THE
2022-23

Medical-Dental-Legal UPDATE

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

American Educational Institute, Inc.

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David R. Victor, JD
President

Dear Registrant:

You practice in a dynamic and challenging environment. While keeping clinically current is imperative, it isn't enough. You must also acquire the skills necessary to navigate a professional liability minefield, manage a more effective and efficient practice, and master a maze of healthcare laws and regulations. ***The 2022-23 Medical-Dental-Legal Update*** is designed to assist you in that endeavor.

In one course you will receive 20 hours of vital instruction from national experts in the fields of law, medicine, asset protection, pharmacology, and practice management. And their presentations include topics ranging from opioid use disorder, chronic heart failure, migraine, office gynecology and lung cancer screening, to asset protection, professional burnout, effective leadership and financial intelligence for the healthcare practice.

To help you assess your level of comprehension we offer brief self-evaluations that may be taken either before or after the presentations concerned. These tests are included in this syllabus and are identified by the black edges of the pages on which they are featured.

As always, I am very interested in your reaction to this year's presentation. Please do me the favor of taking the time to complete the evaluation questions presented on screen for each presentation. In addition, I encourage you to contact any of our faculty members directly with questions or comments.

Finally, I urge you to take advantage of the diversity of professionals enrolled this week. Chances are your classmates include physicians, dentists, and attorneys. What better way to gain another perspective on these multi-faceted issues than to discuss them with a colleague from a different discipline.

Thank you for your participation and please accept my best wishes for a safe, enjoyable and enlightening visit.

Cordially,
American Educational Institute, Inc

David R. Victor, Esq
President

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COURSE OBJECTIVES

After completing ***The 2022-23 Medical-Dental-Legal Update*** you should have acquired the knowledge that will better enable you to better:

- Understand requirements and risks of **Medically Assisted Treatment of opioid use disorder**
- Explain fundamental **financial principles and metrics** necessary for practice economic health.
- Identify diagnostic indications and treatment options for patients with **atopic dermatitis.**
- Identify the clinical manifestations of and pharmacologic treatment options for **chronic heart failure.**
- Discuss current abortive and prophylactic **treatments for migraine.**
- Make **lung cancer screening** decisions
- Recognize the symptoms of **professional burnout** and take measures to avoid it.
- Identify and explain the elements of a **medical malpractice** claim and the stages of its litigation.
- Understand the meaning and role of **emotional intelligence** in a successful healthcare practice.
- Identify and implement the **9 strategies of highly successful leaders**
- Understand the clinical implications of **exercise physiology, aerobic capacity and metabolic equivalents.**
- Identify **CVD lifestyle risk factors and behavioral therapies**.
- Understand tools and techniques to **protect assets against practice risk**
- Discuss the legal status, pharmacology, physiological impact, and treatment implications of **cannabis.**
- Understand the efficacy and mechanisms of action of available **contraceptive methods**.
- Identify and manage **common gynecological problems and procedures**.
- Identify and understand the symptoms and treatment of associated complications of **menopause**.

All learning objectives above address IOM/ACGME core competencies.

THE 2022-23

Medical-Dental-Legal UPDATE

FACULTY DISCLOSURES

The individuals listed below have control over the content of ***The 2022-23 Medical-Dental-Legal Update***. None of them have a financial relationship with a commercial interest whose product or services are discussed in the presentation(s) over which they have control:

David R. Victor, Esq., president, American Educational Institute: course director, *The 2022-23 Medical-Dental-Legal Update*
Mina Guerges, MD, peer reviewer
Elizabeth Prusak, MD, FACOG, faculty member
Frederick M. Cummings, Esq., faculty member
Thomas A. Viola, RPh, CCP, faculty member
Barry A. Franklin, PhD, faculty member
Gerald Levine, MD, CCFP, faculty member
Louis Kuritzky, MD, faculty member
David B. Mandell, JD, MBA, faculty member
David J. Norris, MD, MBA, CPE, faculty member
Dennis Wichern, faculty member

The following faculty members of ***The 2022-23 Medical-Dental-Legal Update*** have a financial relationship with a commercial interest whose products or services are discussed in their presentation:

Dilip K. Moonka, MD, FAST, FAASLD, speaker or consultant for Gilead, Intercept and AbbVie.

Louis Kuritzky, MD

Louis Kuritzky, MD. Of Gainesville, Florida, is a board-certified, family practitioner and a certified Specialist in Hypertension with the American Society of Hypertension. He is clinical faculty at the Family Medicine Residency Program of North Florida Regional Medical Center in Gainesville and a clinical assistant professor emeritus at the University of Florida.

Dr. Kuritzky has given over 1,000 presentations to national and international medical audiences on dozens of clinical topics and has authored over 150 articles in journals including *New England Journal of Medicine*, *JAMA*, *Comprehensive Therapy*, *Hospital Practice*, *Consultant*, *Postgraduate Medicine*, *Journal of Pain and Palliative Care*, and *Patient Care*.

You may contact Dr. Kuritzky with any questions or comments at (352) 377–3193 or by email at lkuritzky@aol.com.

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Understanding and Treating Chronic Heart Failure

Heart Failure Mortality

5-year mortality after a new diagnosis of heart failure with current standard care therapy is approximately

a) 10%
b) 20%
c) 30%
d) 50%

CHF

Are We Too Complacent About the Dx?

Heart Failure
The Hemodynamic Malignancy

"The prognosis of affected individuals is dismal, as fewer than 50% of these people survive 5 years from the time of initial Dx"

Mulrow C. JAMA 1987;259(23):3422-3425

Heart Failure
The Hemodynamic Malignancy

"Mortality from CHF is high, averaging 30% within the 1st year, 50% by 3-4 years, and 80% by 6-10 years"

Anderson J. Modern Medicine 1987;55(May)

Heart Failure: The Hemodynamic Malignancy

A Prospective Cohort Study (n=558)

- Total mortality at 5 years
  - Systolic Dysfunction = 42%
  - Diastolic Dysfunction = 25%

MacCarthy PA, et al Prognosis in HFpEF BMJ 2003;327:78-9

Family Practice, 2017, Vol. 34, No. 2, 161–168
doi:10.1093/fampra/cmw145
Advance Access publication 27 January 2017

Epidemiology

Survival following a diagnosis of heart failure in primary care

Clare J Taylor[a,*], Ronan Ryan[b], Linda Nichols[b], Nicola Gale[c], FD Richard Hobbs[a,†] and Tom Marshall[b,†]

- UK 1^0 Care patients with new Dx (n = 54,313)
- Followed 1998-2012
- Survival:
  - 1 Year: 81.3%
  - 5 Years: 51.5%
  - 10 Years: 29.5%

CHF Vocabulary

Old Terminology	Current Terminology
CHF	Heart Failure (HF)
Systolic Dysfunction EF <40%	HF with Reduced Ejection Fraction HFrEF ('Heff-Reff')
None EF =41%-49%	HF with Mid-range Ejection Fraction HFmrEF*('Heff-Merf')*
Diastolic Dysfunction EF >50%	HF with Preserved Ejection Fraction HFpEF ('Heff-Peff')

*Murphy SP, Ibrahim N, Januzzi JL
JAMA 2020:325(5)August:488-504

HF: Pathophysiologic Definition

- Clinical syndrome resulting from structural or functional impairment of ventricular filling or ejection of blood.
  - Exercise Intolerance (dyspnea & fatigue)
  - Fluid Retention (NOT everyone; ≠CHF)
- Cardiac output(CO) ≠ tissue metabolic needs
  - Sustained Sympathetic Activation
  - Sustained RAAS activation

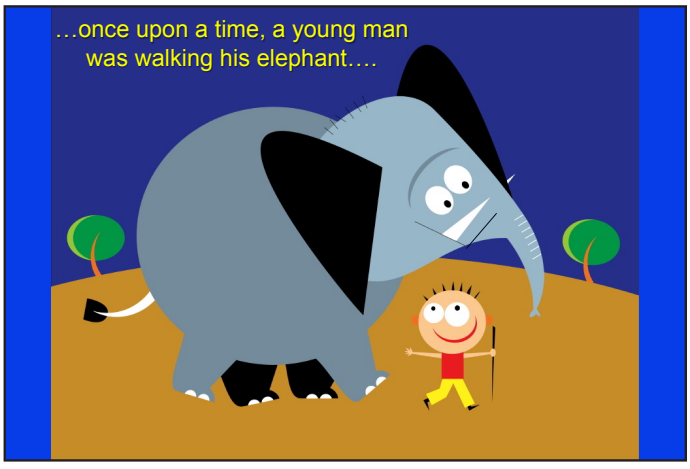
Clyde W. Yancy et al. Circulation. 2013;128:1810-1852

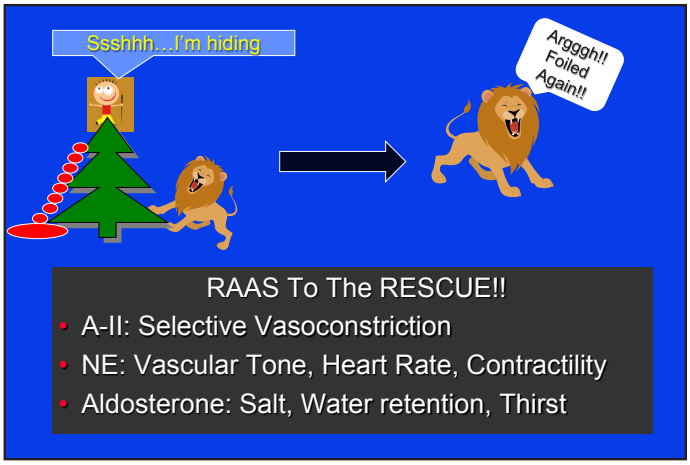
PATHOPHYSIOLOGY

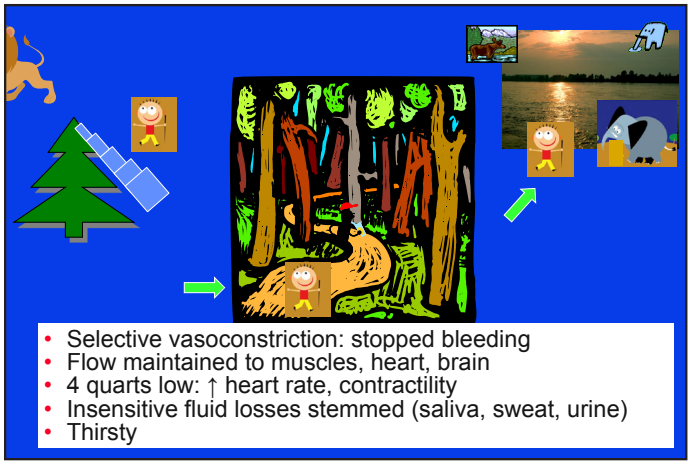
Heart Failure Pathophysiology

The sustained sympathosis of Heart Failure with Reduced Ejection Fraction (HFrEF) is typified by all of the following characteristics except

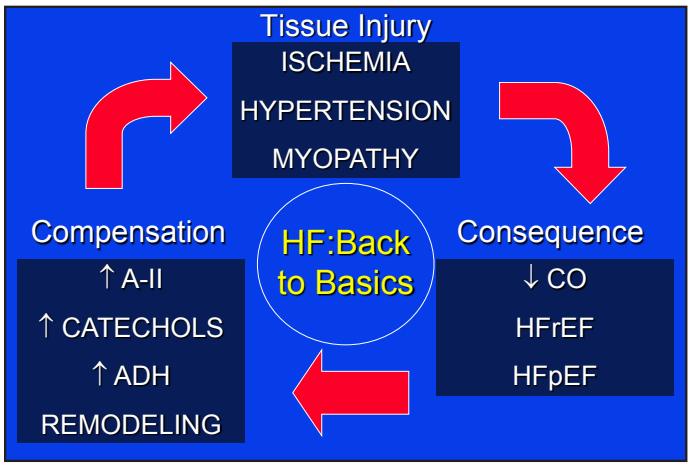
a) Increased norepinephrine
b) Increased angiotensin II
c) Increased aldosterone
d) Decreased generation of myocardial collagen

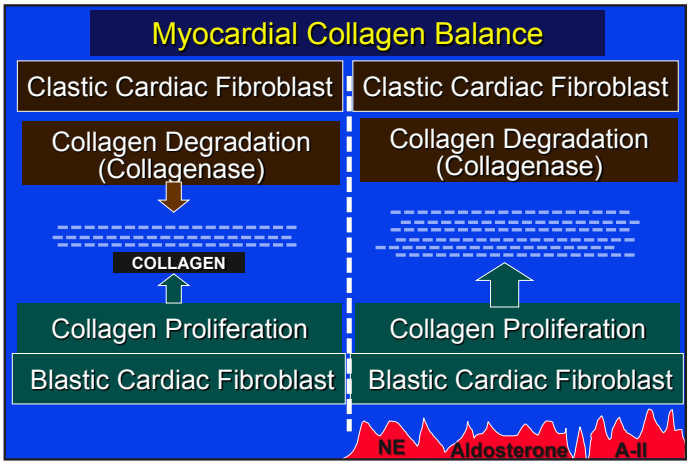


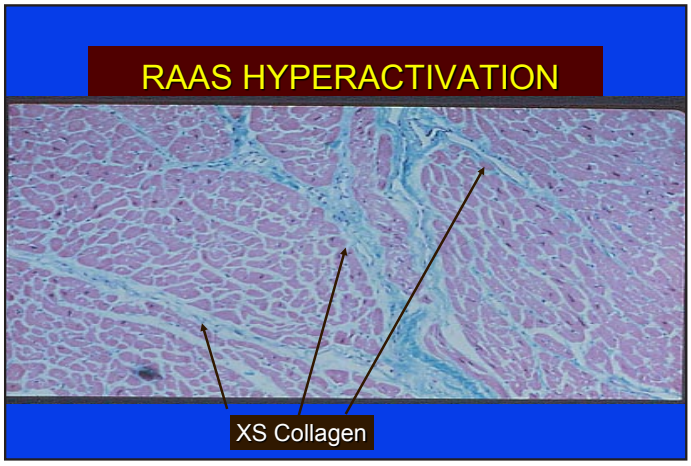

Ssshhh…I'm hiding
Arrggh!! Foiled Again!!
RAAS To The RESCUE!!
• A-II: Selective Vasoconstriction
• NE: Vascular Tone, Heart Rate, Contractility
• Aldosterone: Salt, Water retention, Thirst


