly covered include various types of harassment and discrimination (sex, age, race, disability, etc.), as well as some general civil torts, like defamation and intentional inflection of emotional distress, which are often related to other claims.

On the other hand, if you have *institutionalized* illegal or actionable employment practices, whether overtly or by failing to correct known problems, EPLI insurance is unlikely to cover it. **What is excluded in many cases falls under some sort of institutionalized pattern of an illegal employment practice that is known, open, and part of your practice's policies.** Retaliatory claims and actions seem to be one issue that insurance companies increasingly exclude and there are a number of other strict-liability type statutory liabilities that may or may not be covered as well for violations of federal or state law.

I remind doctors that *just* insuring is typically not enough protection against the wide variety of risk this section addresses. **Employee risk requires several layers of risk management and ideally includes personal asset protection planning for medical practice owners and executives.**

Employee Classification Risk – The Liability of Incorrectly Calling Someone a "Contractor"

Medical practices nationally have faced substantial legal and financial jeopardy due to the

increasing number and aggressiveness of *employee classification audits* by the Department of Labor (DOL). If you have "independent contractors" at your practice you must carefully review the law to make sure that they have been correctly classified them as such to avoid substantial fines and both civil and even criminal legal jeopardy.

When we ask how many employees a client has as part of a risk management analysis we often hear one of the following frightening responses from practice owners:

1. *None, we don't have to worry about that, they are all contractors*; or even better
2. *We lease our employees so we don't really have any employee risk*.

Both of these answers are false on many issues and leave your practice substantially exposed to a variety of labor law and tax law claims including misclassifying someone who is legally an "employee" as a "contractor." Both are very specific legal terms of art with well-defined definitions that go far beyond "picking their own hours."

Many medical practice managers and owners also don't realize that once a violation is established in a Fair Labor Standards Act lawsuit, the **burden is on the employer** to prove why double damages should *not* be awarded and in which case the employer is liable for the employee's legal fees in addition to their own legal fees, costs and penalties.

Moreover, **the owner of the practice and/or the executive responsible for the decisions that led to the violation, can be held *personally* liable along with the company itself**, regardless of laws that limit personal liability in many other contexts. Cases brought under Title VII for discrimination, as one example, require substantial administrative process before employees can go to court. As such, a medical practice's owners, executives, and board members face significant personal has jeopardy that will typically not be covered by medical malpractice, general liability, or personal umbrella insurance policies, so adequate **directors' and officers' liability insurance we previously discussed** is another vital layer in such a plan.

The Tax Consequences of Employee Classification Are Serious

The DOL isn't the only federal agency that has a stake in this issue; the IRS is substantially involved as well. Employment withholding taxes are a major source of both federal revenue and social security payments and are significantly harder to collect directly from contractors than they are from employers. The DOL and the IRS are now working together under joint agreements, citing one recent government press release, "In the last two years, the Wage Hour Division has secured over $18.2 million in back wages for more than 19,000 workers where the primary reason for minimum wage or overtime violations under the Fair Labor Standards Act was that workers were not treated or classified as employees." This represents a 97 percent increase in collections and claims.

Heading Off IRS Audit Exposure by Using the Voluntary Classification Settlement Program

If you think you have an audit exposure, it is best to address it upfront, i.e. call them before they call you. The Voluntary Classification Settlement Program (VCSP) is a voluntary

program that provides an opportunity for taxpayers to reclassify their workers as employees[i] for employment tax purposes for future tax periods, with partial relief from previously misclassified and delinquent federal employment taxes. To participate you must meet certain eligibility requirements and apply to participate in the VCSP by filing *Form 8952, Application for Voluntary Classification Settlement Program*, and enter into a closing agreement with the IRS.

Managing this risk requires that you have your own contracts, processes, and qualifications reviewed by an employment law specialist to determine if you have a tax or labor compliance issues, and to prevent it from happening again.

How is an Independent contractor defined?

Professionals like doctors, dentists, veterinarians, lawyers, accountants, contractors, and subcontractors *who are in an independent trade, business, or profession in which they offer their services to the general public* are generally qualified to act as independent contractors. Whether these people actually are independent contractors or employees depends on the specific context of an employment relationship.

One *very general* rule of thumb is that an individual can be classified as an independent contractor if the employer has a right to control or direct the *result* of the work but not *what* will be done and *how* it will be done. The earnings of a person who is working as an independent contractor are subject to self-employment tax. And employee is generally not an independent contractor if they perform services that can be controlled by an employer (what will be done and how it will be done). This applies even if the employee is given freedom of action.

If an employer-employee relationship exists (regardless of what you call the relationship), the employee is not an independent contractor and their earnings are generally not subject to Self-Employment Tax. However, their earnings as an employee may be subject to FICA (Social Security tax and Medicare) and income tax withholding. For which you as the employer are responsible

The IRS provides specific guidance on determining whether an individual is an independent contractor or an employee. **This comes directly from the IRS but is not a substitute for specific tax or legal advice**. Use it as a starting point on your personal of issues to consider and a caveat on the complexity of these issues that must be professionally addressed to protect your practice and comply with tax and labor laws.

Determining whether those providing services are employees or independent contractors

In determining whether the person providing service is an employee or an independent contractor, all information that provides evidence of the degree of control and independence must be considered.

Common law rules

Facts that provide evidence of the degree of control and independence fall into three categories:

*1. **Behavioral:** Does the company control or have the right to control what the worker does and how the worker does his or her job?*
*2. **Financial:** Are the business aspects of the worker's job controlled by the payer? (These include things like how worker is paid, whether expenses are reimbursed, who provides tools/supplies, etc.)*
*3. **Type of Relationship:** Are there written contracts or employee type benefits (i.e. pension plan, insurance, vacation pay, etc.)? Will the relationship continue and is the work performed a key aspect of the business?*

Businesses must weigh all these factors when determining whether a worker is an employee or independent contractor. Some factors may indicate that the worker is an employee, while other factors indicate that the worker is an independent contractor. There is no "magic" or set number of factors that "makes" the worker an employee or an independent contractor, and no one factor stands alone in making this determination. Also, factors which are relevant in one situation may not be relevant in another.

The key is to look at the entire relationship, consider the degree or extent of the right to direct and control, and finally, to document each of the factors used in coming up with the determination.

Employee Credentialing: Liability for Medical Employers

Many medical practice employees, including doctors, nurses, and various clinical assistants must be very specifically credentialed based on both the specifics of your practice and third-party payer contracts. This additional condition of employment requires a variety credentialing compliance best practices.

Why is This Such a Big Deal, What’s the Worst that Could Happen?

a. Once an error is identified in any one area of your billing practices, you should expect other areas, even non-related ones with lower compliance burdens, to be examined;
b. You face potential civil and criminal liability for billing third-party payers that contractually require specific credentialed care providers;
c. Your practice may face a loss of revenue due to failure to comply and substantial disruption of practice cash flow if an audit or questions arise.
d. You are subject to reputational damage, stress, and substantial legal fees easily in the six-figure or seven figure range;
e. Increased **medical malpractice** risk for potentially not providing the required reasonable *standard of care* if a non-credentialed employee is in the chain of treatment for an affected patient.
f. It may also potentially induce liability insurance carriers to either completely exclude an event or reduce applicable coverage.

Although this process can be managed internally with the right training and by a variety of existing administrative staff, there is professional help available at nearly every scale, from small practices to hospitals. Many practices, especially smaller ones that don't have full time HR managers, find that outsourcing this issue is a time and cost efficient form of risk management of this important issue. Outside professional resources are generally known as credentialing organizations (COs), which operate under the wider banner of HR and employee background-check services. Many of these services have accredited certified provider credentialing specialists that can work with your office and staff as outsourced compliance experts.

In my experience, the biggest benefit a CO can offer is that the best of them go beyond providing just a snapshot of your current credentialing; they also offer a long-range plan to help you *implement and maintain it*.

Some Advantages of Outsourcing This Issue to a Credentialing Organization

1. They manage credentialing proactively instead of reactively and can help avoid loss of time, efficiency and revenue when for instance, doctors or staff are taken out of the office to complete massive amounts of CME all at once on a short deadline;

1. COs are typically better equipped to respond quickly to staff changes including the on-boarding of new staff or doctors, and can help identify and verify what is required bring any new staff into compliance;

2. They typically have software systems that are more consistent and reliable than the self-created systems implemented by most practices internally, typically Excel spreadsheets that need to be manually updated and checked;

3. Using CO software systems is often time and cost efficient in related areas, like insurance credentialing and can help manage a variety of functions including background check compliance, immunizations and hospital privilege policy compliance, as just a few examples.

Risk management in this area again requires that your practice is proactive and discovers and corrects any credentialing gaps in your office before they are an unwelcome surprise discovered by a third party. The liability and financial jeopardy is ultimately that of the practice owners and managers regardless of whether you outsource to a CO or not.

Proactively addressing this serious issue starts with a few simple steps:

1. Have a specific written plan to determine and verify all the required credentialing compliance of each employee and to maintain their compliance status. This applies to both statutory compliance required by law and any other credentialing required as a provider that bills third parties under specific and enforceable contractual requirements;
2. Make a specific person accountable for managing this process and check on that management at least quarterly;
3. Implement appropriate specialty insurance coverage where possible to help protect against any gaps or errors including RAC audit insurance.

HIPPA AND DATA BREACHES: MANAGING YOUR CYBER-LIABILITY RISK

Patient HIPAA and financial data present a daily exposure for physicians and medical practices. In some cases, this breach is from an external source, in other cases it's from an internal source You are reading this hot on the heels of two of the largest data breaches in history. The Anthem breach exposed the Personal Identifying Information (PII) records of up to 80 million patients, but at least according to Anthem, not the actual credit card or healthcare data. What less widely known is that nearly 20 million additional patients who thought this had nothing to do with them may also have been exposed as Anthem has systems and records linked to over 30 other smaller providers for national data base purposes.

PII typically includes names, dates of birth, member ID/social security numbers, addresses, phone numbers, email addresses and even employment information, in other words, most of what you'd need to fill out a credit application.

These are high profile examples that illustrate the extent of the damage that can be done, but readers should not be lulled into thinking that this risk only applies to hospitals, insurance companies and other massive providers, quite the opposite is true. Your practice is substantially more vulnerable to any such breach and I can guarantee that these behemoths have IT security resources and compliance programs that are far ahead of your own, not to mention their ability to survive the many costs of such a claim.

A Private Practice Example of Internal Liability

In Arizona, where I live, one privately held and well respected medical practice recently had up to 40,000 patients' financial data exposed when a secret drug-addict employee in their billing department used patients' credit cards for shopping online, fast food, rims and tires and variety of other charges. This created a massive financial exposure for the practice and a huge reputational hit the true costs of which are hard to determine. Let's walk through the tangible part of the math:

1. The practice had to notify all of them in writing (40,000 letters at an estimated $1.50 each).
2. These notification letters typically offer an apology; inform the recipient of the breach and offer and credit monitoring for a year at cost of $100 per recipient. That's $460,000 in potential exposure plus the incalculable reputational damage, which is actually low.

According to a research report on the costs of data breach conducted by the Ponemon Institute and sponsored by IBM, the numbers for 2014 are disheartening. It's unsurprisingly interesting reading and I highly recommend it if you have organizational responsibility or input for these issues, including a board of directors position. Here's a look at just a fraction of what they report:

1. Breaches have a higher overall cost than in the past

2. More customers leave a business after a breach than before
3. The costs of redress are higher than before including remedial action
4. The average cost per record exposed is substantially greater than our example above; **they put it at $246 per record.**

Perfect Hindsight: Three Essential Layers of Data Risk Management

Layer One: Professional IT Security

A professionally implemented IT security system not only provides hardware, software, training and best practices, it helps illustrate that you made and effort and have an actual plan in place. Even if you get breached, one of the issues that is evaluated in determining your fines and legal culpability is what you did and how reasonable and effective those measures were.

Layer Two: Having Cyber Liability, a.k.a. Data Breach Insurance.

Cyber Liability Insurance (CLI) policies cover a variety of exposures in our increasingly computerized world, including not only outside theft of PPI and medical records but also the intentional theft and misuse of patient data by employees and even what can happen if you or a connected employee lose a laptop, tablet or smartphone with protected information. In the Arizona case both the medical practice and the billing company, which is likely a “business associate” of a medical practice, (if not a wholly owned tax shelter set up by the owner’s CPA as we see with many doctors) which implies liability. Interestingly, the **EPLI**, or employment practices liability insurance previously covered may also provide some protection in such cases. While our coverage of this vital issue focused on its value in protecting your office from an employee lawsuit, good policies often include riders that can help protect you from the liability of the intentional, but unpermitted, actions of an employee as well.

Layer Three: Background Checks and Proper Employee Credentialing.

This specific example involves the billing and subsequent breach occurred at what is ostensibly a third-party company that we can only hope was properly credentialed and in compliance with the requirements of the dermatology practice’s third-party payer contracts. Your HIPAA security procedures should include a review of the entire chain of custody of the confidential data your practice handles and discloses to third parties and that review should include inquiry into any third party’s own background-screening practices. Ask if they indemnify you for loss or misuse of the information you share with them due to their own negligence or breach and always a copy of the “in-force” liability policy they carry that covers you in the event of such a breach. Relying on their assurances of being properly credentialed and insured is not a defense for you.

Managing ***Domestic Employee*** Risk

Employment based lawsuits by various domestic help are a serious and growing threat. Claims by domestic staff including maids, nannies, housekeepers, cooks, gardeners,

personal trainers and etc. are on the rise and include wage and labor issues, sexual harassment, personal injury, wrongful termination, and discrimination. These claims closely mirror the wide range of employment related liabilities we've previously discussed but which are often treated much too casually in the home environment despite the level of liability being the same.

These claims have far reaching and unintended consequences including reputational damage and media attention that come from these claims can be damaging in many ways beyond just the direct liability of a lawsuit judgment itself. This is especially true for high profile individuals with sensitive public personas, even if that public is limited to a high profile locally. Negative publicity can affect promotions, board memberships, speaking engagements and often affects contracts, endorsement deals and even stock prices.

The Four-Layer Risk Management Plan: Household Staff

1. Get a high limit personal liability policy on the home with an umbrella of at least $2MM, and based on your net worth, maybe higher.
2. Have a written employment agreement with staff that includes a confidentiality agreement and mediation and arbitration provisions as conditions of employment. This confidentiality agreement is especially important if you share domestic employees with others in your community or professional and social circles. Due to sheer physical proximity and the casual, if not intimate professional relationship many of us develop with such trusted employees they are often privy to the personal details of your life, relationships, finances and a number of other private details that you probably don't want colored with their interpretation or shared with others;
3. Strongly consider EPLI insurance and Worker's comp coverage that is specific to your home, your business policies do not apply;
4. Stop committing tax fraud and pay them <u>legally</u>. The IRS[ii] says that household employees include housekeepers, maids, babysitters, gardeners, and others who work in or around your private residence as your employee. And We continually find that people that pay their domestic employees in cash are "helping them out" and that "it's just casual and does not really need to be reported. You're wrong on both counts and are technically guilty of tax fraud and subject to a variety of the penalties here that we discussed in the employee classification risk section. Reporting and labor law compliance burdens begin at an exceptionally low threshold, less than $200 per month of repeated payments or a total of only $1900 on an annual basis requires that you legally withhold for both Social Security and Medicare taxes and pay your share of those taxes as an employer. Consult your CPA and local counsel for details specific to your home and employees.

Again, many doctors should consider outsourcing some of this compliance including how staff is paid. There are a variety of services out there like NannyChex and MyHomePay that offer assistance with domestic HR issues including screening, training and payroll.

When conflict arises bear in mind that don't feel sorry for people with household help, in fact, many of them will **be** household help like the allegedly aggrieved party you face. The

final, unspoken layer is always the same; examine proactive asset protection strategies with the help of a qualified and experienced professional, this means not just getting the opinion of your brother-in-law the real estate lawyer.