• Selective vasoconstriction: stopped bleeding
• Flow maintained to muscles, heart, brain
• 4 quarts low: ↑ heart rate, contractility
• Insensitive fluid losses stemmed (saliva, sweat, urine)
• Thirsty


…and they all LIVED happily ever after


Tissue Injury
ISCHEMIA
HYPERTENSION
MYOPATHY
Compensation
↑ A-II
↑ CATECHOLS
↑ ADH
REMODELING
HF:Back to Basics
Consequence
↓ CO
HFrEF
HFpEF


Myocardial Collagen Balance
Clastic Cardiac Fibroblast
Clastic Cardiac Fibroblast
Collagen Degradation (Collagenase)
Collagen Degradation (Collagenase)
COLLAGEN
Collagen Proliferation
Collagen Proliferation
Blastic Cardiac Fibroblast
Blastic Cardiac Fibroblast
NE
Aldosterone
A-II


RAAS HYPERACTIVATION
XS Collagen

Pharmacologic Rx

HFrEF Disease-Modifying Interventions

ACE or ARB
Aldosterone Antagonist
ARB/Sacubitril
Beta Blocker
Hydralazine/Isosorbide
Ivabradine
SGLT2i

Cardiac Rehab
Exercise

ICD
CRT

Home Visits
Frequent Visits
Phone Support

CHF (HFrEF) 1^0 Care Roadmap 2021

Non-Invasive Disease-Modifying Rx

ACE	ARB
Beta-Blocker	Hydralazine/ISDN
Aldosterone Antagonist	Ivabradine
SGLT2-i	Valsartan/Sacubitril

Sx-Modifying Rx
Diuretics Digoxin

Common Modifiable Comorbidities
Anemia, HTN, T-4, Thiamine, Alcohol, COPD, CAD

Lifestyle & Immunizations
Na^+/H_2O, Weight, Exercise, FluVax, PneumoVax

CHF (HFrEF) 1^0 Care Roadmap 2021

Disease-Modifying Rx: Sequential Process

Valsartan/Sacubitril
ACE (if Val/Sac inaccessible)
ARB (if ACE not tolerated)
β-Blocker (metoprolol, carvedilol, bisoprolol)
Aldosterone Antagonist (spironolactone, eplerenone)
Hydralazine/ISDN (if Black)
SGLT2-i (dapagliflozin w/wo DM)
SGLT2-I (DM: dapa, cana, or empagliflozin)
Ivabradine (Corlanor)

Pharmacotherapy Stratification: The "Hardest Pill to Swallow"

"For those already taking an ACEi or an ARB, transition to an ARNI [valsartan/sacubitril] is recommended given superior efficacy."

Murphy SP, et al *JAMA* 2020:325(5):488-504

NYHA Functional Classification (HF & Angina)

- CLASS I. No undue symptoms on ordinary activity. No limitation of physical activity
- CLASS II. Slight to moderate limitation of activity (IIs-IIm); patient comfortable at rest
- CLASS III. Marked limitation of activity; patient comfortable at rest
- CLASS IV. Discomfort with any physical activity; symptoms may exist even at rest

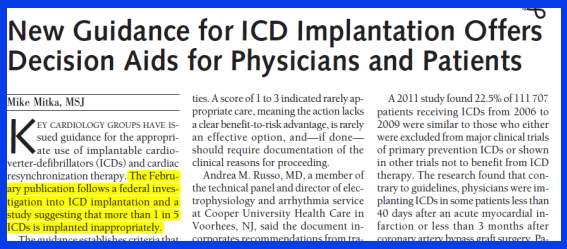
NYHA Functional Classification (SOMA)

S CLASS I. **S**trenuous activity → Sx
O CLASS II. **O**rdinary ADL → Sx
M CLASS III. **M**inimal activity → Sx
A CLASS IV. **A**ny activity/at rest → Sx

Rx

Why Should I Have to Learn All the Treatments?…the Patient Already Has a Cardiologist

Why Should I have to Learn All the Treatments?



New Guidance for ICD Implantation Offers Decision Aids for Physicians and Patients

Mike Mitka, MSJ

KEY CARDIOLOGY GROUPS HAVE ISsued guidance for the appropriate use of implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy. The February publication follows a federal investigation into ICD implantation and a study suggesting that more than 1 in 5 ICDs is implanted inappropriately.

ties. A score of 1 to 3 indicated rarely appropriate care, meaning the action lacks a clear benefit-to-risk advantage, is rarely an effective option, and—if done—should require documentation of the clinical reasons for proceeding.

Andrea M. Russo, MD, a member of the technical panel and director of electrophysiology and arrhythmia service at Cooper University Health Care in Voorhees, NJ, said the document incorporates recommendations from tra-

A 2011 study found 22.5% of 111 707 patients receiving ICDs from 2006 to 2009 were similar to those who either were excluded from major clinical trials of primary prevention ICDs or shown in other trials not to benefit from ICD therapy. The research found that contrary to guidelines, physicians were implanting ICDs in some patients less than 40 days after an acute myocardial infarction or less than 3 months after coronary artery bypass graft surgery. Pa-

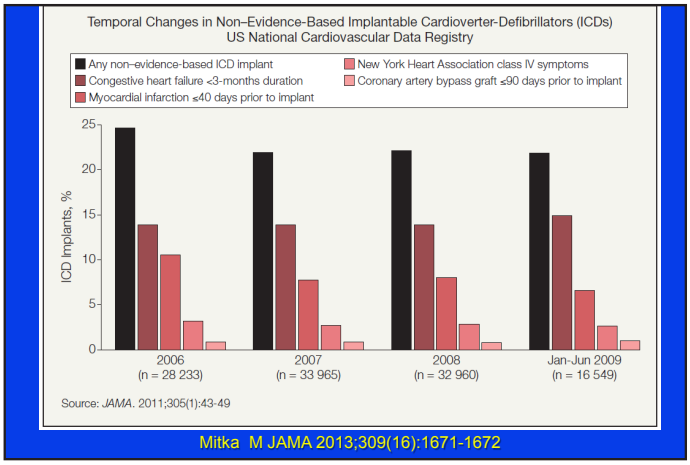
Mitka M JAMA 2013;309(16):1671-1672

WHY

verter-defibrillators (ICDs) and cardiac resynchronization therapy. The February publication follows a federal investigation into ICD implantation and a study suggesting that more than 1 in 5 ICDs is implanted inappropriately.

Mitka M JAMA 2013;309(16):1671-1672

Just Because The Consultant is a CARDIOLOGIST Doesn't Mean That All The Right Stuff Happens All The Time



Mitka M JAMA 2013;309(16):1671-1672

HFrEF Disease-Modifying Interventions

ACE
ARB
Beta Blocker
Aldosterone Antagonist
Hydralazine/Isosorbide
Ivabradine
ARB/Sacubitril
SGLT2-i

Cardiac Rehab
Exercise

ICD
CRT

Home Visits
Frequent Visits
Phone Support

Sacubitril-valsartan

- Sacubitril = neprilysin inhibitor
- Neprilysin inhibition → ↑ vasoactive peptides → vasodilatation, natriuresis/diuresis, ↓ LV remodeling
- Indicated for NYHA II-IV HF*r*EF in place of ACE/ARB
- Increased risk of angioedema w/ concurrent ACEI

Colucci, WS and Pfeffer MA. Use of angiotensin II receptor blocker and neprilysin inhibitor in HF with reduced EF. UptoDate, Gottlieb SS (Ed), UpToDate, Waltham, MA. (Accessed on April 12, 2016).

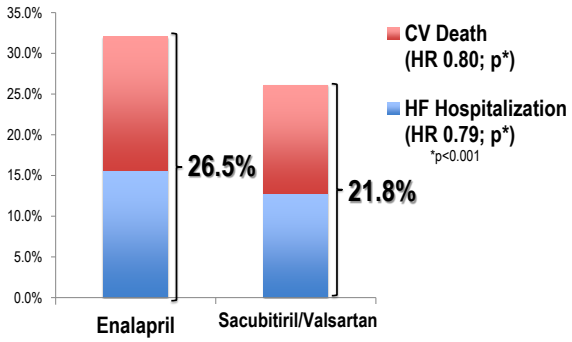
PARADIGM-HF: Sacubitril-valsartan in HF*r*EF

- 8442 HF NYHA II-IV and EF ≤ 40%
- Randomized to:
  - Sacubitril + Valsartan 200mg BID
  - Enalapril 10mg BID
- 27 months
- OUTCOMES:
  - 1° Outcome: Composite CV death or HF Hosp
  - 2° Outcomes: CV Death; All-Cause Death

McMurray JJV et al. N Engl J Med 2014;371:993-1004

PARADIGM-HF: 1° Outcome

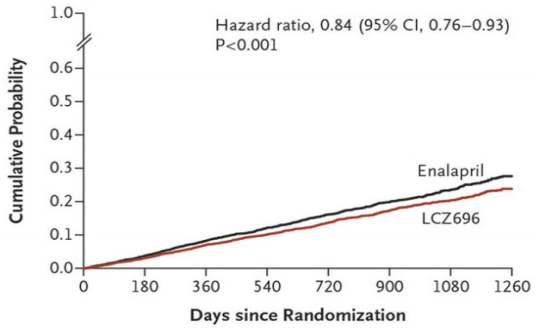
(CV Death or HF Hospitalization; HR 0.80, p*)



McMurray JJV et al. N Engl J Med 2014;371:993-1004

PARADIGM-HF: All-Cause Mortality

Death from Any Cause



McMurray JJV et al. N Engl J Med 2014;371:993-1004

HFrEF Pharmacotherapy: Angiotensin receptor-neprilysin inhibitor

Med (Trial)	N	Endpoint	HR	p
Valsartan/sacubitril (PARADIGM-HF)	8442	All cause mortality HF admission	0.84 0.81	<0.001 <0.001

Murphy SP, et al *JAMA* 2020:325(5):488-504

ACE Inhibitors in Heart Failure (HFrEF)

ACE inhibitors are considered 1st line treatment of HFrEF. Which statement is correct

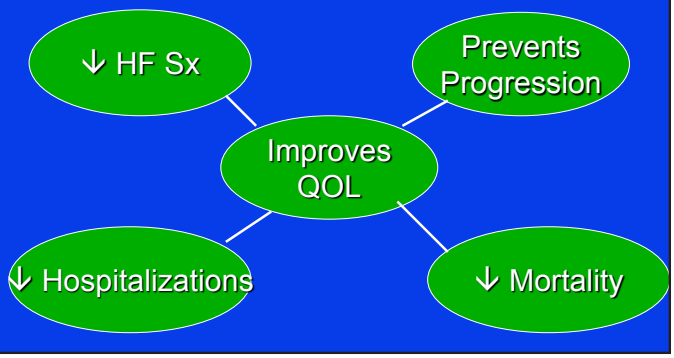
a) Ramipril is the most effective ACEi

b) Lisinopril is the most effective ACEi

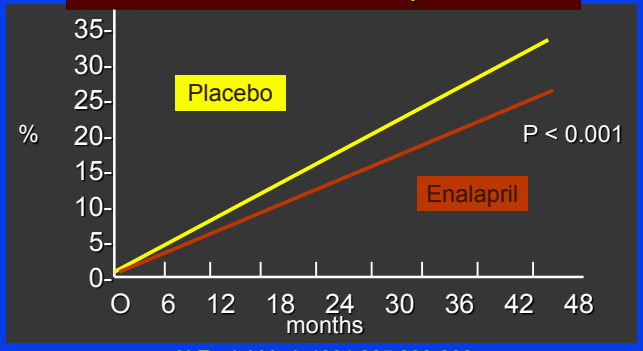
c) Enalapril is the most effective ACEi

d) All ACEi appear to be equally effective

CLINICAL BENEFITS OF *ANY* ACE-I in HF

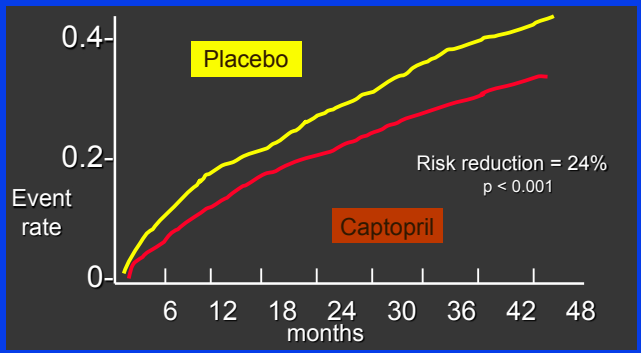


SOLVD: Death or Hospitalization



N Engl J Med 1991;325:293-302

SAVE Trial : CHF, CV, or MI Death



Pfeffer MA N Engl J Med 1992;327(10):669-77

ACE Inhibitors & CHF

- Meta-analysis 32 trials (n = 7,105)
- Most pts severe CHF (EF < 35-40%) Rx ≥ 8 weeks