Managing A Specific Liability: The Office Holiday Party

Holiday party customs can create significant liability for doctors and practice managers. Your managers and employees must know the rules so that a nice gesture doesn't end in a lawsuit. **As the host, you are legally responsible for every guest's safety, conduct and even their "perceptions" of what they might subjectively consider to be harassing or discriminatory**, so use this ten-point checklist as a starting point:

1) **It's Optional.** Don't make it a required event and don't penalize or ostracize those who can't or don't want to come. The optional nature of the event should be explicit in any discussion or written materials around the event.

2) **Avoid Empty Stomachs.** If you are going to serve alcohol, consider food service *mandatory*. This not only helps keep them full so they drink less, but keeps them busy and helps avoid them drinking their dinner.

3) **Control the booze.** The best advice is to serve ***no*** alcohol, as the vast majority of injuries, accidents, assaults, and inappropriate behavior is alcohol related. If you are serving alcohol you should take steps to enforce limits on the amount of alcohol or number of drinks (drink tickets, limiting hosted drink service to a specific time, etc.) any one guest consumes by offering only beer, wine, and low alcohol content mixed drinks. Equally enforce rules about anyone appearing intoxicated being "cut-off" and make this known to all guests in advance.

4) **Think About Getting Them Home**. Any employee that feels impaired should be told they will be provided transport by taxi, Uber, or for bigger group events, you can even consider commercial services like *The Driver Provider*. The cost of providing/reimbursing these services is a fraction of the legal fees you'll face from any harm incurred.

5) **Remind Guests It's Still an "Office" Party.** All codes of language conduct, sexual harassment, and other rules in your employment policy manual that control possible workplace claims of bias and discrimination still apply. This is especially important if we are talking about conduct by an owner or manager that has a position of authority over others in attendance.

6) **Consider Dress Code Rules.** Look for ways to proactively limit inappropriate conduct, speech or behavior, especially at Halloween when many of the commercial costumes seem to include the words "naughty" or "sexy" in the title. I've seen X-rated Christmas sweaters as well, so don't assume other holidays are risk free.

7) **Be inclusive.** Some attorneys go as far as to say that you can't call it a "Christmas" party and should err on the side of caution by calling it a "Holiday" party. While that fine point is debatable, anything that's overtly religious or political is a bad idea given that issues of real or perceived hostility or bias motivate many employment related lawsuits.

8) **Keep Them Busy, Appropriately**. Consider ways to keep guests busy that *all* attendees, including those with physical limits and religious sensitivities, can safely participate in. Avoid games that are overly physical, controversial or which facilitate inappropriate speech and behavior. Real examples we've seen include hanging Mistletoe, playing Cards against Humanity, and even beer pong (yes really, in a surgeon's office).

9) **Consider an Offsite Venue.** We've seen doctors use sporting events, comedy clubs, art and wine parties and a number of other organized activities as well received non-traditional parties. This may help limit liability and protect your office from strangers and other exposures, like a records breach, theft, etc.

10) Check Your Insurance. Both your general liability and workers comp coverage may come into play, make sure you have appropriate limits of both as well an EPLI policy in place in the event of an exposure.

Enforcement and Termination, Firing Without Fear

We always encourage clients to exercise good faith and to try and work out issues with employees in a productive and cooperative way. This is both good business and good risk management as it can hopefully alleviate much of the emotion that leads to employee side litigation. Put bluntly, **hurting someone's feelings increases the likelihood of lawsuit**. Unfortunately, if that fails, you need act decisively and terminate the employee.

Over the just last few years alone I have helped a dozen different clients with issues similar to this fact pattern. In almost every single case the toxic employee that brought suit and/or encouraged others to do so was employed until or just before the time of the suit, fabricated serious and offensive complaints at discharge or in anticipation of discharge.

They also shared one other characteristic, in nearly every case they had been toxic or had been performing poorly for some extended period of time and should have been fired long ago but were not either because of poor management, fear of conflict or because the manager of practice owner was trying to be "nice".

I'm all for charitable giving, but I must be clear on this point; your HR practices are not the place for you to be "charitable" and can cost <u>you and all your other employees</u> your livelihoods. Part of the hesitation we see is based on the fact that most people don't know how to fire and discipline in a safe and effective way, below is a simple outline we use to help you get a handle on a real "process" just like you have for most other operations in your practice.

Start early, even in the interview process and make all employees aware that you have a and employment policy manual, a specific discipline process and high standards that will actually be enforced. Encourage them to communicate on any issues related to the workplace and their performance. Be clear about your expectations and requirements and how they will be enforced. Use a written job description that outlines their responsibilities and your performance expectations and then be ready to back it up.

A BASIC FOUR STEP GUIDANCE AND DISCIPLINE PLAN:

VERBAL – Given instructions, corrective feedback and outline your expectations for behavior or performance that is below par or creates conflict with other employees or patients immediately.

WRITTEN – Upon the SECOND incidence of any undesired behavior or shortfall of the performance the position clearly required and which was clearly outlined in the initial interview and written job description (see how it is repeated, re-enforced and most importantly, DOCUMENTED?) provide specific written record of the issue, save it in their file and provide them notice by giving them a copy.

HAVE AN AFFIRMATIVE AGREMENT – As a last salvage attempt and to preserve a record, use an affirmative agreement that specifies the behavior you need to correct and have the employee agree to specific, immediate changes in their behavior and performance to conform to their job description and previous corrections. Use a written form that they have seen before and that should be in their handbook.

IF ALL THOSE GOOD FAITH ATTEMPTS FAIL, FIRE THEM – If after the three above attempts don't produce the desired results, you've done your part and it's time to discharge the employee; again it is vital to <u>have a process</u>. Get keys, passwords, building entry keys and other security related issues covered and consider changing key locks and alarm codes. Have a witness if possible and follow a specific discharge process including an exit interview. Record the exit interview if possible so that the interaction is documented. If possible provide the employee with a final check they are due or any severance you may offer as a courtesy at the time of discharge, it takes some of the anger they feel away even if they know that being fired was their own fault. Finally, provide them an opportunity to provide feedback, either during the interview or in writing on a form you can provide; give them a chance to speak their mind and vent anger that might result in a lawsuit.

As covered in my previous admonitions, get both EPLI (employment practices liability insurance) and a real, customized employment manual from a top employment law resource, not a free form of the internet or an outdated one you copied from another practice and get legal advice from an experienced employment law attorney sooner rather than later if you feel you have an employee that threatens your practice.

SELF EVALUATION

Identifying and Managing Practice Employment Risks

1. True/False - My practice's employment manual completely protects me from a lawsuit.

2. The average sexual harassment verdict is how much?

a. $500K plus
b. $50K plus
c. It doesn't matter because I don't personally harass anyone

3. My practice's employment manual must be which of the following to be effective legal protection?

a. Custom drafted
b. State specific
c. Should reflect how our business actually operates
d. Distributed to every employee
e. Uniformly applied and enforced
f. All of the above
g. A and B only

4. As a medical practice owner and/or executive I <u>am personally responsible for all of the following</u>, whether I witnessed it or not; sexual harassment, retaliation against an employee, sexual or racial discrimination, how employees treat each other, what my partners do with employees.

a. True
b. False because I have a corporation
c. False because I have an office manager who is legally responsible
d. False because I pay them as contractors

5. EPLI insurance addresses specific risks and financial and legal gaps that are not adequately covered by the three basic polices we assume you've had counsel in properly implementing already including:

a. A medical malpractice insurance policy of at least $1 million per occurrence.
b. A worker's comp policy (aka: employee hurt on the job coverage);
c. A general liability policy (covers slip and fall and other injuries or non-medical liability related to general function of your business);
d. All of the above

6. As an employer I bear legal liability for which of the following issues with my staff?

a. How they are paid
b. What certifications they have
c. How they bill payors for their services
d. What services they are actually billing for
e. All of the above

7. Which of the following types of insurance help protect against employee related legal exposures?

a. D&O (director's and officer's)
b. EPLI
c. Data Breach
d. Worker's Comp
e. General liability policy
f. All of the above

Answer Key: 1. F, 2. A, 3. F, 4. A, 5. D, 6. E, 7. F

Dilip K. Moonka, MD, FAST, FAASLD

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Dr. Moonka has won numerous teaching awards in both the Department of Medicine and in the Division of Gastroenterology. He does clinical research in both liver transplantation and viral hepatitis with numerous publications in both areas, and he is a Fellow of the American Association for the Study of Liver Disease (FAASLD). Dr. Moonka is also a speaker or consultant for Bristol-Myers Squibb, Gilead, and Merck.

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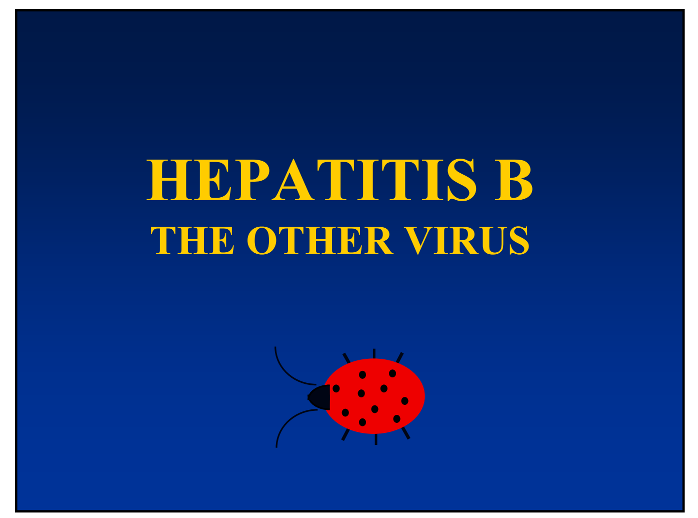
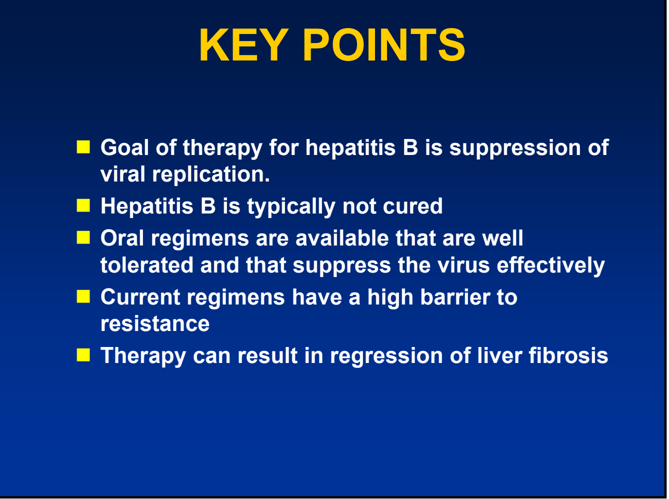
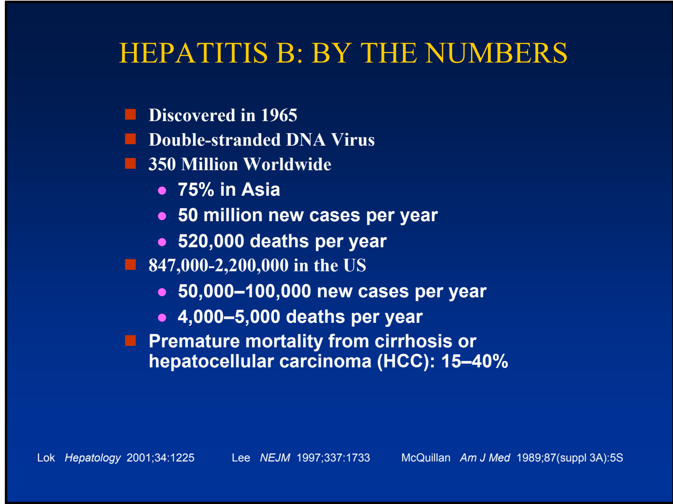
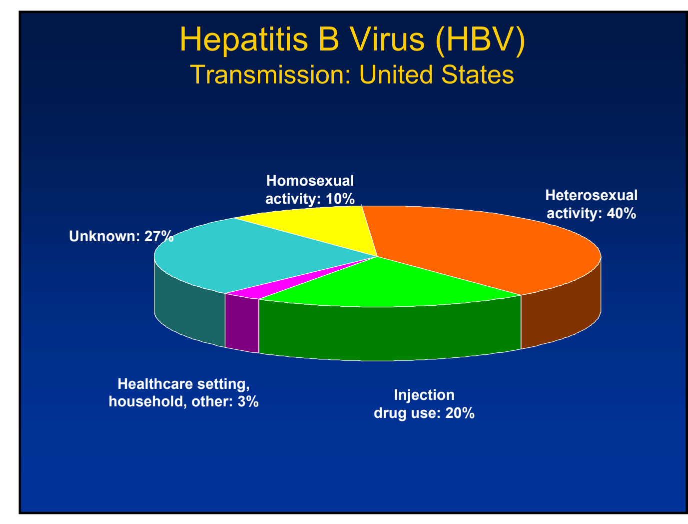
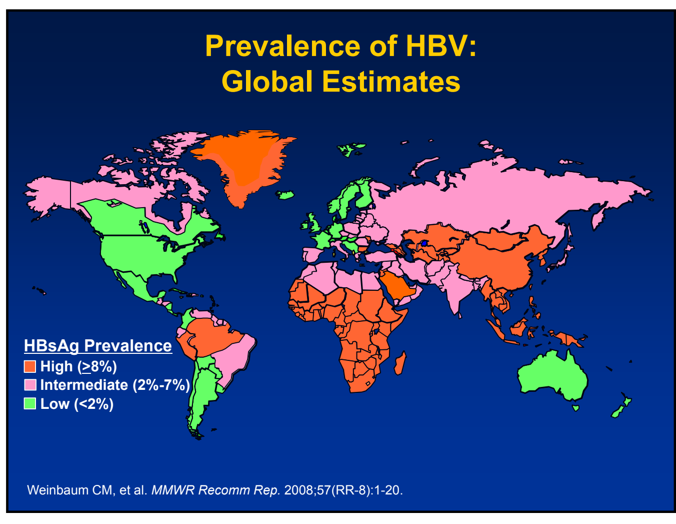
Hepatitis B & C: Risk Factors, Screening Recommendations and Treatment Options

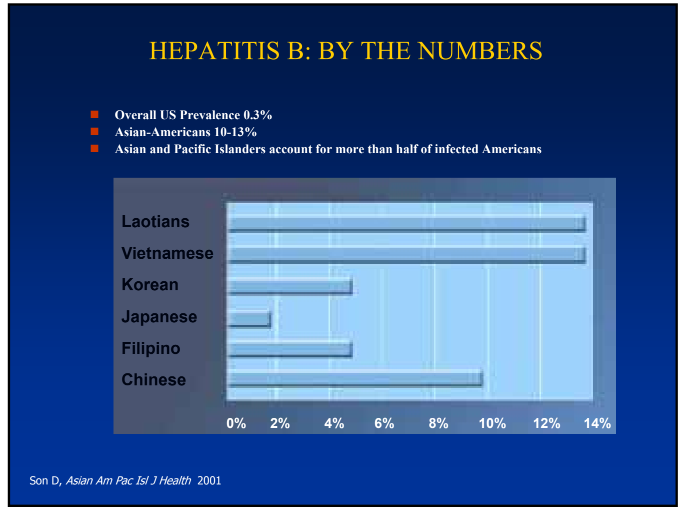












Who Should be Screened? CDC Recommendations

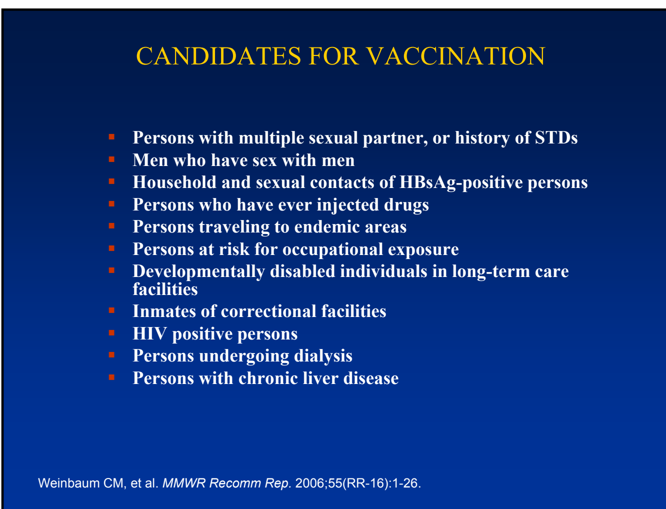
	Populations
Increased HBsAg Prevalence	• Persons born in regions with high or intermediate prevalence of HBV infection (HBsAg prevalence ≥2%) • U.S.-born persons not vaccinated as infants whose parents were born In regions with high prevalence of HBV infection (HBsAg prevalence ≥8%)
Manage Exposures	• All pregnant women • Infants born to HBsAg+ women • Injection drug users • Men who have sex with men • Household, needle-sharing, or sex contacts of persons known to be HBsAg+ persons • Source of blood/body fluid exposures (eg, needlestick, sexual assault)
Prevent Nosocomial Infection	• Donors of blood, plasma, organs, tissue, or semen • Hemodialysis patients
Increased Risk of Medical Consequences	• HIV+ persons • Persons with immunosuppressive therapy • Persons with elevated ALT or AST of unknown etiology

Weinbaum CM, et al. *MMWR Recomm Rep*. 2008;57(RR-8):1-20.

Recommended Counseling Actions for HBsAg-Positive Patients

- Have sexual contacts vaccinated
- Use barrier protection during sexual intercourse if partner not vaccinated or naturally immune
- Do not share toothbrushes or razors
- Cover open cuts and scratches
- Clean blood spills with detergent or bleach
- Do not donate blood, organs or sperm
- Limit alcohol use
- Lipid lowering agents typically safe

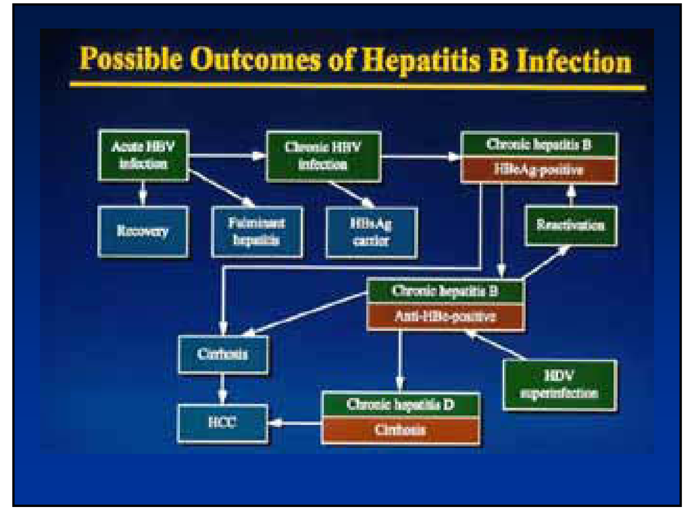
Lok AS, et al. *Hepatology*. 2009;50:661-662. Available at: http://www.aasld.org.

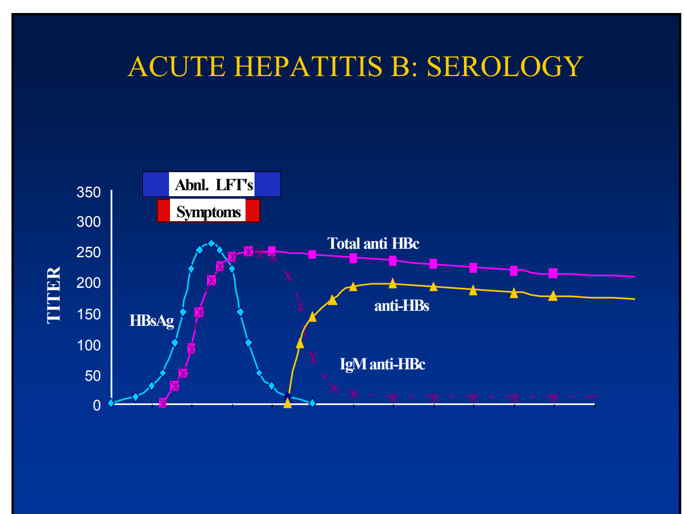


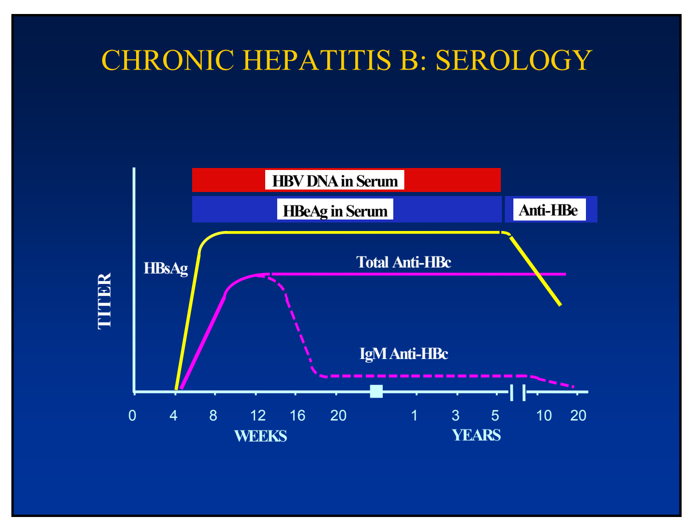
AASLD Guidelines: Periodic Surveillance for Hepatocellular Carcinoma

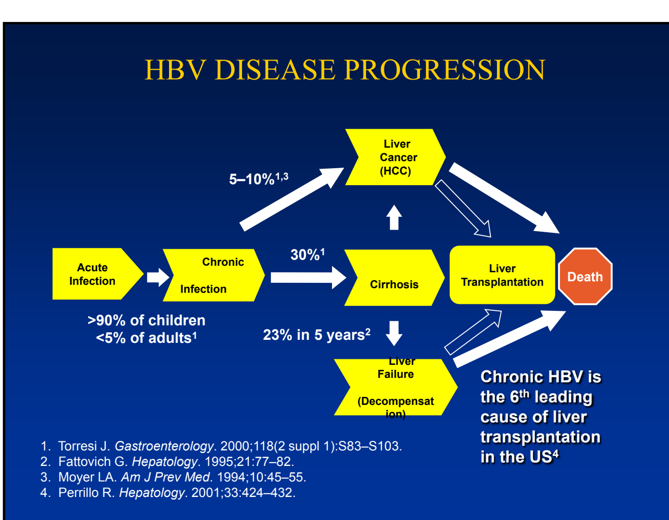
- Hepatitis B carriers at high risk
  - All cirrhotic hepatitis B carriers
  - Family history of hepatocellular carcinoma
  - Asian males ≥40 years of age
  - Asian females >50 years of age
  - Africans >20 years of age
  - High HBV DNA levels and ongoing hepatic inflammatory activity
  - Platelet count <170,000/µL
- Liver ultrasound surveillance
  - HBV guidelines: every 6 to 12 months
  - HCV guidelines: every 6 months

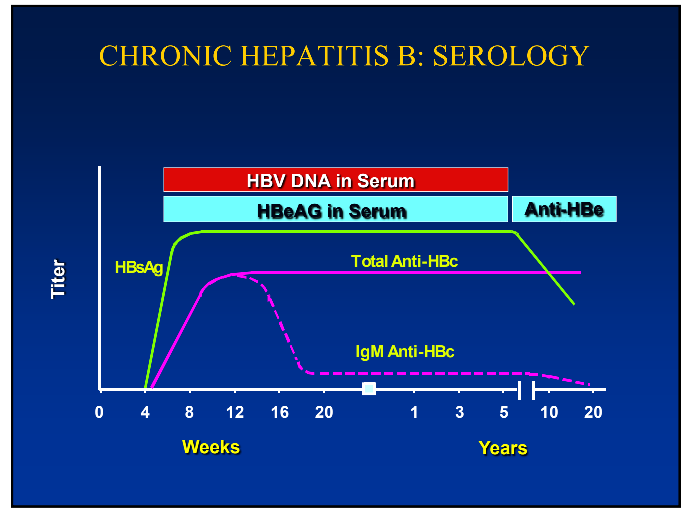
Bruix J, et al. *Hepatology*. 2010;53:1020-1022.

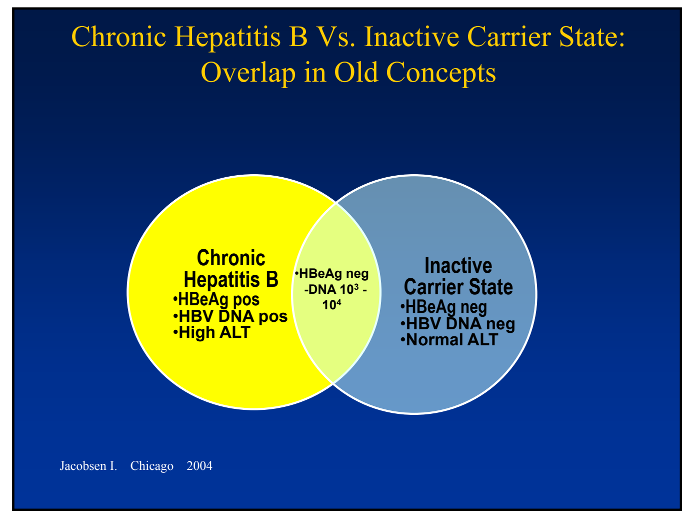


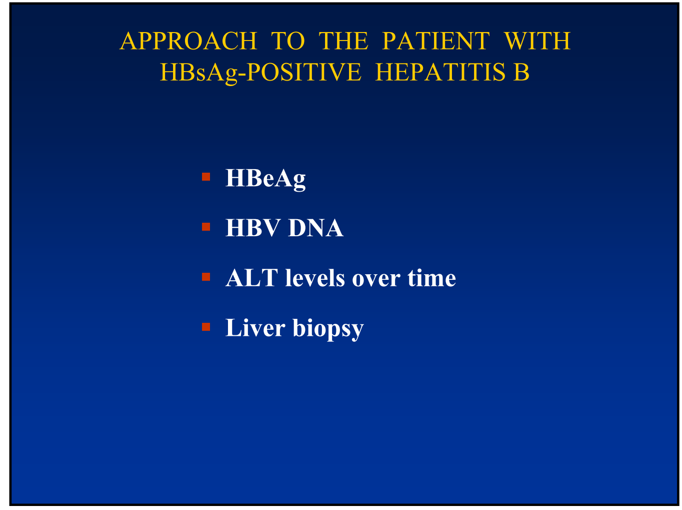

ACUTE HEPATITIS B: SEROLOGY
Abnl. LFT's
Symptoms
TITER
350
300
250
200
150
100
50
0
Total anti HBc
HBsAg
anti-HBs
IgM anti-HBc

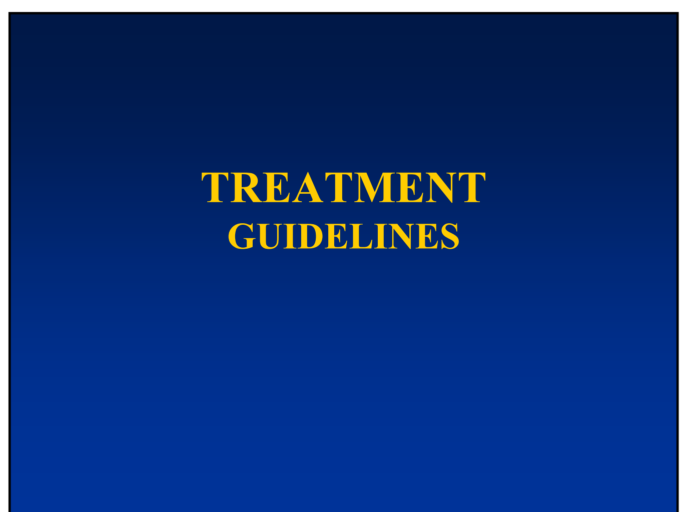

CHRONIC HEPATITIS B: SEROLOGY
HBV DNA in Serum
HBeAg in Serum
Anti-HBe
TITER
HBsAg
Total Anti-HBc
IgM Anti-HBc
0 4 8 12 16 20 1 3 5 10 20
WEEKS
YEARS

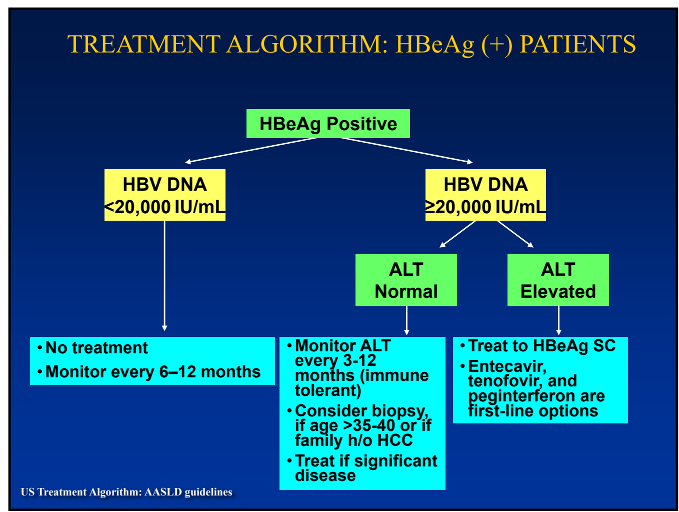

HBV DISEASE PROGRESSION
Liver Cancer (HCC)
5–10%1,3
Acute Infection
Chronic Infection
30%1
Cirrhosis
Liver Transplantation
Death
>90% of children
<5% of adults1
23% in 5 years2
Liver Failure (Decompensation)
Chronic HBV is the 6th leading cause of liver transplantation in the US4
1. Torresi J. Gastroenterology. 2000;118(2 suppl 1):S83–S103.
2. Fattovich G. Hepatology. 1995;21:77–82.
3. Moyer LA. Am J Prev Med. 1994;10:45–55.
4. Perrillo R. Hepatology. 2001;33:424–432.