RESULTS	ACE	PLACEBO
• Mortality	15.8%	21.9%
• Hospitalization or death	22.4%	32.6%

- NO APPRECIABLE DIFFERENCE AMONG STUDY DRUGS (ALL ACE = EFFICACY)

JAMA 1995; 273:1450

HFrEF Pharmacotherapy: ACE Inhibitors

Med (Trial)	N	Endpoint	HR	p
Captopril (SAVE)	2231	All-cause Mortality CV Mortality	0.81 0.79	.02 .01
Ramipril (AIRE)	2006	All-cause Mortality	0.73	.002
Enalapril (SOLVD)	2569	All-cause Mortality HF Mortality	0.84 0.78	.003 .005

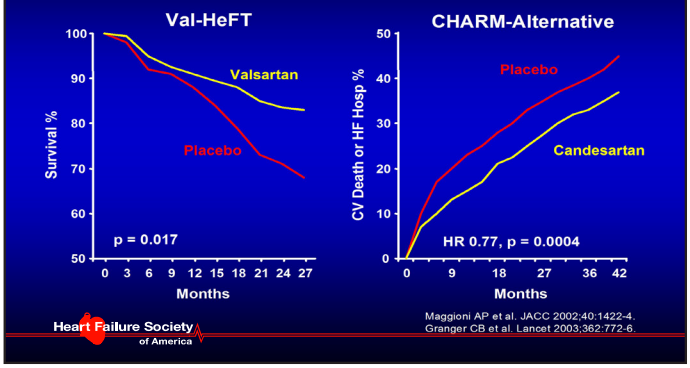
Murphy SP, et al *JAMA* 2020:325(5):488-504

2013 ACCF/AHF HF Guidelines: ARBs

"ARBs are recommended in pts w/ HF*r*EF w/ current or prior Sx who are ACEI intolerant, to reduce morbidity and mortality." **(Class I Rec; LOE: A)**

Clyde W. Yancy et al. 2013 ACCF/AHA HF Guideline. *Circulation*. 2013;128:1810-1852.

ARBS in Patients Not Taking ACE Inhibitors: Val-HeFT & CHARM-Alternative



Heart Failure Society of America

Maggioni AP et al. JACC 2002;40:1422-4.
Granger CB et al. Lancet 2003;362:772-6.

HFrEF Pharmacotherapy: ARBs

Med (Trial)	N	Endpoint	HR	p
Candesartan (CHARM-alt)[1]	2028	CV Death CHF admission	0.80 0.61	.02 <.0001
Valsartan (ValHEFT*)[2]	366	All-cause Mortality HF Admission	0.67 0.47	.017 <0.001

*ValHEFT patients NOT on ACE

[1] Granger CB et al *Lancet* 2003;362:772-776
[2] Maggioni AP et al *J Am Coll Cardiol* 2002;40:1414-1421

Beta Blockers in Heart Failure (HFrEF)

- Which beta blocker has NOT been shown to reduce mortality in HFrEF?

a) bisoprolol
b) metoprolol
c) carvedilol
d) propranolol

2013 ACCF/AHA HF Guidelines: Beta-Blockers (BB)

"1 of the 3 BBs proven to reduce mortality (**bisoprolol, carvedilol, metoprolol succinate**) is recommended for **ALL pts** w/ current or prior symptoms of HF*r*EF to reduce morbidity and mortality."

(Level of Evidence: A)

Clyde W. Yancy et al. 2013 ACCF/AHA HF Guideline. *Circulation*. 2013;128:1810-1852.

The Additional Value of Beta Blockers Post-MI: CAPRICORN

Studied impact of beta blocker (carvedilol) on post-MI patients with LVEF ≤ 40% already receiving contemporary treatments, including revascularization, anticoagulants, ASA, and ACEI:

- All-cause mortality reduced (HR = 0.077; p = 0.03)
- Cardiovascular mortality reduced (HR = 0.75; p = .024)
- Recurrent non-fatal MIs reduced (HR =.59; p = .014)

Dargie HJ. Lancet 2001;357:1385-90.

Heart Failure Society of America

HFrEF Pharmacotherapy: Beta Blockers

Med (Trial)	N	Endpoint	HR	p
Bisoprolol (CIBIS II)	2647	All-cause Mortality Sudden Death	0.66 0.56	<.001 .001
Metoprolol-s (MERIT-HF)	3991	All-cause Mortality HF Death	0.66 0.51	<.001 .002
Carvedilol (US Carvedilol)	1094	All-cause Mortality CV Hospitalization	0.35 0.73	<.001 .04

Murphy SP, et al *JAMA* 2020:325(5):488-504

Aldosterone Blockers in Heart Failure (HFrEF)

According to the 2013 ACC/AHA Heart Failure Guidelines, aldosterone blockers (e.g., spironolactone, eplerenone) should be considered

a) only for HFrEF patients with Ejection Fraction <20%

b) only for HFrEF patients with Ejection Fraction <15%

c) for all HFrEF patients

d) only for HFrEF post-ICD (implantable cardiovertor defibrillator) patients

Aldosterone Antagonist in HF*r*EF

"Clinicians should strongly consider the addition of the aldosterone receptor antagonists spironolactone or eplerenone for *all patients* with HFrEF already on ACEI (or ARBs) and BBs."

-2013 ACC/AHA Guidelines

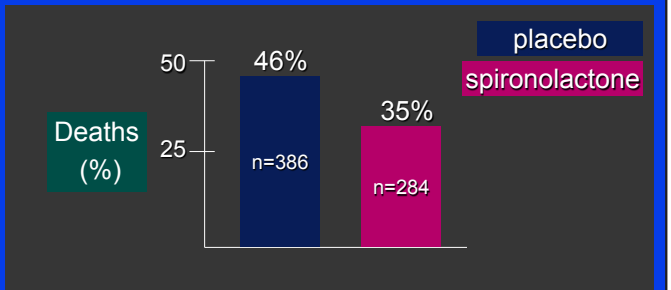
Clyde W. Yancy et al. 2013 ACCF/AHA HF Guideline. *Circulation*. 2013;128:1810-1852.

RALES: Spironolactone in Severe Heart Failure

- STUDY: NYHA III-IV CHF, EF <35% (n =1663)
- INCLUSION: on ACE + loop diuretic with (+ dig or vasodilators OK), K+ < 5.0, Cr < 2.5
- Rx: spironolactone 25 mg QD vs placebo X 3 years

Pitt B, Zannad F, Remme W. et al "The Effect of Spironolactone on Morbidity and Mortality in Pts with Severe Heart Failure" N Engl J Med. 1999;341(10):709-17

Spironolactone in Severe Heart Failure: Results



Pitt B, Zannad F, Remme W. et al "The Effect of Spironolactone on Morbidity and Mortality in Pts with Severe Heart Failure" N Engl J Med. 1999;341(10):709-17

Spironolactone in Severe Heart Failure : Results

	Spironolactone	Placebo
Hospitalizations	260 pts	336 pts
NYHA class ↑	41%	33%
NYHA class ↓	38%	48%
Hyperkalemia	2% ⇔ (NS)	1%
Gynecomastia	10% ⇔	1%

Pitt B, Zannad F, Remme W. et al "The Effect of Spironolactone on Morbidity and Mortality in Pts with Severe Heart Failure" N Engl J Med. 1999;341(10):709-17

HF: Spironolactone

"Blockade of aldosterone receptors by spironolactone, in addition to standard therapy, substantially reduces the risk of both morbidity and death among pts with severe heart failure."

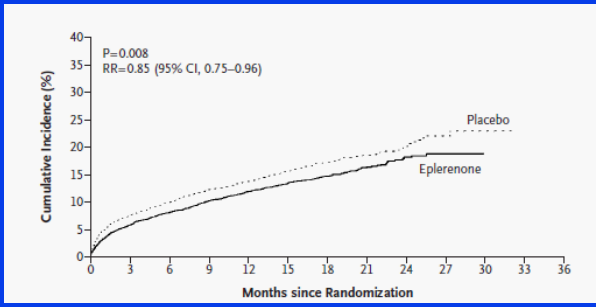
Pitt B, Zannad F, Remme W. et al "The Effect of Spironolactone on Morbidity and Mortality in Pts with Severe Heart Failure" N Engl J Med. 1999;341(10):709-17

EPHESUS
Eplerenone Post-Acute MI HF Efficacy and Survival Study

- Study: RDBPCT in Post-MI HF pts
- Rx: eplerenone 25-50 mg/d vs placebo X 16 months (n=6,632)
- Outcomes:
  - All-cause mortality
  - CV Death
  - CV Hospitalizations

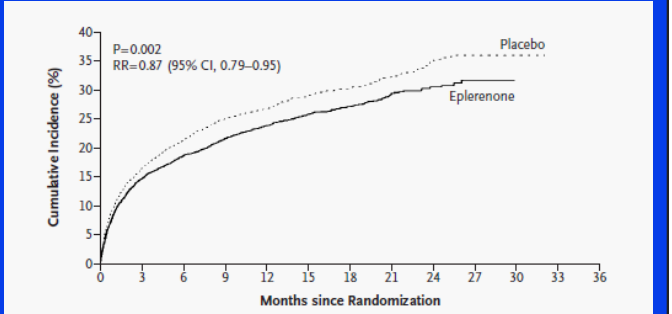
Pitt B et al NEJM 2003;348:1309-1321

EPHESUS: All Cause Mortality



Pitt B et al NEJM 2003;348:1309-1321

EPHESUS: CV Death or CV Hospitalization



Pitt B et al NEJM 2003;348:1309-1321

HFrEF Pharmacotherapy: Mineralcorticoid Receptor Antagonists

Med (Trial)	N	Endpoint	HR	p
Spironolactone (RALES)	1663	All cause mortality HF admission	0.70 0.65	<0.001 <0.001
Eplerenone (EPHESUS)	6642	All-cause Mortality CV death/admission	0.85 0.87	.008 .002

Murphy SP, et al *JAMA* 2020:325(5):488-504

20113 ACCF/AHA Recommendation

"The combination of ISDN/H is recommended for pts self-described as AA w/ NYHA III-IV HF*r*EF receiving optimal tx w/ ACEI/B-blkers."

(*Level of Evidence: A*)

Clyde W. Yancy et al. 2013 ACCF/AHA HF Guideline. *Circulation*. 2013;128:1810-1852.

A-HeFT (African American Heart Failure Trial)

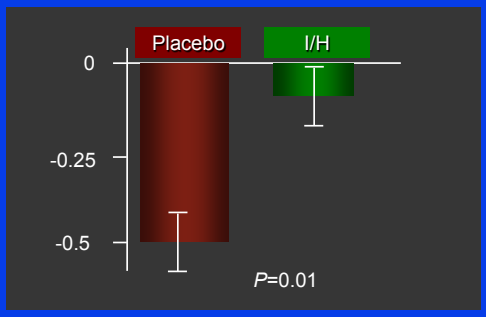
Taylor AL, Ziesche S, Yancy C, et al "Combination of Isosorbide Dinitrate and Hydralazine in Blacks with Heart Failure" N Engl J Med 2004;351:2049-57

A-HeFT

- STUDY: Black patients with CHF, NYHA III-IV (n=1050) followed 18 months
- PREMISE: Previous CHF trials→ beneficial I/H effects in black subgroup
- Rx: isosorbide dinitrate/hydralazine 37.5mg/20 mg one t.i.d. → two t.i.d.

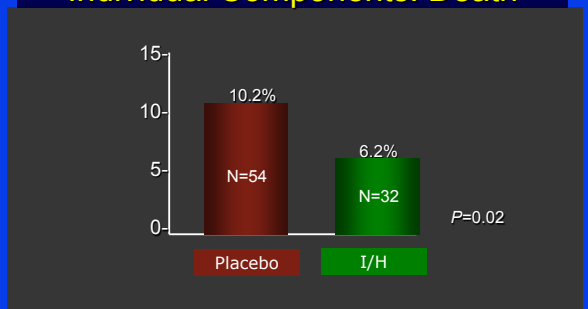
Taylor AL, Ziesche S, Yancy C, et al "Combination of ISDN and Hydralazine in Blacks with Heart Failure" N Engl J Med 2004;351:2049-57

A-HeFT: Primary Endpoint



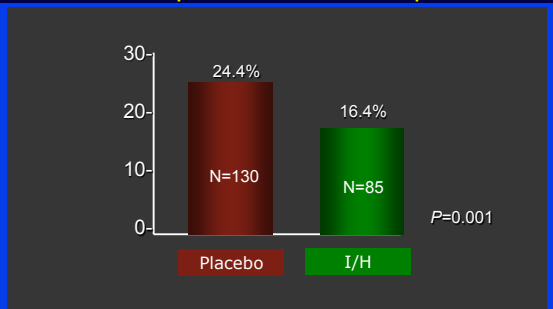
Taylor AL, Ziesche S, Yancy C, et al "Combination of ISDN and Hydralazine in Blacks with Heart Failure" N Engl J Med 2004;351:2049-57

A-HeFT Composite Score Individual Components: Death



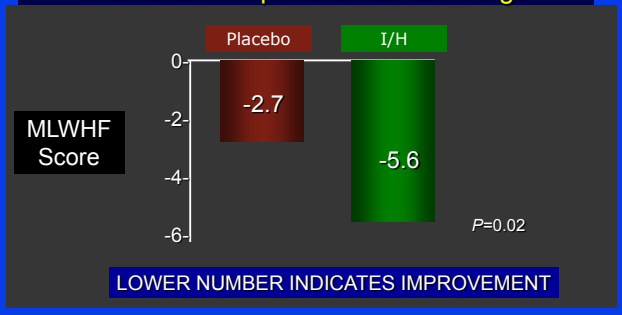
Taylor AL, Ziesche S, Yancy C, et al "Combination of ISDN and Hydralazine in Blacks with Heart Failure" N Engl J Med 2004;351:2049-57

A-HeFT Composite Score Individual Components: 1st HF Hospitalization



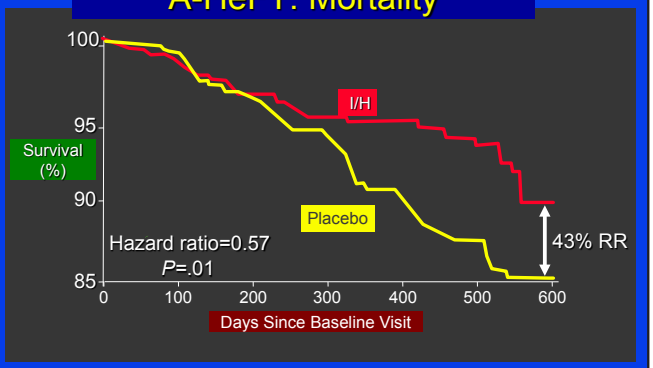
Taylor AL, Ziesche S, Yancy C, et al "Combination of ISDN and Hydralazine in Blacks with Heart Failure" N Engl J Med 2004;351:2049-57

A-HeFT Composite Score
Individual Components: QOL Change



Taylor AL, Ziesche S, Yancy C, et al "Combination of ISDN and Hydralazine in Blacks with Heart Failure" N Engl J Med 2004;351:2049-57

A-HeFT: Mortality



Taylor AL, Ziesche S, Yancy C, et al "Combination of ISDN and Hydralazine in Blacks with Heart Failure" N Engl J Med 2004;351:2049-57

A-HeFT: Adverse Events

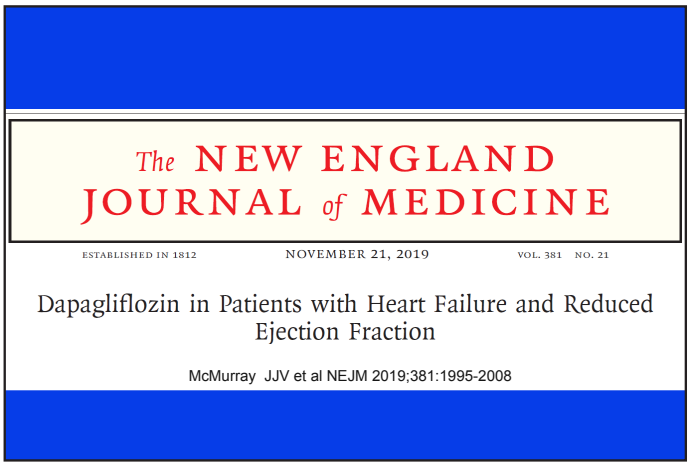
	I/H	Placebo	*P* Value
Headache (all)	47.5%	19.2%	<0.001
Headache (severe)	5.2%	0.9%	
Dizziness	29.3%	12.3%	<0.001
HF Exacerbation	8.7%	12.8%	0.04
HF Exacerbation (severe)	3.1%	7.0%	0.005

Taylor AL, et al N Engl J Med 2004;351:2049-57

HFrEF Pharmacotherapy: Vasodilators

Med (Trial)	N	Endpoint	HR	p
Hydralazine/ISDN (A-HeFT)	1050	All cause mortality HF admission	0.57 0.67	0.01 .001

Taylor AL et al *NEJM* 2004;351:2049-2057



CHF & Dapagliflozin: DAPA-HF Trial DM and non-DM Patients

- Study: RDBPCT (n=4,744) HFrEF
- Inclusion: EF ≤40%
- 1^0 Outcome (composite) at 18.2 months: CV death or worsening HF
- Intervention: dapagliflozin 10 mg/d vs placebo added to GDMT
- Results (1^0 Outcome): 16.3% vs 21.2% (HR = 0.74, p < 0.001)

McMurray JJV et al NEJM 2019;381:1995-2008

CHF & Dapagliflozin: DAPA-HF Trial Premises

- "Large [T2DM] clinical trials have shown that SGLTI reduce the risk of hospitalization for HF."
- "Most patients…did not have HF at baseline, so the benefit…largely reflected *prevention* of incident HF."
- "The reduction in the risk….was observed early after randomization, which raised the possibility of MOA that differed from those usually postulated to explain CV benefits of glucose-lowering Tx."

*Emphasis added

McMurray JJV et al NEJM 2019;381:1995-2008

HFrEF Pharmacotherapy: SGLT2i (Diabetic Subjects)

Med (Trial)	N	Endpoint	HR	p
Canagliflozin[1] (CREDENCE)	4401	HF Admission All-cause Mortality CV Mortality	0.61 0.83 0.78	<0.001 NS 0.05
Empagliflozin[2] (EMPA-REG)	7020	HF Admission All-cause mortality CV Mortality	0.65 0.68 0.62	.002 <0.001 <0.001

[1] Perkovic V, et al *NEJM* 2019;380(24):2295-2306
[2] Zinman B et al *NEJM* 2015;373:22:2117-28

HFrEF Pharmacotherapy: SGLT2i (DM + non-DM Subjects)

Med (Trial)	N	Endpoint	HR	p
Dapagliflozin (DAPA-HF)	4744	CV death, HF admission, HF urgent visit	0.73* 0.75	.002 .002
		CV Death	0.85* 0.79	.23 .06
		All-cause Mortality	0.88* 0.78	.30 .027

*No DM

Petrie MC et al "Effect of Dapagliflozin on Worsening HF Failure and CV Death in Patients With and Without DM" JAMA 2020;323(14):1353-1368

Ivabradine (Corlanor)

- Selective Inhibitor of the "funny channel (I_f)" which modulates SA pacemaker → ↓ Sinus Rate
- Does not affect atrial conduction, AV node, or ventricles → no effect on contractility
  - Difference from BB and CCB
- Reduces HR by ~ 10 bpm → ↓ cardiac workload

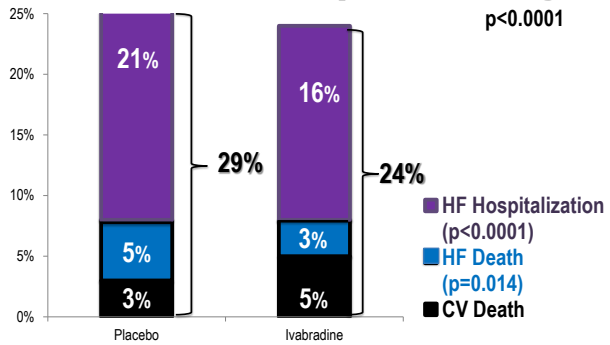
Colucci, WS. Use of beta blockers and ivabradine in heart failure with reduced ejection fraction. In: UpToDate, Gottlieb SS (Ed), UpToDate, Waltham, MA. (Accessed on March 31, 2016).

SHIFT Trial: Systolic Heart Failure tx with I_f Inhibitor Ivabradine Trial

- RCT; 6558 pts w/ HF Sx and LVEF ≤ 35%
  - HR ≥ 70bpm
  - HF Admission in previous year
  - On background GDMT *(ACE/ARB, BB, Aldo Antagonist)*
- 1° Outcome: CV Death or Hosp for worsening HF

Swedberg, Karl et al. Ivabradine and outcomes in chronic heart failure (SHIFT): a randomised placebo-controlled study. The Lancet , Volume 376 , Issue 9744 , 875 – 885.

SHIFT: CV Death *or* Hosp for Worsening HF



Swedberg, Karl et al. Ivabradine and outcomes in chronic heart failure (SHIFT): a randomized placebo-controlled study. The Lancet , Volume 376 , Issue 9744 , 875 – 885.

SHIFT Trial: Ivabradine in Chronic HF

- No increase Serious AES
  - –Increased Sx'tic Bradycardia (5% vs 1%)
  - –Increased Visual side effects (3% vs 1%)
- Conclusion: HR reduction w/ Ivabradine ↓CV Mortality and Hospitalizations for pts with persistent HF Sx, HF > 70bpm on background tx

Swedberg, Karl et al. Ivabradine and outcomes in chronic heart failure (SHIFT): a randomized placebo-controlled study. The Lancet , Volume 376 , Issue 9744 , 875 – 885.

HFrEF Pharmacotherapy: S-A I_f Current inhibitor

Med (Trial)	N	Endpoint	HR	p
Ivabradine (SHIFT)	6558	HF Death	0.74	.014
		HF Admission	0.74	<0.001
		All Cause Mortality	0.90	0.092
		CV Mortality	0.91	0.128

Swedberg K et al *Lancet* 2010;376:875-85

Thiamine and CHF

- 30 CHF pts on Lasix ≥ 80 mg/d chronically
- Rx thiamine IV X 1 week + 200mg/ d PO X 6 weeks vs placebo
- Results of thiamine compared to placebo:
- LV end diastolic function ↑ 22%
- diuresis & Na^+ excretion improved
- NYHA class ↓ from 2.6-2.2

Shimon A, Almog S, Vered Z, et al, "Improved LV Function after Thiamine Supplementation in Pts with CHF" Am J Med 1995; 98:485-490

Thiamine and CHF : Postulates

- Subclinical thiamine deficiency (furosemide known to deplete thiamine)
- diuretic effect of thiamine
- direct cellular thiamine effect
- Commentary: Because the adverse effects were few, and the benefits potentially great, thiamine supplementation could be useful.

Shimon A, Almog S, Vered Z, et al, "Improved LV Function after Thiamine Supplementation in Pts with CHF" Am J Med 1995; 98:485-490

Treating Hypertension to Prevent HF

Aggressive blood pressure control:

Decreases risk of new HF by ~ 50% 56% in DM2

Aggressive BP control in patients with prior MI:

Decreases risk of new HF by ~ 80%

Lancet 1991;338:1281:1281-5 (STOP-Hypertension).
JAMA 1997;278:212-6 (SHEP).
UKPDS Group. UKPDS 38. BMJ 1998;317:703-713.

Heart Failure Society of America

BP Control

- Long-term tx of both systolic and diastolic HTN reduces risk of HF by ~ 50%
  - – 2013 ACCF/AHA HF Guidelines
- SPRINT Trial (n=9,361)
  - –Non-DM pts with HTN were ~40% less likely to develop HF if treated to a goal SBP <120 compared to a SBP goal <140

The SPRINT Research Group. A randomized trial of intensive versus standard blood-pressure control. N Engl J Med 2015;373:2103-2016

Sodium Restriction?

- Obs. study: 902 pts NYHA II-III; Systolic or Diastolic HF
- METHOD: Na+ intake assessed over 36 months using a food freq. questionnaire; pts classified as either Na+ Restricted (<2500mg/d) or Unrestricted (≥2500 mg/d).
- OUTCOME: composite of death or HF hospitalization

Doukky R, Avery E, Mangla A, et al. Impact of Dietary Sodium Restriction on Heart Failure Outcomes. *JCHF.* 2016;4(1):24-35.

Sodium Restriction?

- Na+ Restriction → **Higher Risk of HF hospitalization** or **death** (42% v 26%; HR 1.85; p=0.004)
- Highest risk increase in those not taking ACE/ARB (HR 5.78; P=0.002) and NYHA II (HR 2.36; P=0.003)
- ACCF/AHA SOR for Na+ restriction downgraded
  - Class I (recommended) →Class IIa (reasonable)

Doukky R, Avery E, Mangla A, et al. Impact of Dietary Sodium Restriction on Heart Failure Outcomes. *JCHF.* 2016;4(1):24-35.

CHF (HFrEF) 1^0 Care Roadmap 2021

Disease-Modifying Rx: Sequential Process

Valsartan/Sacubitril
ACE (if Val/Sac inaccessible)
ARB (if ACE not tolerated)
β-Blocker (metoprolol, carvedilol, bisoprolol)
Aldosterone Antagonist (spironolactone, eplerenone)
Hydralazine/ISDN (if Black)
SGLT2-i (dapagliflozin w/wo DM)
SGLT2-I (DM: dapa, cana, or empagliflozin)
Ivabradine (Corlanor)

HFrEF: Rx Dosing

Drug	Start	Target	Drug	Start	Target
Bisoprolol	1.25 mg	10mg mg	Candesartan	4-8 mg	32 mg
Metoprolol XL	12.5-25 mg	200 mg	Losartan	25-50 mg	150 mg
Carvedilol	3.125mg b.i.d.	25 mg b.i.d.*	Valsartan	40 mg b.i.d.	160 mg b.i.d.
Captopril	6.25mg t.i.d.	50 mg t.i.d.	Hydralazine	25 mg t.i.d.	75 mg t.i.d.
Ramipril	1.25 mg	10 mg	ISDN	20 mg t.i.d.	40 mg t.i.d.
Enalapril	2.5mg b.i.d.	10-20 mg	ISDN/Hyrdal	20/37.5 mg t.i.d..	40/75 mg t.i.d.
Lisinopril	2.5-5.0 mg	20-40mg	Eplerenone	25 mg	50mg
Ivabradine	2.5-5 mg b.i.d.	HR 50-60 7.5 mg bid Max	Spironolactone	12.5-25 mg	25-50mg

	Start	Target
Sacubitril/Valsartan	24/26-49/51 mg b.i.d.	97/103 mg b.i.d.