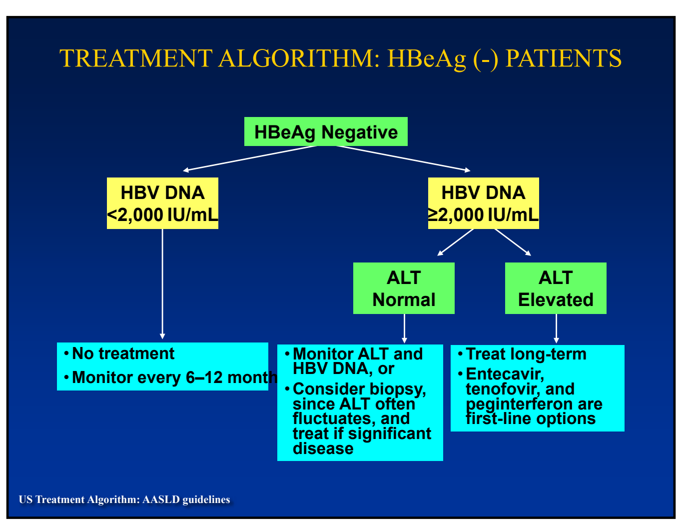

CHRONIC HEPATITIS B: SEROLOGY
HBV DNA in Serum
HBeAG in Serum
Anti-HBe
Titer
HBsAg
Total Anti-HBc
IgM Anti-HBc
0 4 8 12 16 20 1 3 5 10 20
Weeks
Years

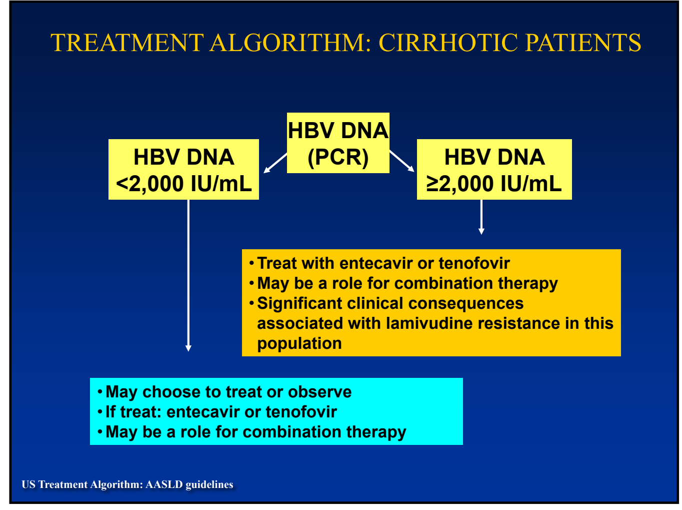

Chronic Hepatitis B Vs. Inactive Carrier State: Overlap in Old Concepts
Chronic Hepatitis B
•HBeAg pos
•HBV DNA pos
•High ALT
•HBeAg neg
-DNA 10³ - 10⁴
Inactive Carrier State
•HBeAg neg
•HBV DNA neg
•Normal ALT
Jacobsen I. Chicago 2004

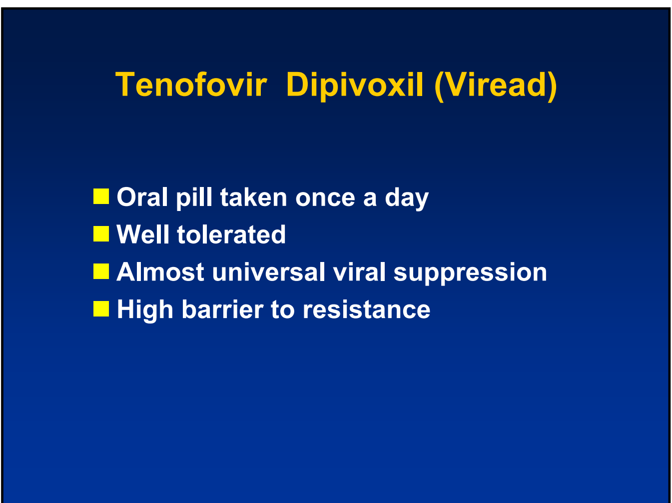

APPROACH TO THE PATIENT WITH HBsAg-POSITIVE HEPATITIS B
HBeAg
HBV DNA
ALT levels over time
Liver biopsy

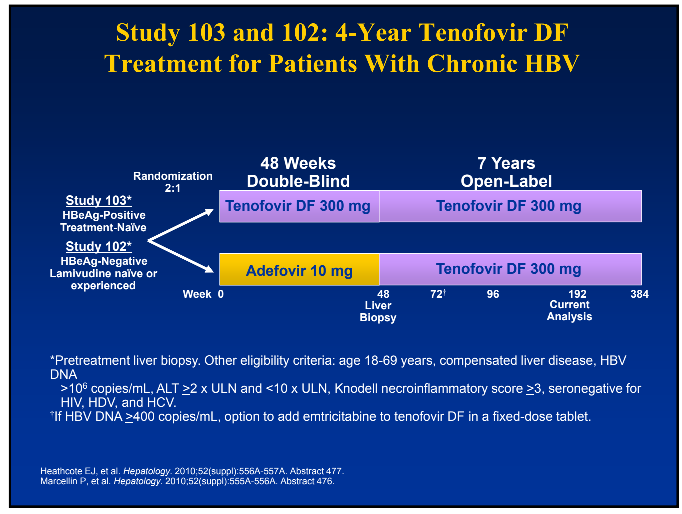

TREATMENT
GUIDELINES

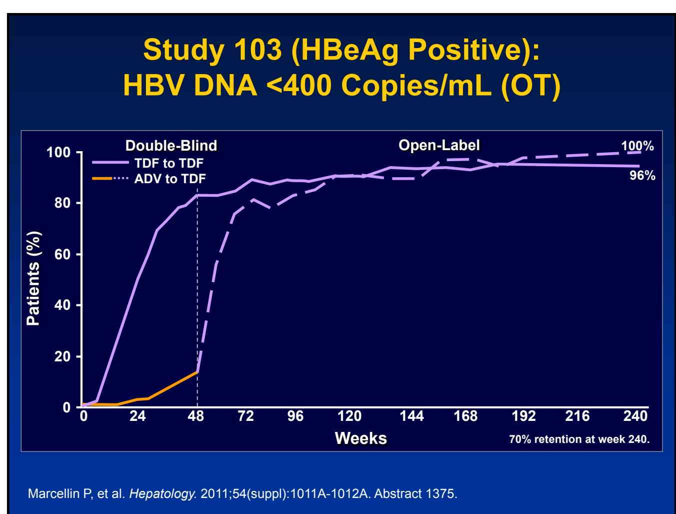

TREATMENT ALGORITHM: HBeAg (+) PATIENTS
HBeAg Positive
HBV DNA <20,000 IU/mL
HBV DNA ≥20,000 IU/mL
ALT Normal
ALT Elevated
• No treatment
• Monitor every 6–12 months
• Monitor ALT every 3-12 months (immune tolerant)
• Consider biopsy, if age >35-40 or if family h/o HCC
• Treat if significant disease
• Treat to HBeAg SC
• Entecavir, tenofovir, and peginterferon are first-line options
US Treatment Algorithm: AASLD guidelines

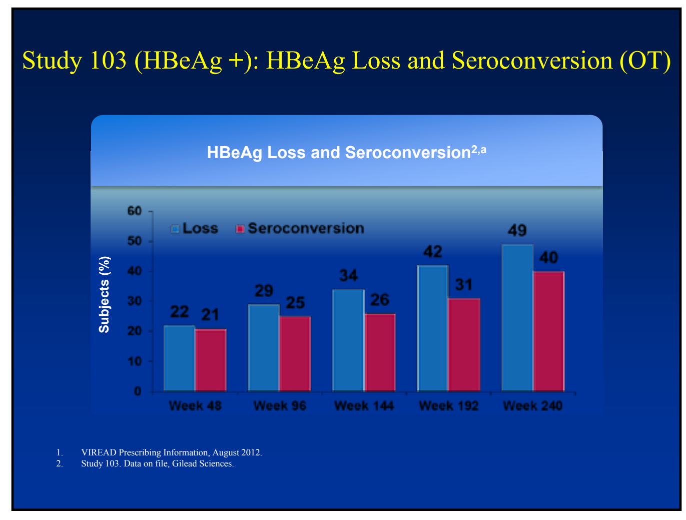

TREATMENT ALGORITHM: HBeAg (-) PATIENTS
HBeAg Negative
HBV DNA <2,000 IU/mL
HBV DNA ≥2,000 IU/mL
ALT Normal
ALT Elevated
• No treatment
• Monitor every 6–12 month
• Monitor ALT and HBV DNA, or
• Consider biopsy, since ALT often fluctuates, and treat if significant disease
• Treat long-term
• Entecavir, tenofovir, and peginterferon are first-line options
US Treatment Algorithm: AASLD guidelines

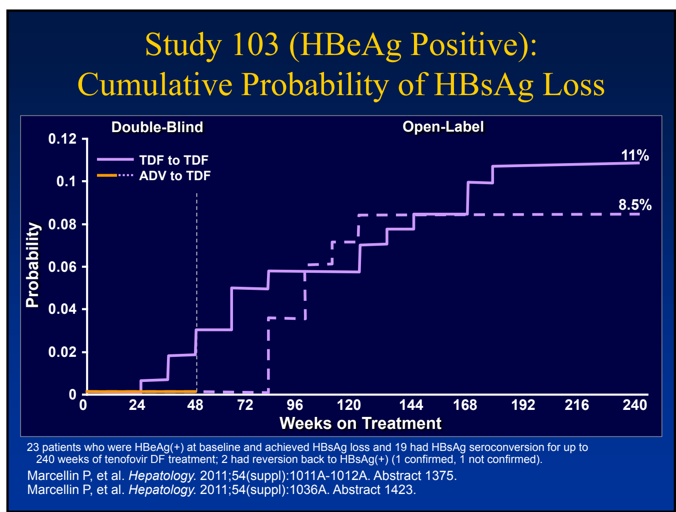

TREATMENT ALGORITHM: CIRRHOTIC PATIENTS
HBV DNA (PCR)
HBV DNA <2,000 IU/mL
HBV DNA ≥2,000 IU/mL
• Treat with entecavir or tenofovir
• May be a role for combination therapy
• Significant clinical consequences associated with lamivudine resistance in this population
• May choose to treat or observe
• If treat: entecavir or tenofovir
• May be a role for combination therapy
US Treatment Algorithm: AASLD guidelines

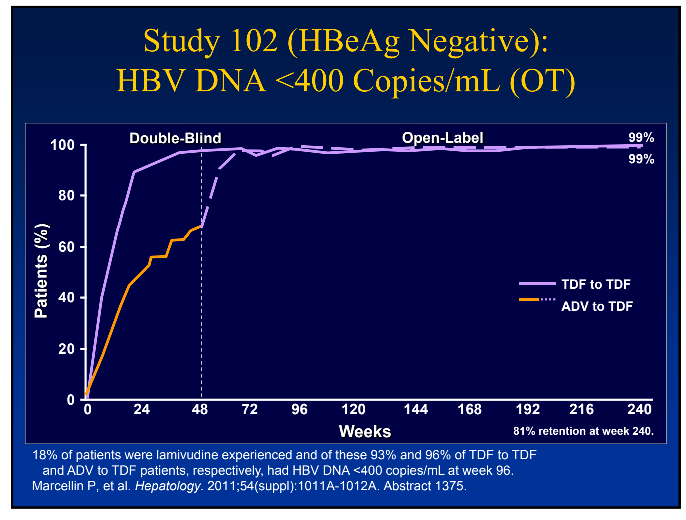

Tenofovir Dipivoxil (Viread)
Oral pill taken once a day
Well tolerated
Almost universal viral suppression
High barrier to resistance

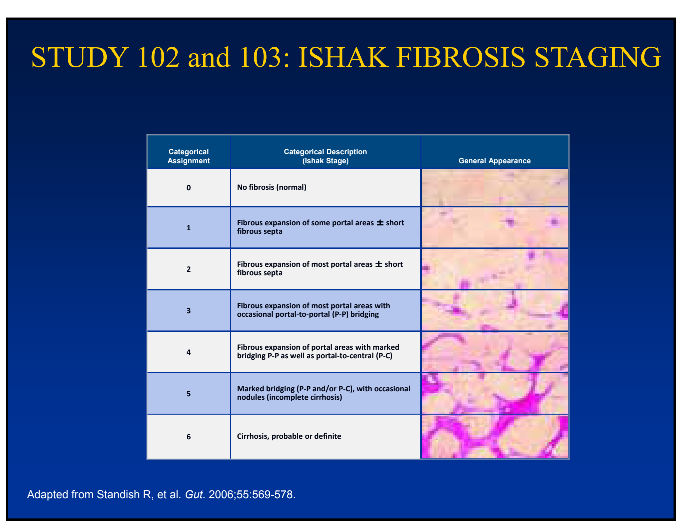

Study 103 and 102: 4-Year Tenofovir DF Treatment for Patients With Chronic HBV
Randomization 2:1
48 Weeks Double-Blind
7 Years Open-Label
Study 103* HBeAg-Positive Treatment-Naïve
Study 102* HBeAg-Negative Lamivudine naïve or experienced
Tenofovir DF 300 mg
Tenofovir DF 300 mg
Adefovir 10 mg
Tenofovir DF 300 mg
Week 0
48 Liver Biopsy
72†
96
192 Current Analysis
384
*Pretreatment liver biopsy. Other eligibility criteria: age 18-69 years, compensated liver disease, HBV DNA >10⁶ copies/mL, ALT ≥2 x ULN and <10 x ULN, Knodell necroinflammatory score ≥3, seronegative for HIV, HDV, and HCV.
†If HBV DNA ≥400 copies/mL, option to add emtricitabine to tenofovir DF in a fixed-dose tablet.
Heathcote EJ, et al. Hepatology. 2010;52(suppl):556A-557A. Abstract 477.
Marcellin P, et al. Hepatology. 2010;52(suppl):555A-556A. Abstract 476.



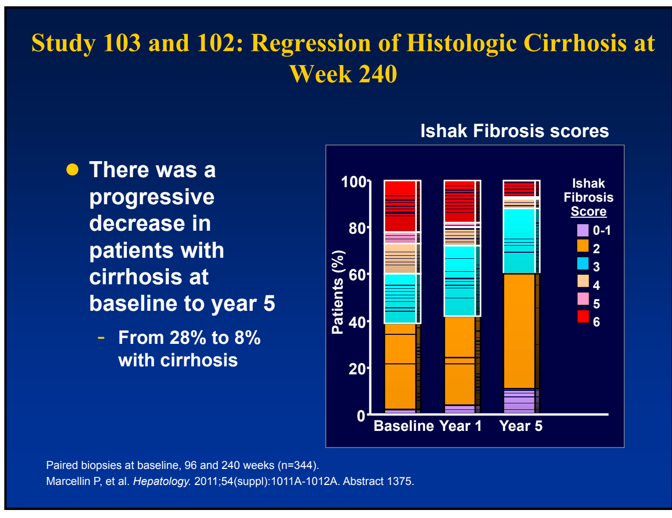


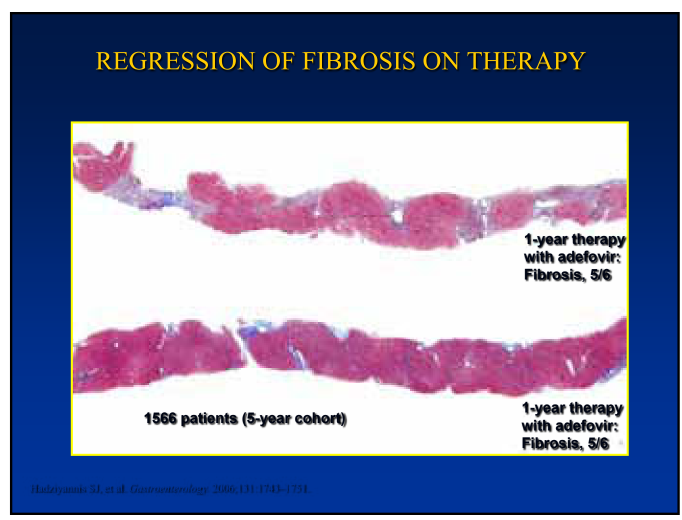


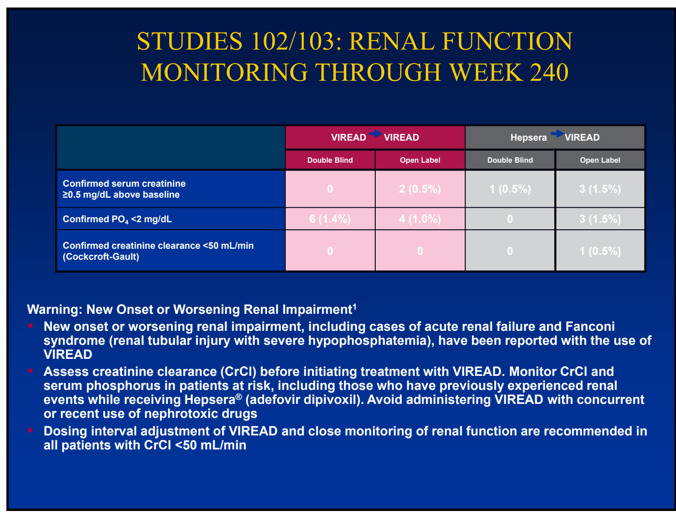




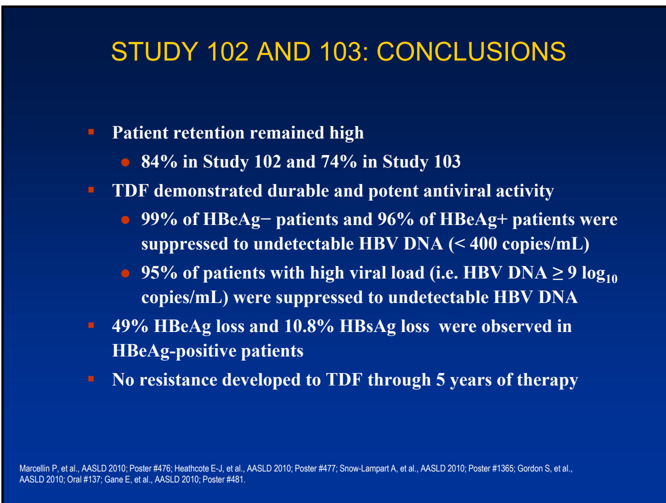
Categorical Assignment	Categorical Description (Ishak Stage)	General Appearance
0	No fibrosis (normal)	
1	Fibrous expansion of some portal areas ± short fibrous septa	
2	Fibrous expansion of most portal areas ± short fibrous septa	
3	Fibrous expansion of most portal areas with occasional portal-to-portal (P-P) bridging	
4	Fibrous expansion of portal areas with marked bridging P-P as well as portal-to-central (P-C)	
5	Marked bridging (P-P and/or P-C), with occasional nodules (incomplete cirrhosis)	
6	Cirrhosis, probable or definite	