Murphy SP Ibrahim NE, Januzzi JL JAMA 2020;324(5):485-504

SELF EVALUATION

Understanding and Treating Chronic Heart Failure

1. Which of the following statements is true regarding long-term heart failure outcomes?

a. Because of evolution in pharmacotherapy, predicted 5 year survival is >95%
b. Because of more frequent ICD implantation, 5 year survival is >90%
c. Despite evolution in pharmacotherapy and mechanical devices, 5 year mortality remains near 50%

2. The New York Heart Association (NYHA) classification of heart failure is stratified

a. Symptoms as precipitated by activity (e.g., symptoms at rest versus with ordinary activity)
b. Ejection fraction
c. End-diastolic ventricular volume
d. Echocardiographic ventricular relaxation dynamics

3. A mechanism by which renin-angiotensin-aldosterone activation induces adverse myocardial remodeling is

a. Stimulation of myocardial collagen deposition by norepinephrine, angiotensin II and aldosterone
b. Angiotensin-I induced myocardial cell apoptosis
c. Aldosterone-induced hyperkalemia
d. Renin-dependent magnesium depletion

4. What is the role of the SGLT2 inhibitor dapagliflozin in heart failure?

a. It is considered last resort for type II diabetics with HFpEF
b. It is only efficacious in HF in patients with type I diabetes
c. It is only efficacious in HF patients with type II diabetes
d. It is efficacious for HFrEF (aka systolic dysfunction) in diabetics as well as non-diabetics

5. Which beta-blocker is NOT FDA-approved for treatment of heart failure?

a. Bisoprolol
b. Carvedilol
c. Metoprolol
d. Atenolol

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

David B. Mandell, JD, MBA

David B. Mandell, JD, MBA, of Ft. Lauderdale, Florida, is a practicing attorney in The Law Offices of David B. Mandell, PC and a principal of the wealth management firm OJM Group, LLC. He specializes in risk management, asset protection, and financial planning and has authored a number of books for doctors including, *Wealth Planning for the Modern Physician: Residency to Retirement*. 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.

You may contact Mr. Mandell with any questions or comments at (877) 656–4362 or by email at mandell@ojmgroup.com.

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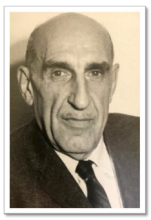
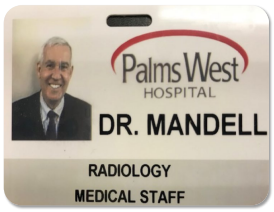
ABOUT ME





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TODAY'S PRESENTATION

1. Background on physician financial stress
2. Asset protection fundamentals
3. Shielding physicians' & dentists practice and personal assets
4. Recent developments in statutes and cases

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PHYSICIANS STRESSED ABOUT LIABILITY

- 87 percent of respondents said they are moderately-to-severely stressed/burned out on an average day.*
- Concern about liability and lawsuits are a motivating force behind the skyrocketing costs associated with "defensive medicine"**
- 2016 PubMed study: "Exploring Physicians' Dissatisfaction and Work-Related Stress: Development of the PhyDis Scale"

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

**Peter Ubel, "Do Malpractice Fears Cause Physicians To Order Unnecessary Tests?" Forbes.com, October 22, 2013

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TYPES OF LIABILITY FACING PHYSICIANS & DENTISTS

- Medical/dental malpractice
- Employer liability
  - Sexual harassment ("hostile work environment"); Wrongful termination (protected classes); Violation of fiduciary duty (qualified plans)
- Billing issues
  - Over-billing, improper billing, fraud, violation of anti-kickback rules, Stark rules, etc.
- HIPAA
- Premises liability
- Personal liability

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ASSET PROTECTION FUNDAMENTALS

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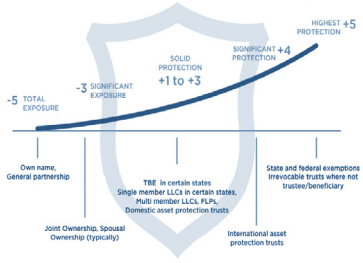
ASSET PROTECTION "SLIDING SCALE"



*The scale presumes tools are created and utilized properly and when fraudulent transfer rules will not apply.

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BEST ASSET PROTECTION NOT AP

- Why wealth protection MUST be tied to wealth creation: timing
- Like tax planning: economic substance
- Top (+5) tools are primarily not AP tools
- AP must be implemented in a multidisciplinary approach

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PRACTICE ASSET PROTECTION

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PRACTICE/ANCILLARIES PROTECTION

- Insurances
- Choice of entity
- LLC lease-backs
- Qualified retirement plans
- Non-qualified plans
- Advanced tools

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INSURANCES AS FRONT-LINE PROTECTORS

- Types of policies
  - Medical or dental malpractice
  - General Liability
  - Cyber
  - Landlord
  - Other
- Be aware of coverage limitations, deductibles
- Review and get second opinions

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CHOICE OF ENTITY FOR NON-PRACTICE BUSINESSES

	Corporation	LLC
Inside Protection	Yes. General corporate law principles.	Yes. General corporate law principles.
Outside Protection	**None, unless licensure for professional corporations.**	Charging order protections available. (+2)

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PROTECTING EQUIPMENT & REAL ESTATE

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MAXIMIZE PROTECTIVE BENEFIT PLANS

- **Shields #1 asset – cash flow**
- Qualified retirement plans (QRPs): state exemption laws vary
  - Most states also protect QRPs to an unlimited value
  - Some states: value limitations
  - Some states: timing claw-backs
- Non-qualified plans – depends on funding mechanism
  - COLI – about 20 states provide (+5) exemption
  - Other states: can use trusts or LLCs

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PERSONAL ASSET PROTECTION

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TITLING ASSETS: DOES IT PROTECT?

- Spousal
- Basics: Tenancy in common, joint tenancy
- Tenancy by the Entirety (TBE)
- Community Property

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START WITH EXEMPT ASSETS (+5)

- (+5) Federal or state exempt asset
- No gifting, compliance, accounting fees or special taxes
- Protection cannot be matched by any other planning
- Federal bankruptcy exemptions for QRPs and IRAs
- States vary widely
  - Homestead
  - QRPs, IRAs
  - Life insurance and annuities

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LLCs (+2): IDEAL FOR MOST ASSETS BEYOND EXEMPTIONS

- Inside Creditors
- Outside Creditors Isolates their lawsuit damage only to LLC property
  - Creditors can only get "charging order" against the LLC interest (+1 to +3) depending on use, compliance
  - Should tie into your estate plan
- "Building blocks" of asset protection
- *Control and Access*

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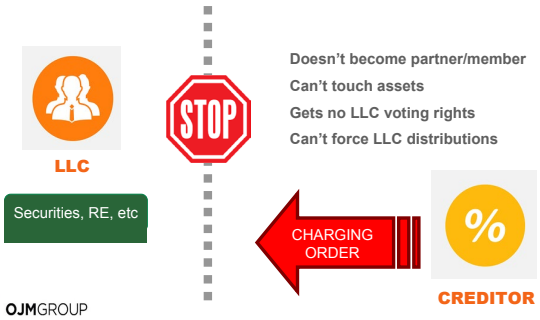
WHAT A "CHARGING ORDER" MEANS



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KEYS TO PROTECTION: LLCs

- Proper operating agreement
- Compliance with annual formalities
- Non-asset protection purpose: estate planning/gifting
- Jurisdiction: use the best state, when you have options
- Many LLCs are lacking in 1 of the 4 elements above: vulnerable
- Key: experienced attorney who has annual monitoring/gifting plan

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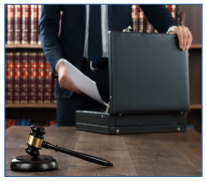
USING TRUSTS TO SHIELD ASSETS

- Revocable trusts
  - "Family," "living," "loving trusts"
  - Valuable for probate avoidance, in event of incapacity
  - No asset protection while you are alive
- Irrevocable trusts
  - Many types, including ILITs, GRATs, CRTs and DAPTs
  - Because they are irrevocable, strong asset protection
  - **DAPT is most innovative, newest**
    - 20 states
    - "Hybrid" version for other states
    - Different than LLCs



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PROTECTING THE HOME

- Homestead protection is best
- Tenancy by the entirety (TBE) in those states that protect TBE well
- Next best option:
  - Usually debt shield

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NEW STATUTES & CASES IN ASSET PROTECTION

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NEW STATUTES

- Exemption improvements
  - CA homestead
    - From $75,000-$150,000
    - To $300,000- $600,000
- DAPT adoption
  - Latest states: Indiana and Connecticut
- LLC & DAPT improvement
  - Ohio LLC: expressly in statute -- no foreclosure or equitable remedies and no right to retain possession (already a non-"blank check" charging order statute)
  - Ohio: Allows a family-owned LLC to be a DAPT trust company

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CASE 1:
MANICHAEAN CAPITAL, LLC v. EXCELA TECHNOLOGIES, INC.

- Delaware LLC case
- Court allowed "Reverse Piercing"
- Unique facts not common for doctors
  - $60 million statutory merger remedy
  - Parent-subsidiary where sub under-capitalized
  - Court allowed sub creditors to penetrate up to parent
- Does this impact viability of Delaware LLCs for outside protection?

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CASE 2:
EARTHGRAINS BAKING CO. v. SYCAMORE

- 10th Circuit Court of Appeals Case
- Court has authority to order the assets held by an LLC to be liquidated and the proceeds to be transferred to a managing member's creditor to satisfy a charging order (reach into the LLC to its assets)
- However, appears to be the case when there have been distributions from the LLC that should have gone to the creditor anyway as well as other egregious conduct
- Does this impact viability of LLCs to shield assets in the 10th Circuit? (WY, UT, CO, KS, NM, OK)
- Is it limited to states that allow a Court a "blank check" power to expand/innovate the "charging order" remedy?

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ABOUT OJM GROUP

- Unique, fee-based wealth management firm
- 1,000 physician clients in 48 states
- Multidisciplinary; three divisions
- Corporate and personal planning
- Goal: Reducing physician financial stress

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HOW WE WORK WITH PHYSICIANS

- **Investing**
  - RIA
  - Fiduciary, independent custodian
  - Tax-focused
- **Insurance and Benefits**
  - Life, disability, long term care insurance
  - Through partner firm, P&C coverages
  - Qualified and non-qualified plans
- **Consulting**

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PERSONAL WEALTH PLANNING

DIAGNOSTIC vs. TREATMENT

ADVICE & EXPERTISE FOR A FLAT FEE

BUILDING A RELATIONSHIP

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CONTACT THE PRESENTER

- **Contact the presenter**
  - David B. Mandell, JD, MBA
  - 877.656.4362
  - mandell@ojmgroup.com
- **Free resources**
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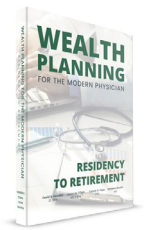

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SELF EVALUATION

Protecting Personal and Practice Assets from Professional and Business Risk

1. According to the Healthcare Finance News survey referenced in the talk, the percentage of physicians surveyed who felt moderately-to-severely stressed was:

a. 17%
b. 37%
c. 47%
d. 87%

2. T/F - Medical malpractice is one of many potential liability sources for most doctors.

3. Which of the following asset protection tools generally get the top (+5) protective rating:

a. Family limited partnerships
b. Community property
c. Spousal ownership
d. State or federally exempt assets

4. Which are often called the “building blocks” of asset protection:

a. Non-qualified plans
b. Limited liability companies (LLCs)
c. Irrevocable trusts
d. Revocable trusts

5. T/F - Revocable trusts do not provide asset protection to you as the grantor while you are alive.

Answer Key: 1. D, 2. T, 3. D, 4. B, 5. T

Elizabeth M. Prusak, MD, FACOG

Elizabeth M. Prusak, MD, FACOG, of Indianapolis, Indiana is board certified by the American Board of Obstetricians and Gynecologists as well as the North American Menopause Society. In addition to private practice, she is an American Board of Gynecology oral board exam instructor as well as an educator, private instructor and medical writer. Dr. Prusak utilizes a holistic approach in her practice and has spoken nationally to medical audiences on managing patients with difficult gynecological issues.

You may contact Dr. Prusak with your questions and comments by email at ElizabethPrusak@Yahoo.com.

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Office Gynecology for the Non-Specialist

OBJECTIVE

- To explain the most common office gynecologic procedures and problems that are encountered by the internal medicine physician

TO BEGIN

Referral to the Gynecologist is ALWAYS appropriate and welcomed

INITIAL EXAM

- All female patients:
  - Inquiry regarding abnormal bleeding or discharge menstrual irregularities, pelvic discomfort, changes in or abnormality of bowel or bladder function, pruritus or lesions of the vulva.
  - Careful general exam should include survey of the neck, breast, axilla, abdomen, groin, and legs.
  - Complete pelvic exams:
    - Inspection and palpation of the external genitalia
    - Bimanual and vaginal exam
    - Speculum exam of the cervix and vagina
    - Rectal exam including recto-vaginal exam

PAP SMEAR

- Single diagnostic screening technique which has had the longest impact into the reduction of mortality in cervical cancer
- Ideal Target population: Screening all women above 21 years.