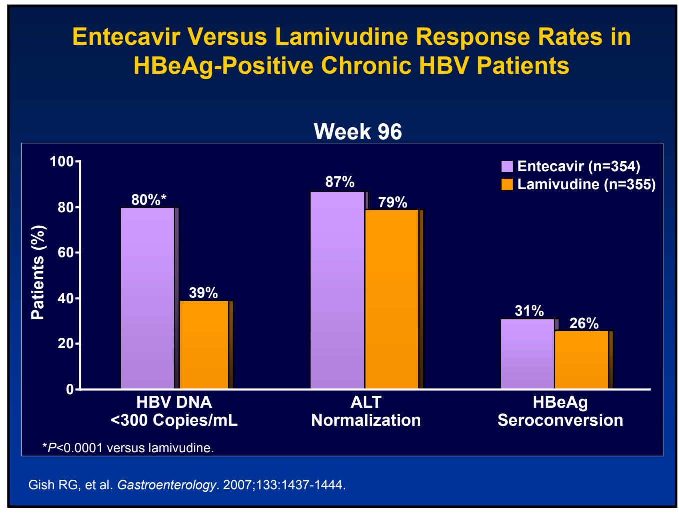


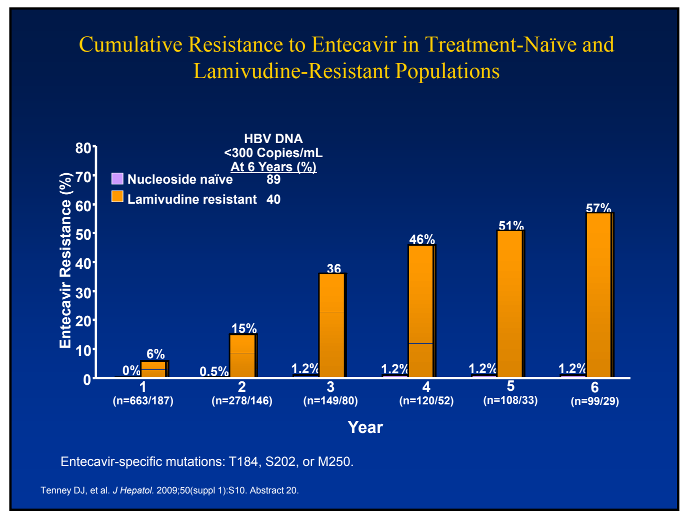




	VIREAD → VIREAD		Hepsera → VIREAD	
	Double Blind	Open Label	Double Blind	Open Label
Confirmed serum creatinine ≥0.5 mg/dL above baseline	0	2 (0.5%)	1 (0.5%)	3 (1.5%)
Confirmed PO_4 <2 mg/dL	6 (1.4%)	4 (1.0%)	0	3 (1.5%)
Confirmed creatinine clearance <50 mL/min (Cockcroft-Gault)	0	0	0	1 (0.5%)

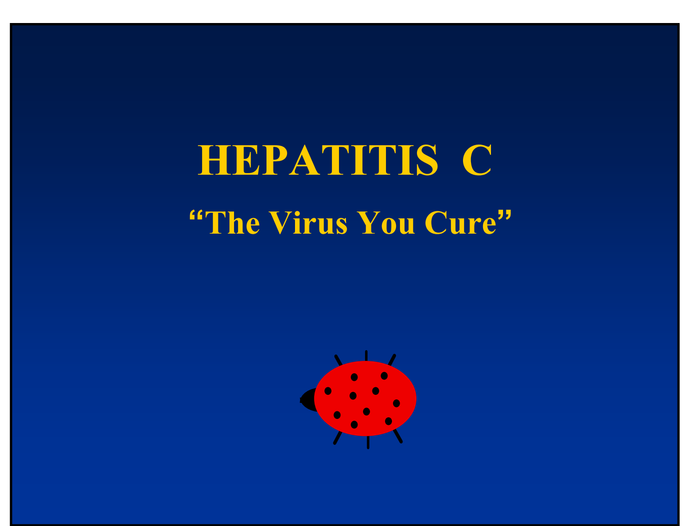






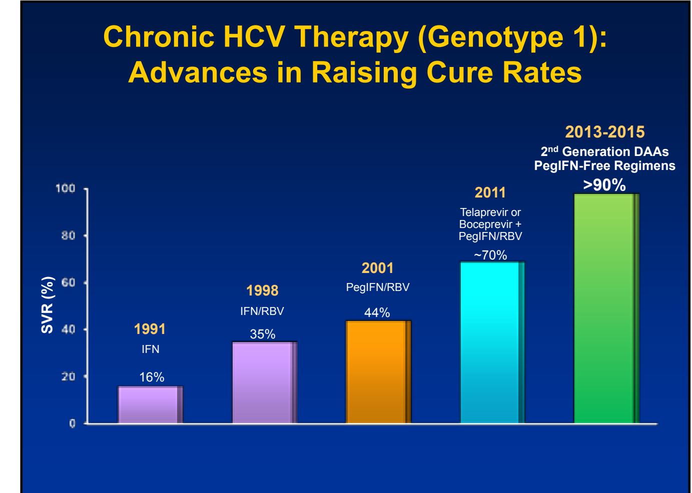
Tenofovir Alafenamide (TAF)

- Pro-drug of tenofovir.
- Excellent distribution in lymphocytes and hepatocytes
- Lower concentrations in kidney
- Equivalent to tenofovir dipivoxil in antiviral efficacy
- Even less effect on renal function



KEY POINTS

- Goal of therapy for hepatitis C is to cure the virus.
- Current "sustained response rates" (SVR) are over 95% for almost all individuals
- Successful therapy alters clinical outcomes in infected individuals
- "Hard to treat" subpopulations are now almost non- existent
- Success in therapy has changed our approach to screening



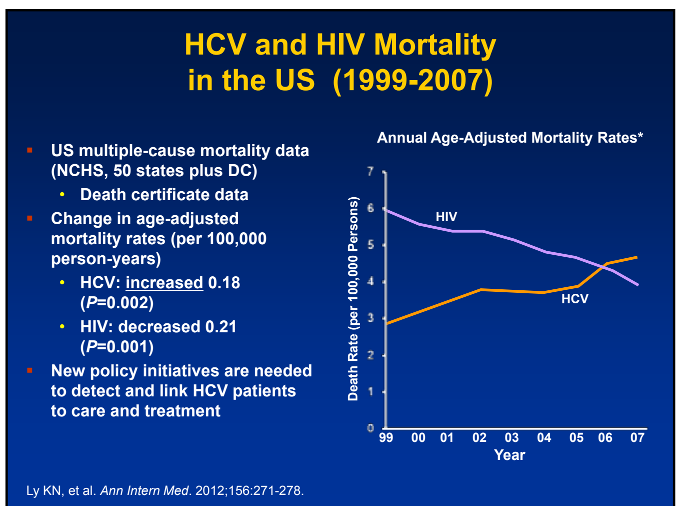
Therapy Moving Forward: Late 2015-2016

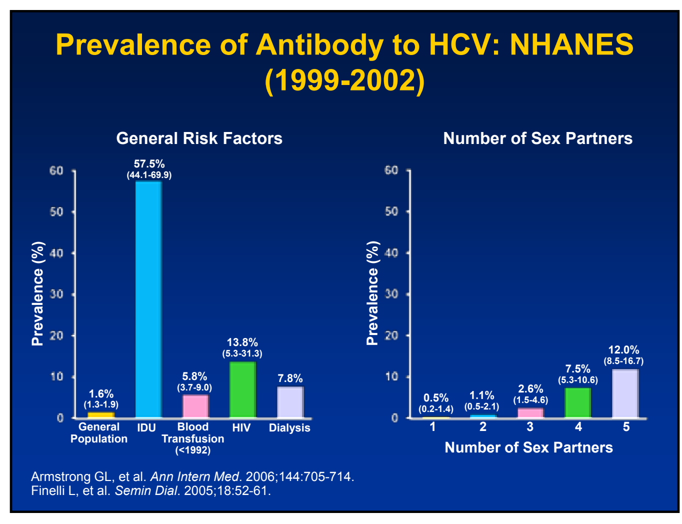
- All Oral
- > 95% cure
- < 12 weeks of therapy
- Well tolerated
  - <1% discontinuation

Clinical Considerations on the Progression of HCV Infection: Rule of 20

- Of patients infected with HCV
  - 20% will clear virus
  - 75% to 85% will develop chronic infection
  - 5-20% will develop cirrhosis
  - Typically takes at least 20 years to develop cirrhosis
  - 5-20% of patients with cirrhosis will develop liver cancer
  - 19,659 deaths from hepatitis C in 2014

http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#section2.

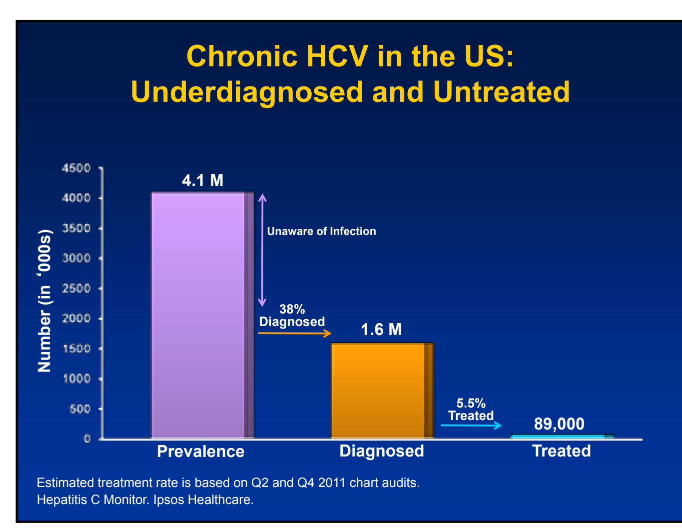




HCV Screening and Testing Recommendations (AASLD/IDSA/CDC)

- Behaviors that place a person at high risk for HCV infection
  - Injected illegal drugs (past and current)
  - Recipients of transfusions, blood products or organ transplants: before July, 1992
  - History of incarceration
  - Infection with HIV
  - Long term hemodialysis
  - Children born to HCV-infected mothers
  - Health care, emergency medical and public safety workers after needle sticks, sharps, or mucosal exposure to HCV-positive blood
  - Signs and symptoms of chronic liver disease including elevated liver enzymes
  - Intranasal illicit drug use
  - Tattoo in an unregulated setting

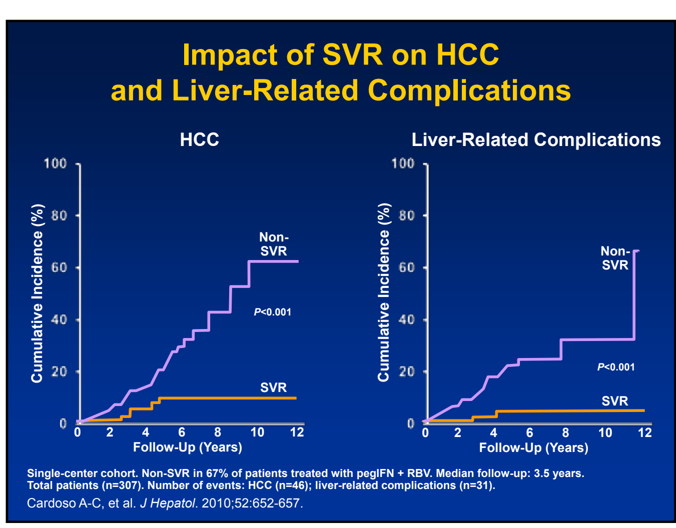
Recommendations for Testing, Managing, and Treating Hepatitis C. http://hcvguidelines.org



Birth Cohort Testing for HCV Infection: All individuals born between 1945-1965

- Retrospective analysis (2004-2010)
  - Enhanced surveillance sites
    - Colorado, Connecticut, Minnesota, NY
  - Past or current HCV infection (n=110,223)
    - Born before 1945, 1945-1965, after 1965
- 68% of positive HCV laboratory markers reported to health departments were from persons born between 1945-1965
  - Only 66% of these had a CDC risk indication for HCV testing
- Implications
  - Support recommendation for 1-time screening of all persons born between 1945-1965
  - Recommended by U.S. Preventive Services Task Force

Mahajan R, et al. *Hepatology.* 2012;56(suppl 4):649A-650A. Abstract 944.