PAP SMEAR

- High Risk Group:
  1. Early sexual activity
  2. Early childbearing
  3. Multiple sex partners
  4. HPV and Herpes Simplex Virus II infection, HIV, DES exposure
  5. Immunosuppressed patients
  6. Smoking

COLPOSCOPY

COLPOSCOPE

- Use of a magnifying instrument to identify abnormal (precancerous, cancerous) areas of cervical mucosa
- Usually performed at 10-20x magnification

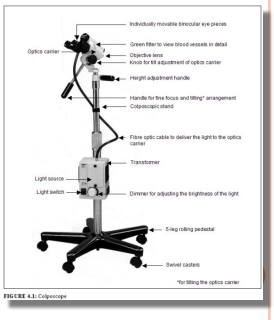

FIGURE 4.1: Colposcope

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COLPOSCOPY

- Indications
  - In abnormal pap smear, it determines the site of abnormal cells and thus eliminate hazards of diagnostic conization
  - Atypical squamous cells of undetermined significance (ASCUS - H or + high risk HPV)
    - Low grade squamous intraepithelial lesion (LGSIL)
    - High grade squamous intraepithelial lesion (HGSIL)
    - Carcinoma in-situ or invasive carcinoma
    - Atypical glandular cells
    - 2 positive HPVs

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COLPOSCOPY

- Indications
  - Radiation changes
    - Following radiation , pap smear is occasionally abnormal
  - HPV and Herpes infection
  - DES exposed offspring
  - Pregnant patients can undergo colposcopy

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WET MOUNT, GRAM STAINING, AND VAGINAL CULTURES

- ***Cervicitis*** and ***vaginitis*** are the most frequent complaints evaluated by internal medicine physician and the gynecologist
- Organisms most often associated with cervicitis:
  - Chlamydia trachomatis (most common)
  - Neisseria gonorrhea
  - Herpes simplex II

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WET MOUNT, GRAM STAINING, AND VAGINAL CULTURES

- In vaginitis, the most common offending organisms can be easily diagnosed by simple wet smear
  - Candidiasis – Candida albicans
  - Trichomoniasis – Trichomonas vaginalis
  - Bacterial Vaginosis – Gardnerella vaginalis and anaerobic bacteria

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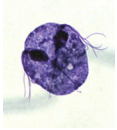
TRICHOMONAS- AN STD

- TRICHOMONAS VAGINALIS
  - The organism seen are actively motile, normally moving with the direction of flagella.



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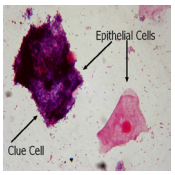
BACTERIAL VAGINOSIS- SEXUALLY ASSOCIATED



- GARDNERELLA VAGINALIS
  - Will show the typical clue cells which consists of epithelial cells that appear stippled or granulated.
  - KOH added to the discharge. This produces a fishy amine odor which is the basis for the **Whiff test**.
  - Will appear as highly motile curved bacterial rods with cork-screw spinning action which is seen in approximately 50% of cases.

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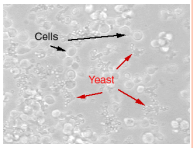
Yeast Infection- Change in Bacterial Flora

- CANDIDA ALBICANS
  - Typical hyphae and spore formation is also seen in wet smears. It is however, better visualized with KOH smears.



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What's This?

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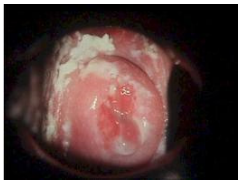
Actually that was Feta Cheese… The Recurrent Yeast Infection

- Consider other causes
- Estrogen replacement, oral contraceptives
- Non candida cultures
- Suppressive therapy



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CULTURE & SENSITIVITY STUDIES

- Routine bacterial culture of the vaginal discharge may be misleading and of no diagnostic value
- It is however indicated in the following:
  - 1. Recurrent infection
  - 2. Abscess of vulva, groin, and pelvis

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Abnormal Uterine Bleeding Preliminary Workup

- Inspection
- Causes: PALM-COEN
  - Infection
  - Atrophy
  - Structural
  - Malignancy
  - Anovulation
- Workup: Vaginal Cultures, Transvaginal Ultrasound, Endometrial Biopsy/Hysteroscopy, Possible D&C

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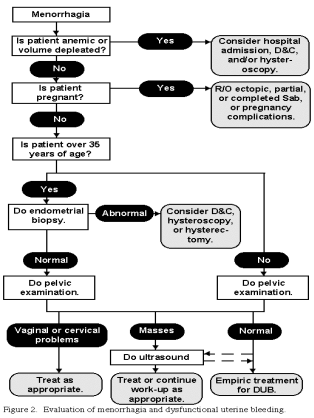

Figure 2. Evaluation of menorrhagia and dysfunctional uterine bleeding.
13-8

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Abnormal Uterine Bleeding- Indications for an Endometrial Biopsy

- Postmenopausal bleeding
- Irregular/heavy vaginal bleeding after age 45
- Irregular/heavy vaginal bleeding prior to 45 with risk factors
- Suspicious ultrasound/imaging

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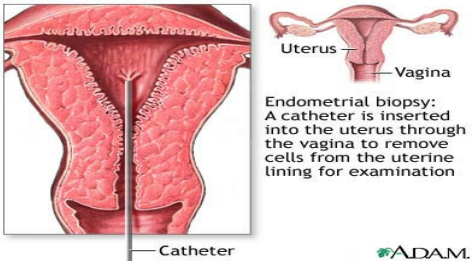
DIAGNOSIS



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ENDOMETRIAL BIOPSY

- **Benefits**
  - Low risk of uterine perforation (1/1000)
  - Gives tissue for diagnosis
  - Sensitivity for diagnosing neoplasia similar to D&C
  - Minimal bleeding
  - Unlike D&C, no anesthesia needed

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ULTRASOUND

- Noninvasive imaging technique utilizing acoustic waves similar to sonar
- Ultrasound is approximately 90% accurate in recognizing the presence of a pelvic mass but does not establish a tissue diagnosis.

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ULTRASOUND

- Disadvantage:
  - Poor penetration of bone and air, thus the pubic symphysis and air-filled intestines and rectum often inhibit visualization.
- Advantages:
  - Real time nature of the image
  - Absence of radiation
  - Ability to perform the procedure in the office during or immediately after a pelvic examination
  - Ability to describe the findings to the patient while she is watching

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ULTRASOUND

- Ultrasound evaluation of endometrial pathology involves measurement of the endometrial thickness or stripe.
  - The normal endometrial thickness is 4mm or less in a postmenopausal woman not taking hormones.
  - The thickness varies in perimenopausal women at different times of the menstrual cycle

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Vulvar and Vaginal Disorders

- Bartholins Cyst/Abscess
- Vulvar Cyst/Abscess
- Vaginal cysts
- Vulvar lesions and malignancies

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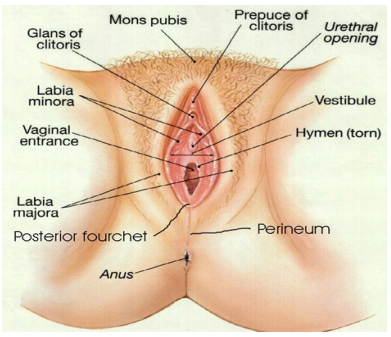

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Bartholins Gland Cyst/Abscess

- Causes are multifactorial
  - Low yield for vaginal cultures
- Biopsy required after age of 40
- Incision and Drainage
- Marsupialization
- Excision

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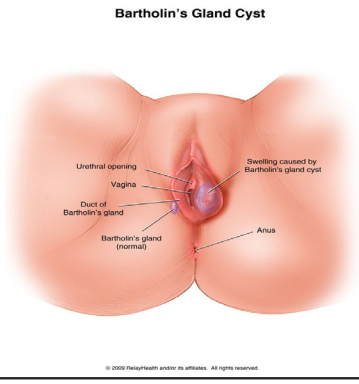
Bartholins Gland Cyst/Abscess



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Vulvar Lesion

- Any abnormality of the vulva needs to be biopsied
- When in doubt, biopsy

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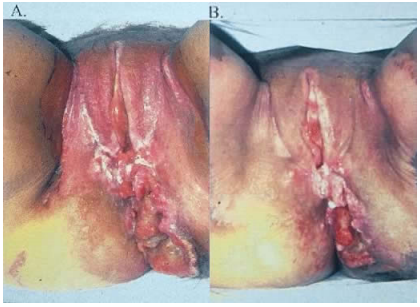
An obvious abnormality…



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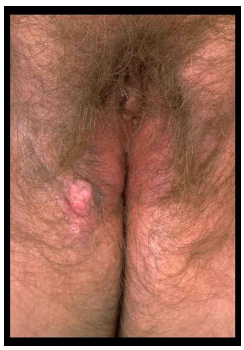
A subtle presentation of vulvar carcinoma…



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Contraception

- Birth control pills
  - CDC Contraceptive 2010 guidelines
- Intrauterine Devices
  - Financial approval
- Nuva ring
- Patch
- Sterilizations
- Condoms

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Pelvic Inflammatory Disease

- Acute or chronic infection of the reproductive tract
- Causes
  - Gonorrhea, Chlamydia, E. coli, Polymicrobial
- Risk factors
  - Previous infection, multiple partners, IUD
- Moderate to severe lower pelvic pain
- Possible cervical motion tenderness
- Inpatient vs. Outpatient management
- Treatments and Evaluation

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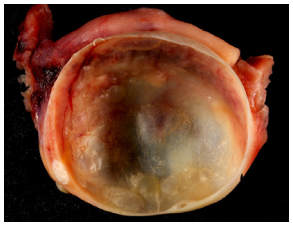
Ovarian Cysts and Rupture

- Sharp stabbing pain
- Watchful waiting vs. Admission
- Management and Follow up



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Ectopic Pregnancy

- Vaginal bleeding, pain and a positive pregnancy test is an ectopic pregnancy until proven otherwise!
- Risk factors:
  - Prior ectopic
  - Tubal sterilization
  - IUD
- Management
  - Ultrasound, repeat BHCG, referral

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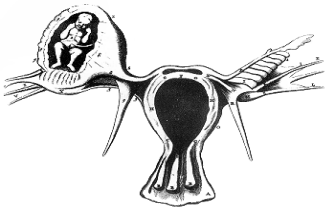
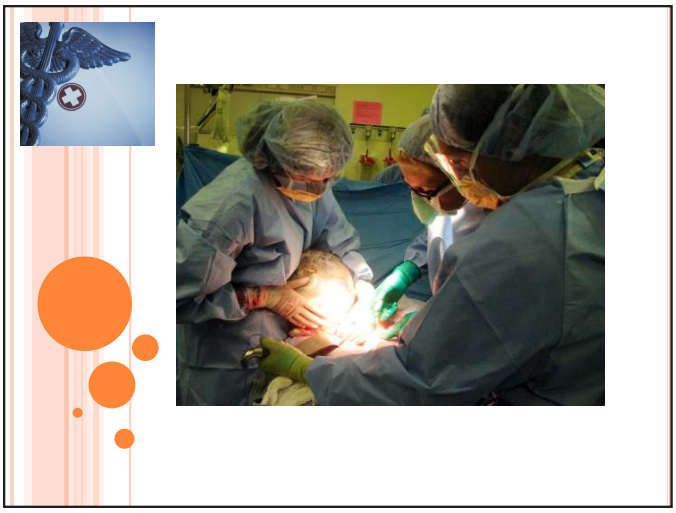
Drawing of an ectopic pregnancy from the 17th century





SELF EVALUATION

Office Gynecology for the Non-Specialist

True/False

1.___ A colposcopy is a procedure done by a gynecologist that examines the cervix under magnification after the patient has had an abnormal pap.

2.___ The most common organism associated with cervicitis is trichomonas.

3.___ Bacterial vaginosis is a sexually transmitted disease.

4.___ The most common radiologic test in the diagnosis of Gynecologic conditions is the pelvic MRI.

5.___ Typically, cultures are not necessary during incision and drainage of a bartholins cyst.

6.___ An ectopic pregnancy is a surgical emergency.

7.___ The first step in the evaluation of postmenopausal bleeding is a thorough history and physical exam.

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

Barry A. Franklin, PhD

Barry A. Franklin, PhD, of West Bloomfield, Michigan, serves as Director, Preventive Cardiology and Cardiac Rehabilitation, at Beaumont Health, Royal Oak, MI, as well as Professor, Internal Medicine, Oakland University William Beaumont School of Medicine. He is past president of the American Association of Cardiovascular and Pulmonary Rehabilitation and the American College of Sports Medicine. Currently he serves on the Board of the American Society for Preventive Cardiology.

Dr. Franklin is past editor in chief of the *Journal of Cardiopulmonary Rehabilitation and Prevention* and currently serves on the editorial boards of 15 other journals. He has written or edited more than 700 scientific and clinical publications, including 103 book chapters and 27 books including his latest, *"GPS for Success:Skills, Strategies and Secrets of Superachievers"* which can be ordered at www.DrBarryFranklin.com. Dr. Franklin has given over 1000 invited presentations worldwide. In 2015, he was listed in *The World's Most Influential Scientific Minds* (Clinical Medicine).

You may contact Dr. Franklin with your questions or comments at Barry.Franklin@Beaumont.edu, or through his website: www.drbarryfranklin.com.

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Barry A. Franklin, PhD
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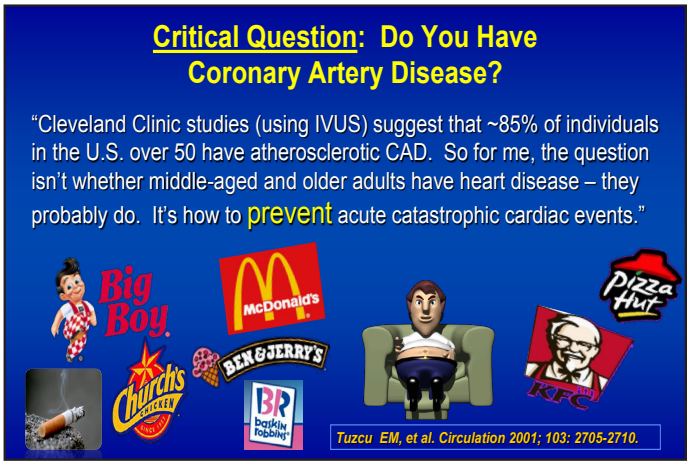
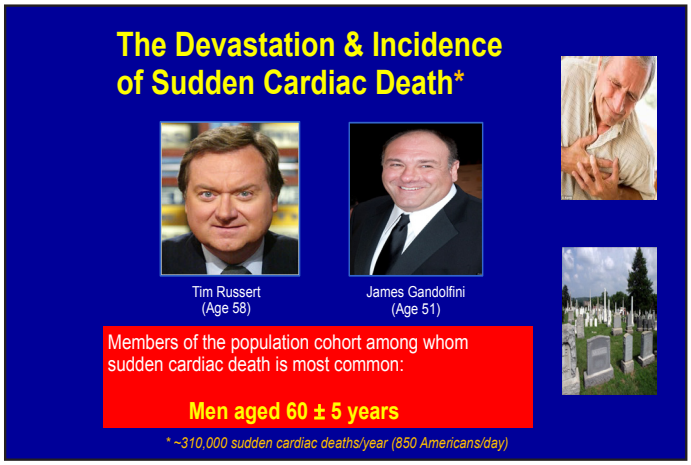
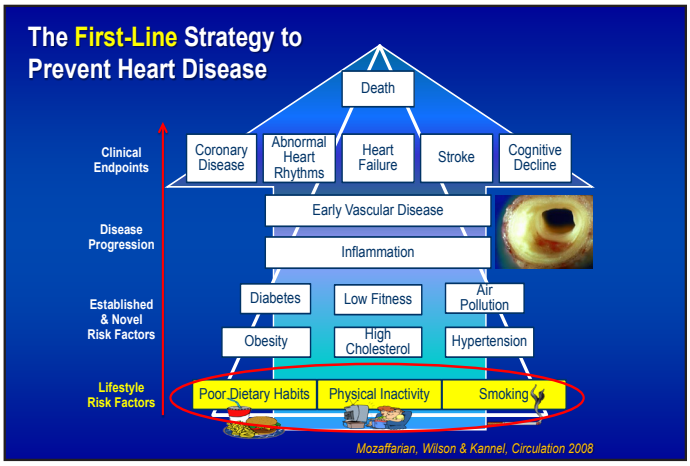
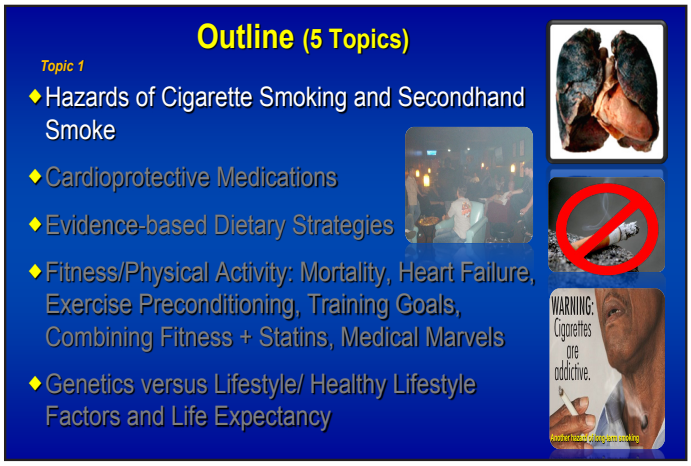
Cardiovascular Disease Lifestyle Risk Factor and Behavioral Therapies









Papers

Mortality in relation to smoking: 50 years' observations on male British doctors

Richard Doll, Richard Peto, Jillian Boreham, Isabelle Sutherland

Abstract

Objective To compare the hazards of cigarette smoking in men who formed their habits at different periods, and the extent of the reduction in risk when cigarette smoking is stopped at different ages.
Design Prospective study that has continued from 1951 to 2001.
Setting United Kingdom.
Participants 34 439 male British doctors. Information about their smoking habits was obtained in 1951, and periodically thereafter; cause specific mortality was monitored for 50 years.
Main outcome measures Overall mortality by smoking habit, considering separately men born in different periods.
Results The excess mortality associated with smoking chiefly involved vascular, neoplastic, and respiratory diseases that can be caused by smoking. Men born in 1900-1930 who smoked only cigarettes and continued smoking died on average about 10 years younger than lifelong non-smokers. Cessation at age 60, 50, 40, or 30 years gained, respectively, about 3, 6, 9, or 10 years of life expectancy. The excess mortality

Introduction

During the 19th century much tobacco was smoked in pipes or as cigars and little was smoked as cigarettes, but during the first few decades of the 20th century the consumption of manufactured cigarettes increased greatly.[1] This led eventually to a rapid increase in male lung cancer, particularly in the United Kingdom (where the disease became by the 1940s a major cause of death). Throughout the first half of the 20th century the hazards of smoking had remained largely unsuspected.[1] Around the middle of the century, however, several case-control studies of lung cancer were published in Western Europe[2-4] and North America,[5-16] leading to the conclusion in 1950 that smoking was "a cause, and an important cause" of the disease.[2]

1951 prospective study

This discovery stimulated much further research into the effects of smoking (not only on lung cancer but also on many other diseases), including a UK prospective study of smoking and death among British doctors that began in 1951 and has now continued for 50 years.[11-17] The decision that this study would be conducted

Editorial by Stampfer

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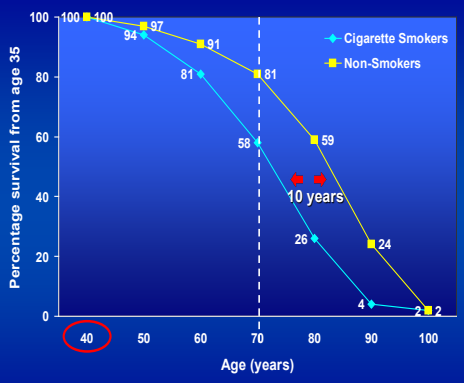
Richard Doll *emeritus professor of medicine*
Richard Peto *professor of medical statistics and epidemiology*
Jillian Boreham *senior research fellow*
Isabelle Sutherland *research assistant*
Correspondence to: R Doll
secretary@ctsu.ox.ac.uk

BMJ 2004;328:1519–33

BMJ 2004;328:1519



BMJ 2004;328:1519

SPECIAL ARTICLE

21st-Century Hazards of Smoking and Benefits of Cessation in the United States

Prabhat Jha, M.D., Chinthanie Ramasundarahettige, M.Sc., Victoria Landsman, Ph.D., Brian Rostron, Ph.D., Michael Thun, M.D., Robert N. Anderson, Ph.D., Tim McAfee, M.D., and Richard Peto, F.R.S.

ABSTRACT

BACKGROUND

Extrapolation from studies in the 1980s suggests that smoking causes 25% of deaths among women and men 35 to 69 years of age in the United States. Nation-

From the Center for Global Health Research, Toronto (P.J., C.R., V.L.); the Food and Drug Administration, Rockville

Life expectancy was shortened by ~ 11-12 years among the current smokers, as compared with those who had never smoked.

Cessation before the age of 40 years reduced the risk of death associated with continued smoking by about 90%.

years of age gained about 10, 9, and 6 years of life, respectively, as compared with those who continued to smoke.

CONCLUSIONS

Smokers lose at least one decade of life expectancy, as compared with those who have never smoked. Cessation before the age of 40 years reduces the risk of death associated with continued smoking by about 90%.

Prabhat Jha et al. NEJM 2013;368:341

Special Report

Cardiovascular Effects of Secondhand Smoke

Secondhand smoke increases the risk of coronary heart disease and cardiac events by ~ 30%.

Circulation 2005;111:2684-2698

The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

Smoke-free Legislation and Hospitalizations for Acute Coronary Syndrome

Jill P. Pell, M.D., Sally Haw, B.Sc., Stuart Cobbe, M.D., David E. Newby, Ph.D., Alastair C.H. Pell, M.D., Colin Fischbacher, M.B., Ch.B., Alex McConnachie, Ph.D., Stuart Pringle, M.D., David Murdoch, M.B., Ch.B., Frank Dunn, M.D., Keith Oldroyd, M.D., Paul McIntyre, M.D., Brian O'Rourke, M.D., and William Borland, B.Sc.

ABSTRACT

Since the end of March 2006, smoking has been prohibited by law in all enclosed public places throughout Scotland.

Overall, the number of admissions for acute coronary syndrome decreased from 3235 to 2684 – a 17% reduction (95% CI, 16 to 18)* – as compared with a 4% reduction in England (which has no such legislation) during the same period and a mean annual decrease of 3% (maximum decrease, 9%) in Scotland during the decade preceding the study.

chi-square test for trend) that was confirmed by a decrease in their geometric mean concentration of serum cotinine from 0.68 to 0.56 ng per milliliter (P<0.001 by the test).

CONCLUSIONS

The number of admissions for acute coronary syndrome decreased after the implementation of smoke-free legislation. A total of 67% of the decrease involved nonsmokers. However, fewer admissions among smokers also contributed to the overall reduction.

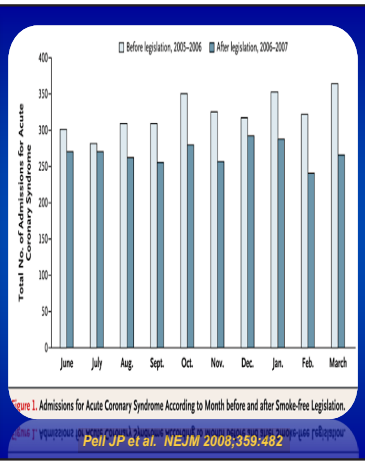


Figure 1. Admissions for Acute Coronary Syndrome According to Month before and after Smoke-free Legislation.

Pell JP et al. NEJM 2008;359:482

Influence of Secondhand Smoke on the Triggering of Acute Cardiac Events

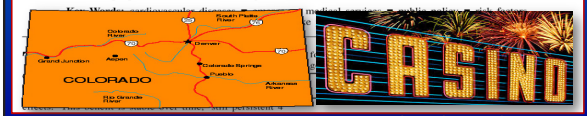
Changes in Ambulance Calls After Implementation of a Smoke-Free Law and Its Extension to Casinos

Stanton A. Glantz, PhD; Erin Gibbs, BS

Background—Casinos are often exempted from legislation mandating smoke-free environments, potentially putting

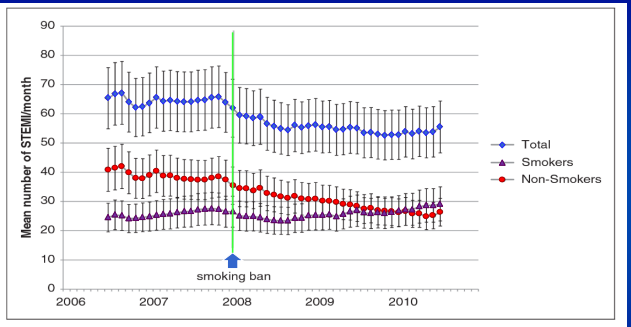
Initial implementation of the smoke-free law (which exempted casinos) was followed by a significant 22.8% drop in ambulance calls from locations other than casinos, but no significant change in calls from casinos. The law requiring smoke-free casinos taking effect was followed by a 19.1% drop in ambulance calls from casinos, but no change in calls originating outside casinos.

means that more people will suffer medical emergencies. (*Circulation*. 2013;128:811-813.)



Glantz SA et al. Circulation 2013;128:811-813

Smoking Ban in Public Areas: Bremen Germany



These results may be explained by the protection of non-smokers from passive smoking and the absence of such an effect in smokers by the dominant effect of active smoking.