AASLD/IDSA/CDC Guidelines for Counseling Hepatitis C Infected Persons

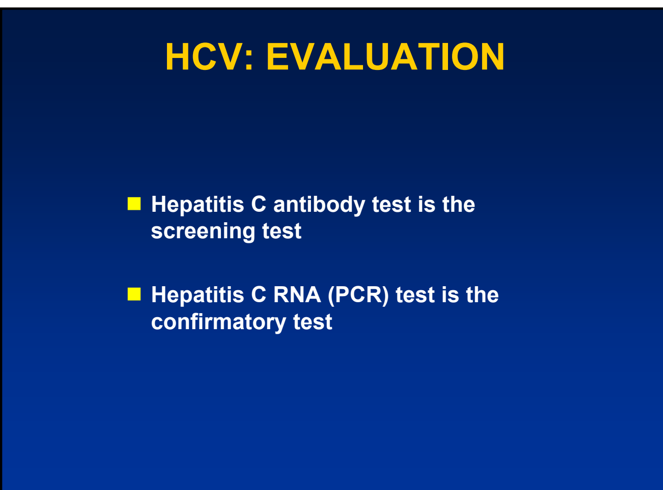
- All infected individuals should be evaluated by a practitioner prepared to provide comprehensive education and management including antiviral therapy
- Persons infected with hepatitis C should refrain from excessive alcohol use
- Infected individuals should be screened for hepatitis B and HIV
- Individuals with hepatitis C should be evaluated for advanced fibrosis using liver biopsy or non-invasive modalities
- Infected individuals should be vaccinated against hepatitis A and B if not immune

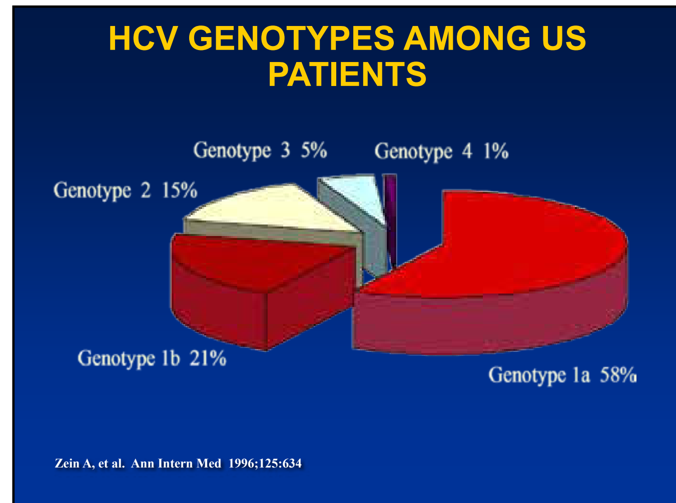
Recommendations for Testing, Managing, and Treating Hepatitis C. http://hcvguidelines.org

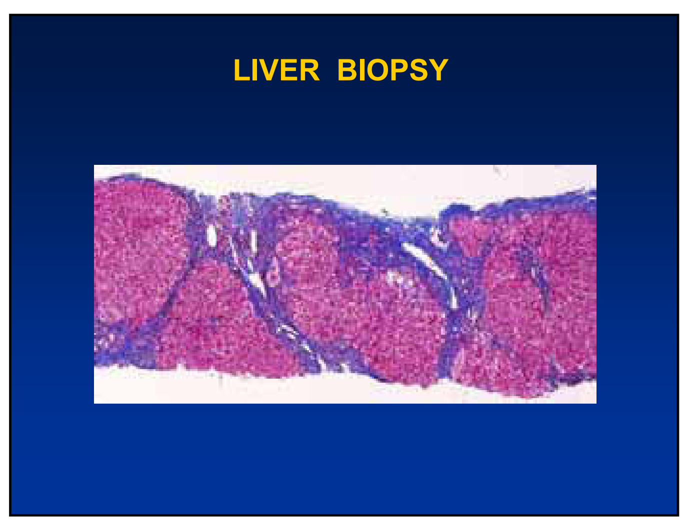
AASLD/IDSA/CDC Guidelines for Counseling Hepatitis C Infected Persons

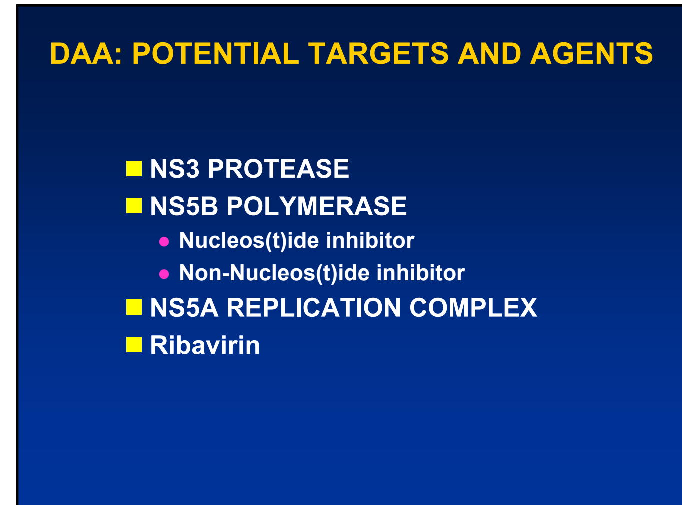
- Persons with HCV infection should be counselled to avoid sharing toothbrushes and dental or shaving equipment, and be cautioned to cover any bleeding wound
- Persons with HCV infection should be advised not to donate blood and to discuss HCV serostatus prior to donation of body organs, other tissue, or semen
- Persons with HIV infection and those with multiple sexual partners or sexually transmitted infections should be encouraged to use barrier precautions to prevent sexual transmission. Other persons with HCV infection should be counseled that the risk of sexual transmission is low and may not warrant barrier protection.
- Persons should be counseled to stop using illicit drugs and enter substance abuse treatment. Those who continue to inject drugs should be counseled to take measures to prevent transmission
- Household surfaces and implements contaminated with visible blood from an HCV-infected person should be cleaned using a dilution of 1 part household bleach to 9 parts water. Gloves should be worn when cleaning up blood spills

Recommendations for Testing, Managing, and Treating Hepatitis C. http://hcvguidelines.org



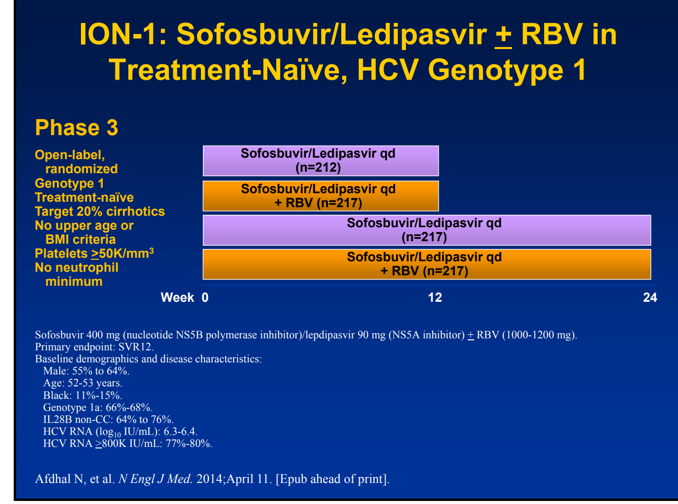


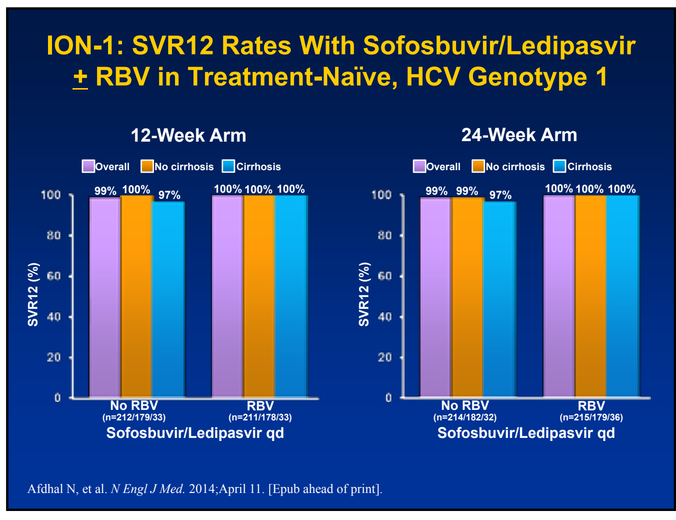


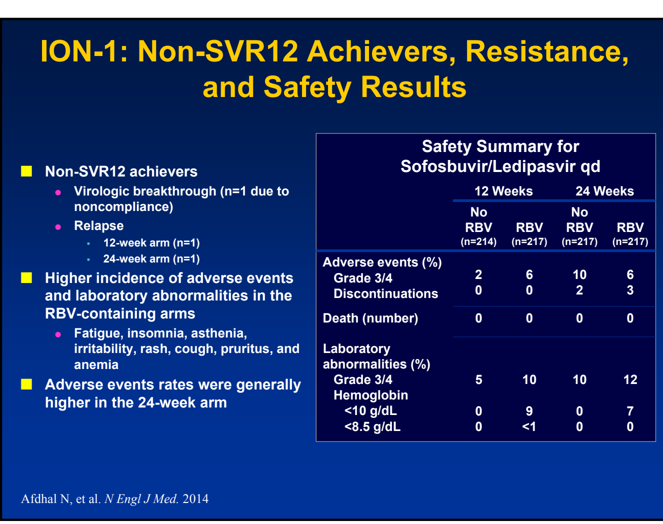


HARVONI: Sofosbuvir-Ledipasvir Based Regimens

- Ledipasvir is an NS5A inhibitor
- Sofosbuvir is HCV polymerase inhibitor
- Harvoni
  - Effective against genotype 1
  - Avoid or use with caution with amiodarone
  - Avoid if creatinine clearance < 30 ml/min

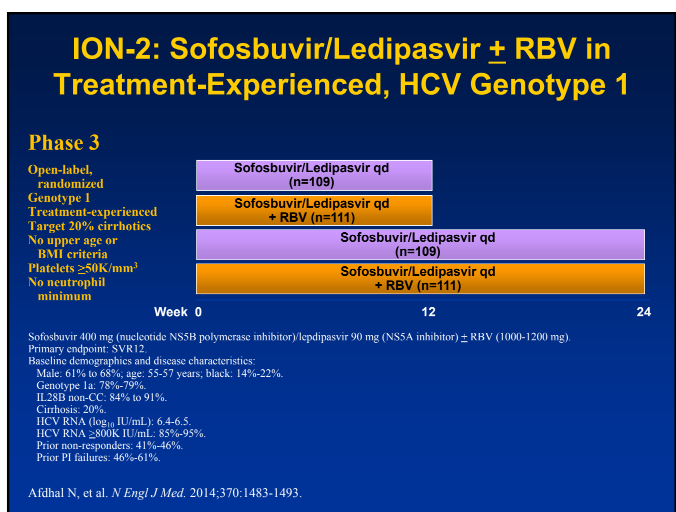


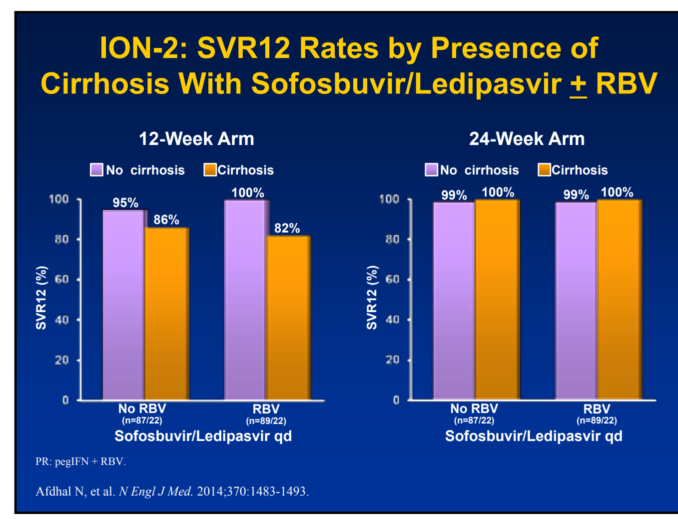




Safety Summary for Sofosbuvir/Ledipasvir qd

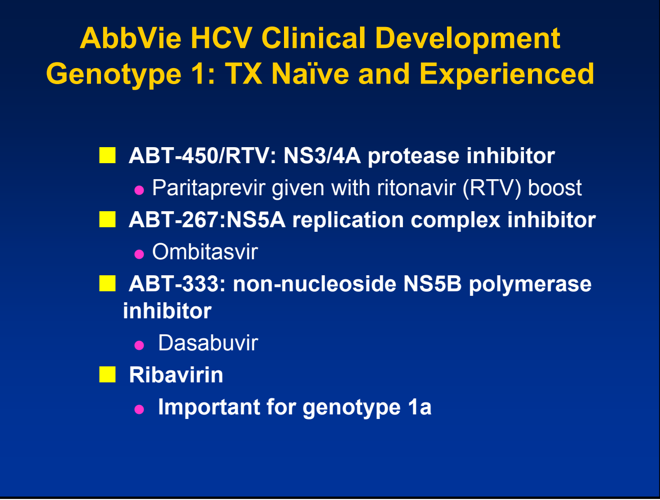
	12 Weeks No RBV (n=214)	12 Weeks RBV (n=217)	24 Weeks No RBV (n=217)	24 Weeks RBV (n=217)
Adverse events (%)				
Grade 3/4	2	6	10	6
Discontinuations	0	0	2	3
Death (number)	0	0	0	0
Laboratory abnormalities (%)				
Grade 3/4	5	10	10	12
Hemoglobin				
<10 g/dL	0	9	0	7
<8.5 g/dL	0	<1	0	0

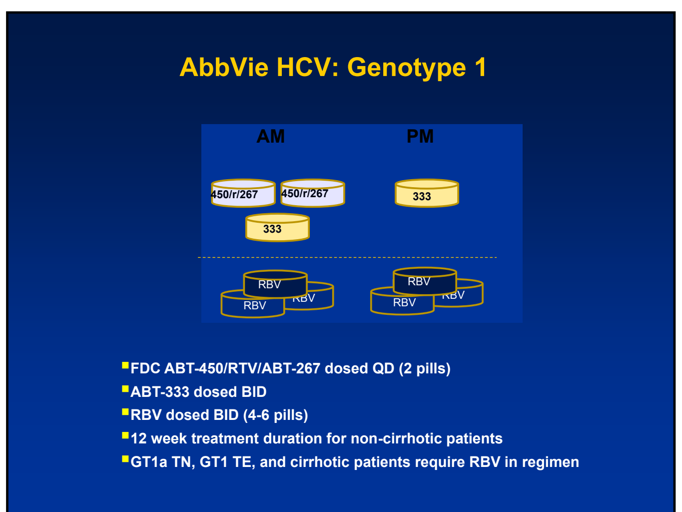


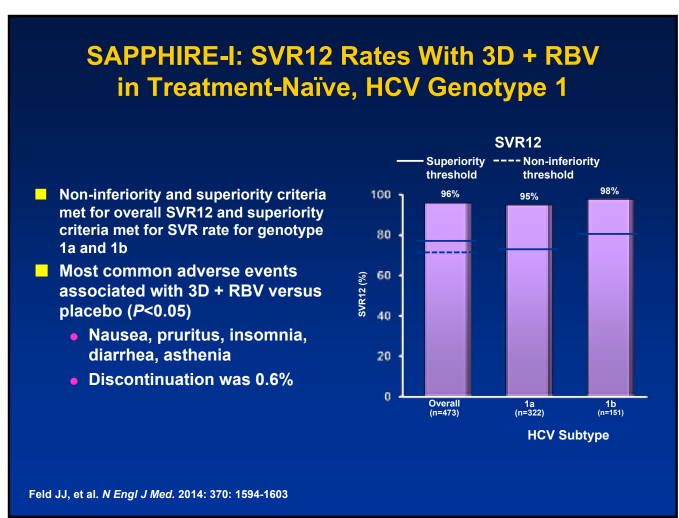


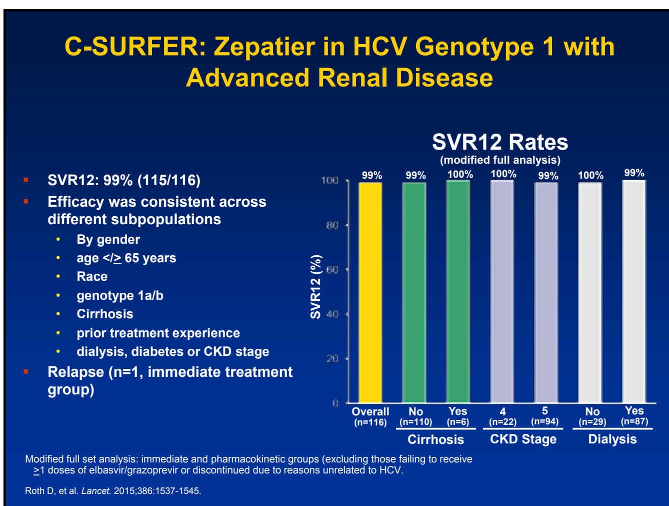
Sofosbuvir-Ledipasvir Based Regimens (Harvoni)

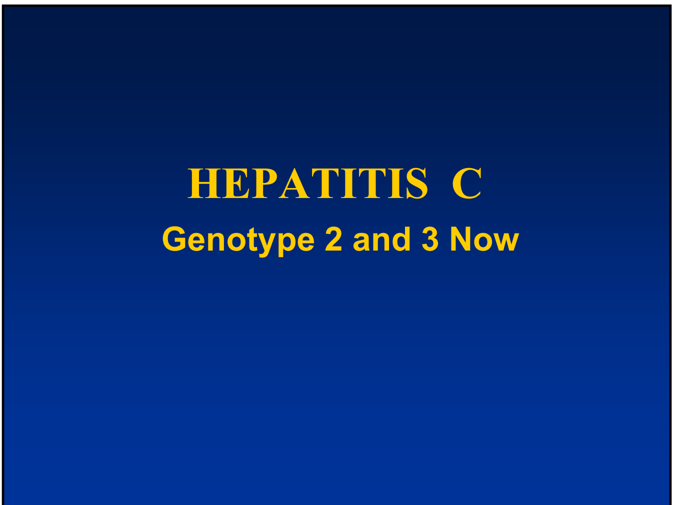
- 12 weeks in treatment naïve patients
- 12 weeks in treatment experienced without cirrhosis
- 24 weeks in treatment experienced with cirrhosis.
- 8 weeks
  - Treatment naïve
  - No cirrhosis
  - Viral titer less than 6 million IU/ml

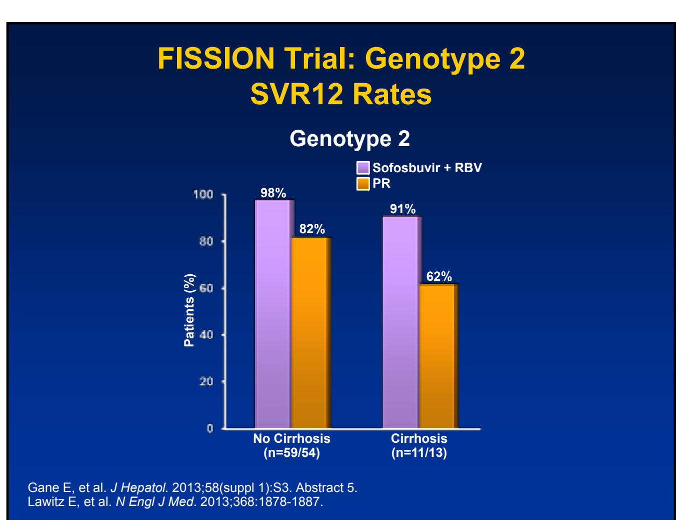


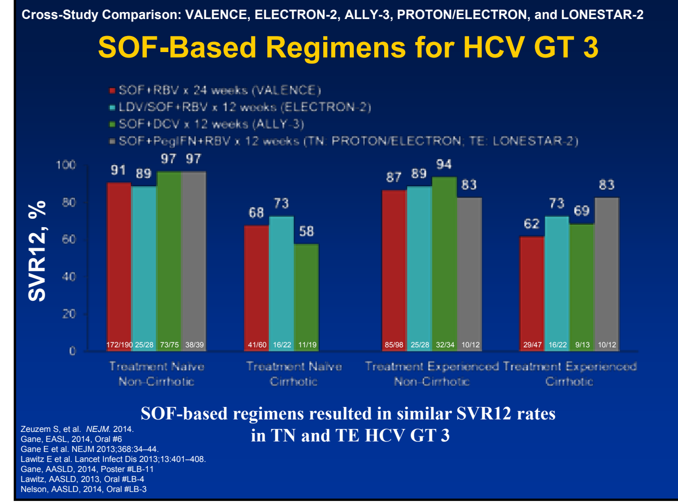


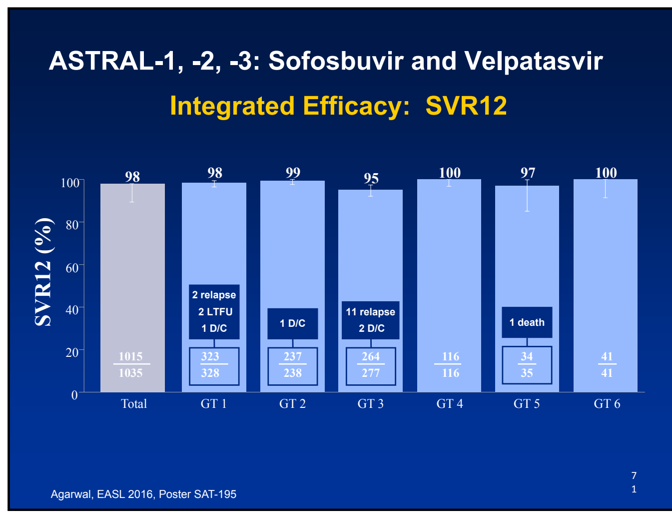



C-SURFER: Zepatier in HCV Genotype 1 with Advanced Renal Disease
SVR12: 99% (115/116)
Efficacy was consistent across different subpopulations
By gender
age </≥ 65 years
Race
genotype 1a/b
Cirrhosis
prior treatment experience
dialysis, diabetes or CKD stage
Relapse (n=1, immediate treatment group)
SVR12 Rates
(modified full analysis)
SVR12 (%)
99% 99% 100% 100% 99% 100% 99%
Overall (n=116)
No (n=110)
Yes (n=6)
4 (n=22)
5 (n=94)
No (n=29)
Yes (n=87)
Cirrhosis
CKD Stage
Dialysis
Modified full set analysis: immediate and pharmacokinetic groups (excluding those failing to receive ≥1 doses of elbasvir/grazoprevir or discontinued due to reasons unrelated to HCV.
Roth D, et al. Lancet. 2015;386:1537-1545.

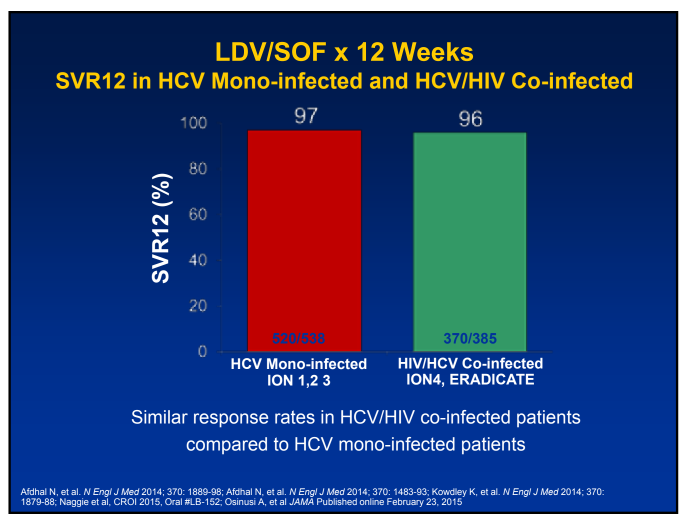

HEPATITIS C
Genotype 2 and 3 Now

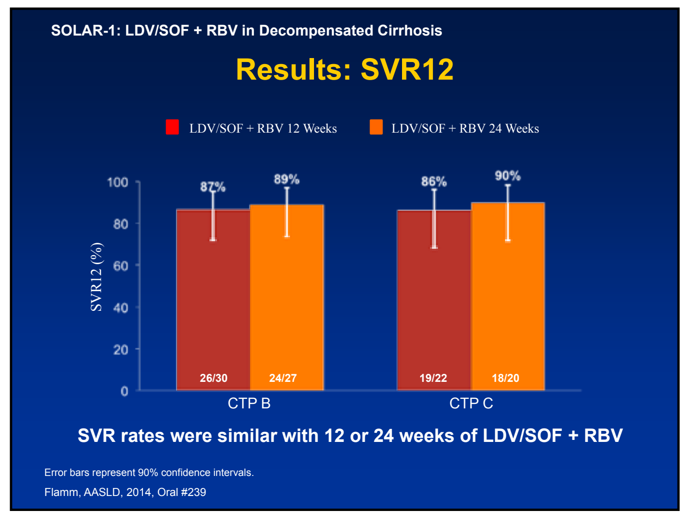

FISSION Trial: Genotype 2
SVR12 Rates
Genotype 2
Sofosbuvir + RBV
PR
Patients (%)
98% 82% 91% 62%
No Cirrhosis (n=59/54)
Cirrhosis (n=11/13)
Gane E, et al. J Hepatol. 2013;58(suppl 1):S3. Abstract 5.
Lawitz E, et al. N Engl J Med. 2013;368:1878-1887.

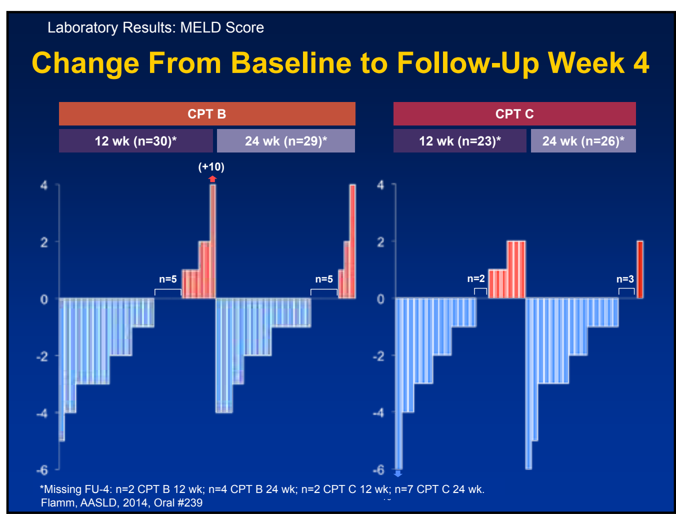

Cross-Study Comparison: VALENCE, ELECTRON-2, ALLY-3, PROTON/ELECTRON, and LONESTAR-2
SOF-Based Regimens for HCV GT 3
SOF+RBV x 24 weeks (VALENCE)
LDV/SOF+RBV x 12 weeks (ELECTRON-2)
SOF+DCV x 12 weeks (ALLY-3)
SOF+PegIFN+RBV x 12 weeks (TN: PROTON/ELECTRON, TE: LONESTAR-2)
SVR12, %
91 89 97 97
68 73 58
87 89 94 83
62 73 69 83
Treatment Naive Non-Cirrhotic
Treatment Naive Cirrhotic
Treatment Experienced Non-Cirrhotic
Treatment Experienced Cirrhotic
SOF-based regimens resulted in similar SVR12 rates in TN and TE HCV GT 3
Zeuzem S, et al. NEJM. 2014.
Gane, EASL, 2014, Oral #6
Gane E et al. NEJM 2013;368:34–44.
Lawitz E et al. Lancet Infect Dis 2013;13:401–408.
Gane, AASLD, 2014, Poster #LB-11
Lawitz, AASLD, 2013, Oral #LB-4
Nelson, AASLD, 2014, Oral #LB-3

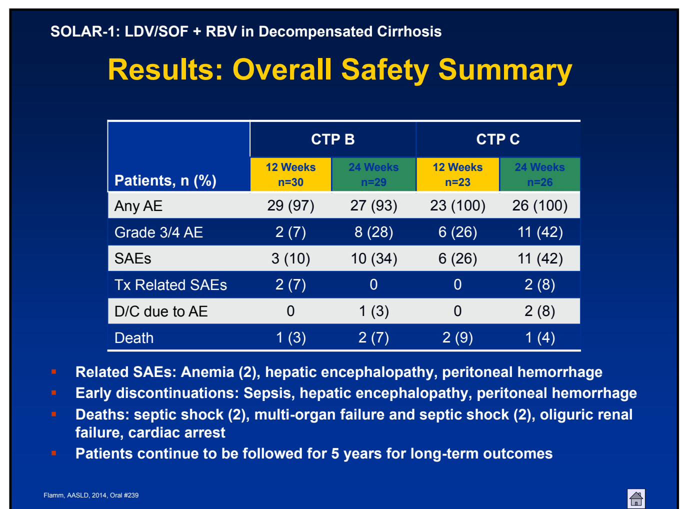

ASTRAL-1, -2, -3: Sofosbuvir and Velpatasvir
Integrated Efficacy: SVR12
SVR12 (%)
98 98 99 95 100 97 100
2 relapse
2 LTFU
1 D/C
1 D/C
11 relapse
2 D/C
1 death
1015/1035
323/328
237/238
264/277
116/116
34/35
41/41
Total
GT 1
GT 2
GT 3
GT 4
GT 5
GT 6
Agarwal, EASL 2016, Poster SAT-195

DIFFICULT TO TREAT SUBPOPULATIONS
Co-infection
Autoimmune Disease
Anemia
Renal Insufficiency
Mental Health Disease
Substance Abuse
Cardiopulmonary Disease
Decompensated Cirrhosis









Patients, n (%)	CTP B		CTP C	
	12 Weeks n=30	24 Weeks n=29	12 Weeks n=23	24 Weeks n=26
Any AE	29 (97)	27 (93)	23 (100)	26 (100)
Grade 3/4 AE	2 (7)	8 (28)	6 (26)	11 (42)
SAEs	3 (10)	10 (34)	6 (26)	11 (42)
Tx Related SAEs	2 (7)	0	0	2 (8)
D/C due to AE	0	1 (3)	0	2 (8)
Death	1 (3)	2 (7)	2 (9)	1 (4)

SELF EVALUATION

Hepatitis B & C: Risk Factors, Screening Recommendations and Treatment Options

1. Which is true of the hepatitis B transmission?

a. Vertical transmission from mother to infant can occur but is infrequent
b. The hepatitis B virus can be transmitted effectively through sex
c. The hepatitis B vaccine is effective but does not protect against all routes of transmission
d. Individuals travelling to endemic areas should be vaccinated if they are sexually active
e. Strategies to prevent vertical transmission are effective 80% of the time

2. Appropriate first line therapies for hepatitis B include:

a. Tenofovir
b. Lamivudine
c. Entecavir
d. A and C
e. All of the above

3. Which of the following statements is correct about hepatitis C (HCV)?

a. A majority of infected individuals will clear the virus on their own but it can take decades to do so.
b. Patients who clear the virus spontaneously will lose the hepatitis C antibody but will remain positive for the hepatitis C RNA.
c. Without effective therapy, infected individuals can develop cirrhosis typically in 5-10 years.
d. Liver cancer is prevalent in patients with hepatitis C with or without cirrhosis.
e. Over 90% of infected individuals can attain “cure” with currently available therapy.

4. Which of the following statements is correct?

a. Successful anti-viral therapy for hepatitis C can effectively put the virus into remission.
b. Successful therapy for hepatitis C eliminates the risk of liver cancer.
c. Successful therapy for hepatitis C in patients with cirrhosis, markedly decreases the risk of liver failure.
d. All of the above
e. None of the above

5. Appropriate first line therapies for hepatitis B include:

a. Tenofovir
b. Lamivudine
c. Entecavir
d. A and C
e. All of the above

6. Which of the following statements is correct?

a. Successful anti-viral therapy for hepatitis C can effectively put the virus into remission.
b. Successful therapy for hepatitis C eliminates the risk of liver cancer.
c. Successful therapy for hepatitis C in patients with cirrhosis, markedly decreases the risk of liver failure.
d. All of the above
e. None of the above

7. Which recommendations for care of patients with HCV is correct?

a. A positive hepatitis C antibody test should be followed by the hepatitis C RNA (PCR) test.
b. While statin dugs are effective in the control of hyperlipidemia, in patients with HCV, their risks exceed their benefits.
c. Patients with HCV should be vaccinated for hepatitis A but not hepatitis B
d. In patients with HCV, screening for liver cancer with the alpha-fetoprotein blood test, every six months, is adequate and critical.
e. Because therapy for HCV has become so effective, establishing the level of liver fibrosis no longer has value.

Answer Key: 1. B, 2. D, 3. E, 4. C, 5. D, 6. C, 7. A,

Wayne H. Lipton

Wayne H. Lipton, of Rockville Centre, NY, is founder and managing partner of Concierge Choice Physicians, LLC one of the largest providers of concierge medicine in the country offering the opportunity to blend concierge care with existing practice or as a stand-alone model and serving primary care physicians, specialists, as well as large and small groups. He has a biochemistry degree from Harvard College and attended business school at University of Chicago.

Mr. Lipton was chief operating officer for both PhyMatrix, a public healthcare company, and Physicians Choice, a Connecticut IPA and practice management company. He was also president of Richmond Way Stores, a local chain of drug stores, serves on the board of trustees at South Nassau Communities Hospital, and has been a guest lecturer at the Wharton School of Business.

You may contact Mr. Lipton with your questions and comments at (877) 888-5565, or by email at WLipton@choice.md.

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Concierge Medicine: Understanding the Model and its Variations
Wayne H. Lipton

I. Compensation to practices for visits and services

- A. Cash only Providers
- B. Third party payment
  - i. Government Programs
  - ii. Insurances/TPA's etc.

II. The changes in Healthcare that created a need

- A. The need to reduce overall medical costs
- B. The first impact is at the weakest link- The Physician

III. What is the "Concierge Model"?

- A. Membership
- B. Service Improvements
- C. Direct payment Approach

IV. What types of providers have participated?

- A. Internists
- B. Family Physicians
- C. Specialists
- D. Pediatricians

V. The History of Concierge Care

- A. 1998 in Seattle
- B. 2001 in Florida
- C. 2005 in New York

DETAILS OF THE MODEL AND CHARACTERISTICS

I. Consumer-driven decision

- A. Prices are supposed to reflect the market
- B. Driven by what the patient is willing to pay
- C. Higher prices mean fewer members, more turnover and higher levels of service

II. What does the patient want that they do not get already?

- A. Convenience
- B. Connectivity and Communication
- C. One to one mapping
- D. Advocacy
- E. Interactions with the System
- F. Interactions with Payors
- G. Interaction with Family Members
- H. Advice
- I. Help with Coordination of Care
- J. Help with understanding what the options are and what the choices mean

III. Proactive Approach vs a Reactive Approach

IV. Part time vs Full time models

V. FULL MODELS

- A. What is the history?
- B. Who can do a full model?
- C. What are the requirements?
- D. What are the benefits?
- E. What are the challenges?
- F. Why consider a full model and why not consider it?

VI. PART TIME MODELS

- A. How does this work?
- B. What are the benefits?
- C. What are the challenges?
- D. Specialists and Hybrid models
- E. Mixing the hybrid model with a traditional practice
- F. Hybrid vs full in vertically integrated models of care

VII. Insurance, Medicare and Medicaid with Concierge Care

VIII. What does the physician want to deliver and avoid?

IX. Balance of the use of their time and the effectiveness of extenders

- A. Is this just another administrative fee?
- B. Is your time being compensated appropriately?
- C. Do you have the time and how do you make the time
- D. How do extenders work into the concierge programs?

X. Are there more tests and are they efficacious?

- A. Medically necessary vs add- ons

XI. Functional Medicine and Concierge Care

XII. Covered vs. Non-Covered services

XIII. Medicare and Physicals

XIV. Care Coordination

XV. Telemedicine and Concierge Care

XVI. Home Visits and Concierge Care

XVII. Patient retention and Patient recruitment

XVIII. Functionality that often is additional to the practice (new overhead):

- A. Billing
- B. Initial Integration costs
- C. Communication
- D. Coverage
- E. Staff with customer service background
- F. Membership amenities
- G. Help with submission and tax documents

H. Marketing and Sales

XIX. Current trends in Practice and Concierge Care

XX. Vertical integration and practice value

XXI. ACO's and Concierge Care

XXII. Employment and Concierge Care Models

A. Compensation based on additional services, coverage, RVU's

XXIII. The future of Concierge Care Models

A. Direct Medicine
B. Concierge vs Urgent Care
C. Primary care performed by extenders vs Physicians

SELF EVALUATION

Concierge Medicine: Understanding the Model and its Variations

True/False

1. Concierge Care started in Florida

2. Concierge Care works only in wealthy communities

3. Some specialists can participate in a Concierge Program

4. Price points of programs vary from state to state

5. Enhanced communication is an important part of a Concierge Program

6. Medicare is compatible with Concierge programs built around non-covered services

7. Concierge practices generally are transitions from existing practices

Answer Key: 1. F, 2. F, 3. T, 4. T, 5. T, 6. T, 7. T

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Understanding and Complying with The False Claims Act

Disclaimer

THE INFORMATION PRESENTED IS NOT MEANT TO CONSTITUTE LEGAL ADVICE. CONSULT YOUR ATTORNEY FOR ADVICE ON A SPECIFIC SITUATION.

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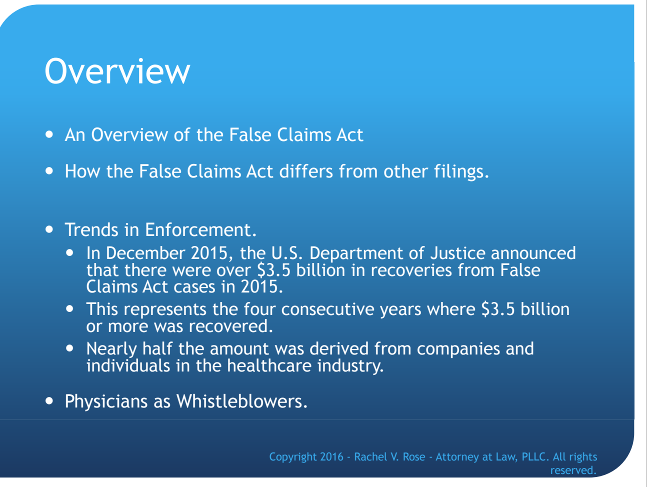

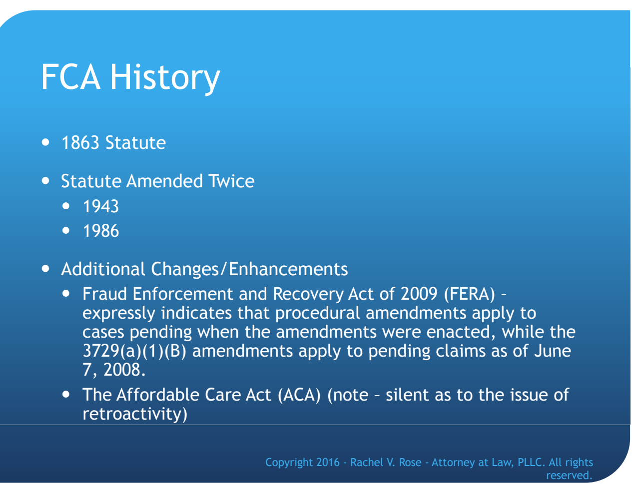

Establishing a prima facie FCA case

- Begin with §3729(a)(1), where the plaintiff MUST prove:
  - (1) defendant presented or caused to be presented to an agent of the United States a claim for payment;
  - (2) the claim was false or fraudulent; and
  - (3) the defendant knew the claim was false or fraudulent.

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The FCA provides liability when a person…

- (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval (*Warner Chilcott DOJ settlement, $125 million for criminal and civil (Oct. 29, 2015);*
- *(B) knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim;*
- *(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);*

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Liability Continued…

- (D) has possession, custody or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;
- (E) is authorized to make or deliver a document certifying receipt of property used, or to be used by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;
- (F) knowingly busy, or receives a pledge of an obligation or debt… who lawfully may not sell or pledge property; and
- (G) … is liable to the U.S. Government for not less than $5,500 and not more than $11,000, plus treble damages per violation.

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Pre and Post FERA - §3729(a)(2)

- 31 USC §3729(a)(2) (1994) (emphasis added).
- Liability applies when a defendant "knowingly makes, uses, or causes to be made or used, a false record or statement *to get false or fraudulent claims paid or approved by the government*."

- Post FERA, now §3729(a)(1)(B) (emphasis added).
- Liability is present for any person who "knowingly makes, uses, or causes to be made or used, a false record or statement *material to a false or fraudulent claim*."
- ***TAKE AWAY - the new version BROADENS the intent required to trigger liability.***

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What does a "false claim" look like?

"A false claim may take many forms, the most common being a claim for goods or services not provided or provided in violation *of contract terms, specification, statute or regulation*."

(S. Rep. No. 99-345 at 9, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274 (emphasis added).

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Categorizing a False Claim

- Factually False/Worthless Services Theory
- Legally False (Express)
- Legally False By Implied Certification
- Reverse False Claim

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Factually False/Worthless Services Theory

- A submission for payment is based on goods not delivered or services not rendered.
- Commonly found with durable medical equipment or services billed for by physicians and not performed.
- Providers should be conscience of "up-coding."

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Legally False (Express)

- Medicare Provider Agreement
  - 42 CFR §424.510(d)(3)
  - Signer "attests that the information is accurate and that the provider is aware of and abides by the all applicable statutes, regulations and program instructions."

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Legally False By Implied Certification

- Occurs when, "a claimant seeks and makes a claim for payment from the government without disclosing that it violated regulations that affected its eligibility for payment." *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 305 (3d. Cir. 2011).
- "It's premised on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition for payment." *Id. quoting Mikes*, 274 F.3d at 699.
- Split in the circuits (1st and 7th) lead to the U.S. Supreme Court granting Cert. *Universal Health Services, Inc. v. Escobar.*

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Universal Health Services, Inc. v. United States ex rel. Escobar, No. 15-7

- "**Issue**: (1) Whether the "implied certification" theory of legal falsity under the FCA – applied by the First Circuit below but recently rejected by the Seventh Circuit – is viable; and (2) whether, if the "implied certification" theory is viable, a government contractor's reimbursement claim can be legally "false" under that theory if the provider failed to comply with a statute, regulation, or contractual provision that does not state that it is a condition of payment, as held by the First, Fourth, and D.C. Circuits; or whether liability for a legally "false" reimbursement claim requires that the statute, regulation, or contractual provision expressly state that it is a condition of payment, as held by the Second and Sixth Circuits. http://www.scotusblog.com/case-files/cases/universal-health-services-v-united-states-ex-rel-escobar/

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Reverse False Claims

- Look at the Post-1986 Amendments
- Section 3729(a)(1)(G) - the "reverse" false claims section.
- Liability can be imparted where one acts improperly – not to get money from the government, but to avoid having to pay money to the government.

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How does the FCA differs from other lawsuits?

- Under seal
- Recovery is shared by the government and the whistleblower
- Heightened pleading standard
- Original source of information.
- Procedural requirements.

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Differences with FCA Actions

- If the government intervenes in the *qui tam* action it has the primary responsibility for prosecuting the action. § 3730(c)(1).
- It can dismiss the action, even over the objection of the relator, so long as the court gives the relator an opportunity for a hearing (§ 3730(c)(2)(A)).
- If a relator seeks to settle or dismiss a *qui tam* action, it must obtain the consent of the government. § 3730(b)(1).
- When the case is proceeding, the government (§ 3730(c)(2)(C)) and the defendant (§ 3730(c)(2)(D)) can ask the court to limit the relator's participation in the litigation.

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Awards – Section 3730(d)

- If gov't intervenes, then relator is entitled to receive between 15 and 25 percent of the amount recovered by the government.
- If the gov't declines, then the relator's share is increased to 25-30 percent of the total damages.
- If a *qui tam* action is successful, the relator also is entitled to legal fees and other expenses of the action by the defendant.

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Enforcement Trends and the Employer's Perspective.

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The Healthcare Industry

- Significant Area of Vulnerability
- December 4, 2012: Department of Justice Press Release
  - Attorney General's Office Reiterated the Following:
    - Commitment to combating fraud in healthcare;
    - Combined Agency Effort between HHS and the DOJ when the Health Care Fraud Prevention and Enforcement Action Team (HEAT) was established; and
    - Commended whistleblowers for looking out for the best interests of tax payers.

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FY 2012 Highlights

- UBS - $780 million (securities/tax)
- Amgen - $762 million (off-label marketing)
- GlaxoSmithKline - $3 billion (illegal marketing)
- Abbott - $1.5 billion (off-label marketing)
- Top 30 False Claims Act Settlements FY2012
  - Over 60% Healthcare
  - 5 out of 30 were Securities Industry

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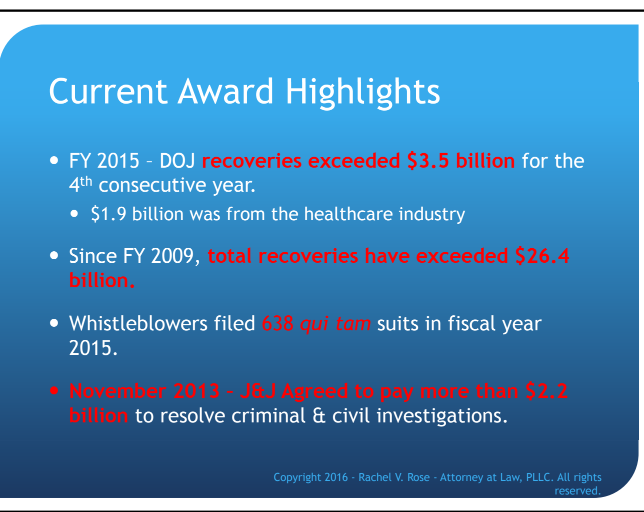

FY 2015 Highlights

- GENZYME: On September 3, 2015, a biotechnology subsidiary of a foreign pharmaceutical company agreed to settle civil and criminal misbranding claims against the company in relation to its alleged unlawful distribution of an adulterated device. FINE: agreed to pay a $32.5 million criminal penalty, and agreed to enter into a Corporate Integrity Agreement, in addition to a $22.28 million civil penalty the company paid in 2013 regarding the same claims.
- ADVENTIST: On September 4, 2015, a Georgia hospital system and a physician employee agreed to pay more to settle allegations that they submitted false claims to federal health care programs and also violated the Stark Law. FINE: The health system agreed to pay $25 million, as well as contingent payments of up to $10 million, and the physician agreed to pay $425,000. The federal government received $24.6 million and Georgia received $758,960.

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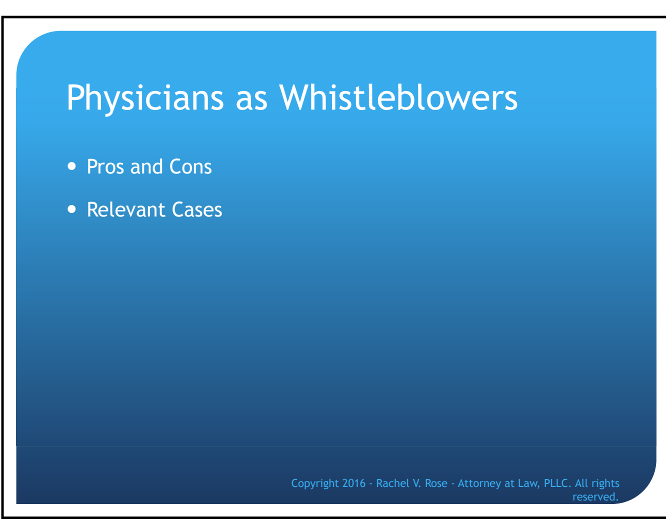

Take-Aways

- An ERM approach can help mitigate liability associated with the FCA.
- As indicated by recent laws and regulations in healthcare and the securities industry, the government is increasingly supporting the FCA.
- By performing adequate due diligence on multiple facets of an entity's operations and implementing adequate compliance programs, the likelihood of an FCA cause of action can be reduced.

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SELF EVALUATION

Understanding and Complying with The False Claims Act

1. True/False - False Claims Act cases differ procedurally from other lawsuits.

2. True/False - The U.S. Government has recovered more than $3.5 billion per year for four consecutive years.

3. The False Claims Act had two major amendments since 1863 that occurred in the following years:

a. 1943
b. 1986
c. 1943 and 1986
d. None of the above.

4. Under the False Claims Act, a plaintiff MUST prove:

a. defendant presented or caused to be presented to an agent of the United States a claim for payment;
b. the claim was false or fraudulent;
c. the defendant knew the claim was false or fraudulent
d. All of the above.

5. True/False - A false claim may take many forms, the most common being a claim for goods or services not provided or provided in violation of contract terms, specification, statute or regulation.

6. True/False - Under the "factually false/worthless services theory," a submission for payment is based on goods not delivered or services not rendered.

7. The False Claims Act suit differs from other lawsuits because:

a. It is filed under seal
b. Recovery is shared by the government and the whistleblower
c. Both a and b.
d. Neither a nor b.

Answer Key: 1. T, 2. T, 3. C, 4. D, 5. T, 6. T, 7. C