Schmucker J et al. Eur J Prev Cardiol 2014;21:1180-1186

Outline

Topic 2

- Hazards of Cigarette Smoking and Secondhand Smoke
- Cardioprotective Medications
- Evidence-based Dietary Strategies
- Fitness/Physical Activity: Mortality, Heart Failure, Exercise Preconditioning, Training Goals, Combining Fitness + Statins, Medical Marvels
- Genetics versus Lifestyle/ Healthy Lifestyle Factors and Life Expectancy

Cardioprotective Medications

Aspirin

Statin (Cholesterol Lowering)

Beta- blockers (Post MI, LV dysfunction)

ACE-I or ARB (EF ≤ 40%, DM, HTN)

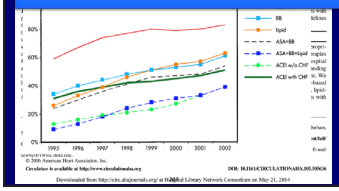
18 - 44% Risk Reduction (Median, 23%)

Health Services and Outcomes Research

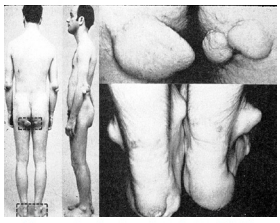
Long-Term Adherence to Evidence-Based Secondary Prevention Therapies in Coronary Artery Disease

Nearly 30% of patients were not consistently using aspirin, and fewer than half reported consistent long-term use of ß blockers, lipid-lowering therapy, or combinations of these life-saving drugs.

In multivariate analysis, nonadherence remained significantly associated with increased all-cause mortality risk for ß blockers (hazard ratio [HR] 1.50, 95% CI 1.33 – 1.71), ACE inhibitors (HR 1.74, 95% CI 1.52 – 1.98), and statins (HR 1.85, 95% CI 1.63 – 2.09). Ho PM et al. Am Heart J 2008



FROM THE EDITOR

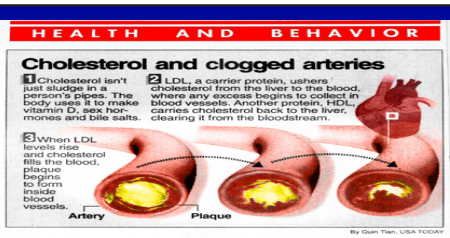


Extreme Hypercholesterolemia = Malignant Atherosclerosis

In adults with plasma total cholesterol (TC) levels <150 mg/dl, atherosclerotic plaques large enough to narrow arterial lumens rarely develop and symptomatic or fatal organ ischemia rarely occurs. Most such adults live in underdeveloped countries or in the Eastern world or both.

hypertension and cigarette smoking is high but the level of plasma TC is low, i.e., <150 mg/dl, the occurrence of symptomatic or fatal coronary heart disease is virtually nonexistent. About 15 years ago, I visited Kampala, Uganda, and examined many aortas, coronary arteries and

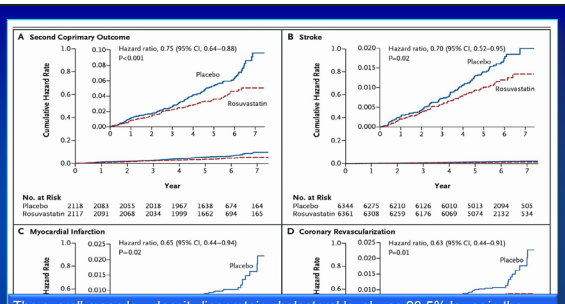
HEALTH AND BEHAVIOR



Cholesterol-lowering drugs to play larger role in heart health

TC ↓	LDL↓	HDL↑
22% - 47%	27% - 60%	7%

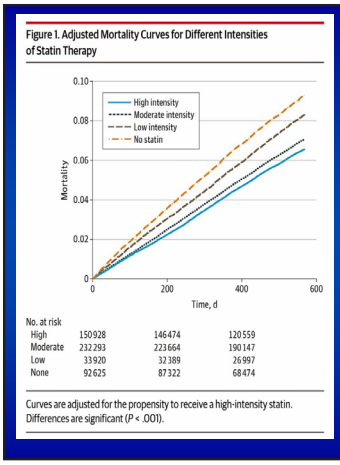
*Roberts WC. AJC 2006;78:1550



The overall mean low-density lipoprotein cholesterol level was 26.5% lower in the rosuvastatin group than in the placebo group.

Treatment with rosuvastatin at a dose of 10 mg/day resulted in a significantly lower risk of cardiovascular events (25%-37%) than placebo in an intermediate-risk, ethnically diverse population without cardiovascular disease .

Heart Outcomes Prevention Evaluation (HOPE)-3 Trial NEJM April 2016

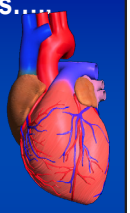


- **High-Intensity Statins Increase Survival**
  - rosuvastatin 20 or 40 mg or atorvastatin 40 or 80 mg

Rodriguez F et al. JAMA Cardiol 11/09/2016

Resting Heart Rate and Blood Pressure ?
Lower #'s Associated with Longer Lives…..

In conclusion, in post-MI pts, this meta-regression of randomized clinical trials robustly suggests that the benefit of drugs modifying HR is strongly related to the magnitude of reduction in resting HR.



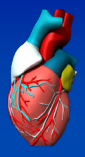
Each 10-bpm reduction in resting HR is estimated to reduce the relative risk of cardiac death by about 30%.

Tenormin
Lopressor
Toprol-XL
Inderal

Cucherat M. Eur Heart J 2007;28:3012

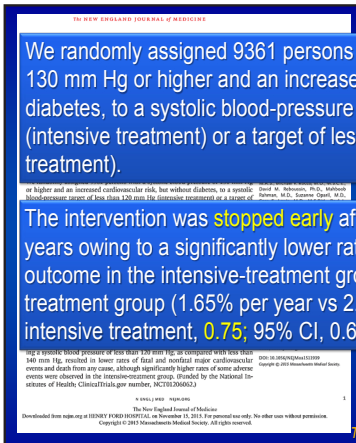
Resting Heart Rate: Lower is Better*

In general, a slower resting heart rate means a longer life – probably because a slower heart rate exerts less stress on blood vessel walls.



Studies have shown that men and women with slower resting heart rates (< 60 bpm) have fewer cardiac events and a lower risk of dying from CVD than those with faster rates (> 80 bpm)

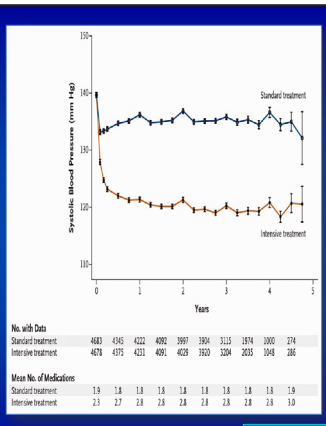
** Saxena A et al. Mayo Clin Proc 2013 (December)*

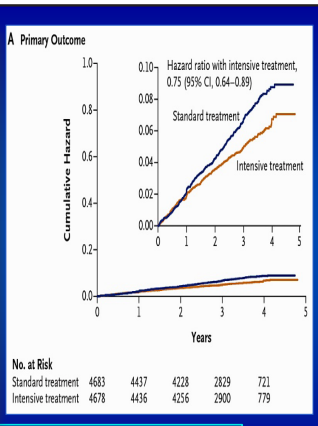


We randomly assigned 9361 persons with a systolic blood pressure of 130 mm Hg or higher and an increased cardiovascular risk, but without diabetes, to a systolic blood-pressure target of less than 120 mm Hg (intensive treatment) or a target of less than 140 mm Hg (standard treatment).

The intervention was stopped early after a median follow-up of 3.26 years owing to a significantly lower rate of the primary composite outcome in the intensive-treatment group than in the standard-treatment group (1.65% per year vs 2.19% per year; hazard ratio with intensive treatment, 0.75; 95% CI, 0.64 to 0.89; p<0.001).

This article was published on Nov. 9, 2015 at NEJM.org



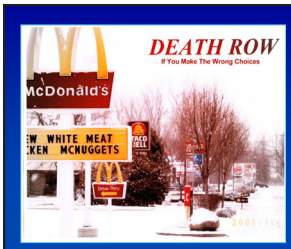


This article was published on Nov. 9, 2015 at NEJM.org

Outline

Topic 3

- Hazards of Cigarette Smoking and Secondhand Smoke
- Cardioprotective Medications
- Evidence-based Dietary Strategies
- Fitness/Physical Activity: Mortality, Heart Failure, Exercise Preconditioning, Training Goals, Combining Fitness + Statins, Medical Marvels
- Genetics versus Lifestyle/ Healthy Lifestyle Factors and Life Expectancy



"Our excessive intake of meat is killing us. We fatten our cows and pigs, kill them, eat them, and then they kill us!"

William C. Roberts, M.D.

INVITED COMMENTARY

Holy Cow! What's Good for You Is Good for Our Planet

This is the first large-scale prospective longitudinal study showing that consumption of both processed and unprocessed red meat is associated with an increased risk of premature mortality from all causes as well as from cardiovascular disease and cancer.

Plant-based foods are rich in phytochemicals, bioflavonoids, and other substances that are protective. In other words, what we *include* in our diet is as important as what we *exclude*, so substituting healthier foods for red meat provides a double benefit to our health.

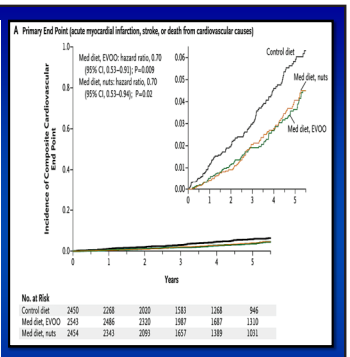
Pan et al[3] reported that adjustment for saturated fat, dietary cholesterol, and heme iron accounted for some but not all of the risk of eating red meat. Thus, other mechanisms such as nontraditional risk factors may be involved.

For example, a recent study by Smith[4] found that high-fat, high-protein, low-carbohydrate (HPLC) diets (which are usually high in red meat, such as the Atkins and Pa-

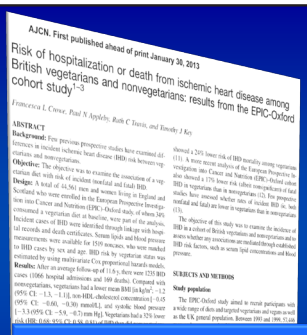
tion experts about what constitutes a healthy way of eating:

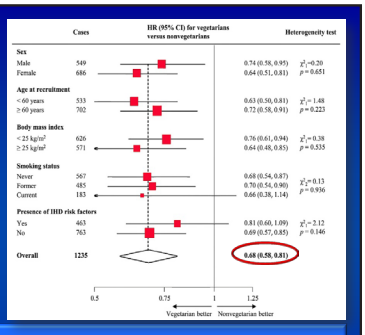
- little or no red meat;
- high in "good carbs" (including vegetables, fruits, whole grains, legumes, and soy products in their natural forms);
- low in "bad carbs" (simple and refined carbohydrates, such as sugar, high-fructose corn syrup, and white flour);
- high in "good fats" (ω-3 fatty acids found in fish oil, flax oil, and plankton-based oils);
- low in "bad fats" (trans fats, saturated fats, and hydrogenated fats);

Arch Intern Med 2012;172(7):563



Among persons at high cardiovascular risk, a Mediterranean diet supplemented with extra-virgin olive oil or nuts reduced the incidence of major cardiovascular events by ~ 30%.





Vegetarians had a 32% lower risk (HR: 0.68; 95% CI: 0.58, 0.81) of IHD than did nonvegetarians, which was only slightly attenuated after adjustment for BMI and did not differ materially by sex, age, BMI, smoking, or the presence of IHD risk factors.

Crowe FL et al. Am J Clin Nutr 2013; 1-30/2013

Trans fatty acids can adversely affect:

LDL and HDL cholesterol levels

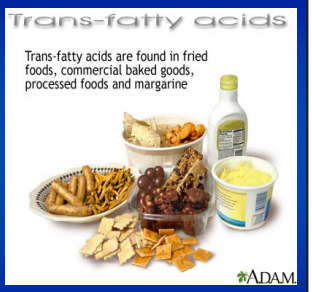
LP(a) and triglycerides

Vascular inflammation IL-6, TNF, CRP

Trans fatty acids increase:

Coronary heart disease

Diabetes

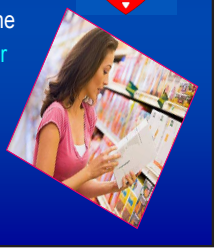


Mozaffarian D. et al Circulation 2012

How Much Trans Fat per Day ?
Remember : Zero isn't Zero….

The AHA recommends limiting the amount of trans fats you eat to less than 1% of your total daily calories. That means if you need 2,000 calories a day, no more than 20 of those calories should come from trans fats. Avoid foods listing hydrogenated or partially hydrogenated on the label…..

That's Less Than 2 Grams of Trans Fats a Day



How Much Salt Are You Eating?

Beware of the Sodium in these ***"Salty Six"*** Foods


Bread and rolls


Cold cuts & Cured meats

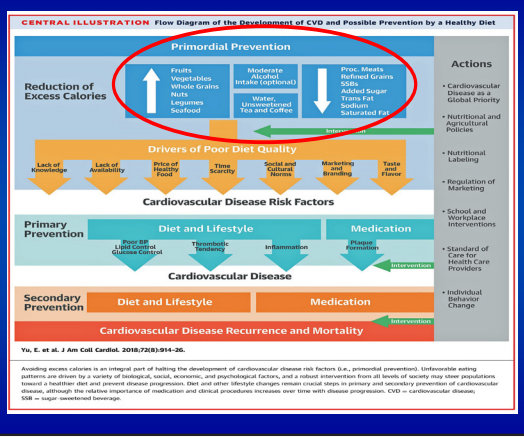

Pizza


Poultry

Soup


Sandwiches

* The average American consumes ~ 3,400 mg of sodium daily – > twice the 1,500 mg recommended by the AHA. More than 75% of the sodium consumption comes from processed and restaurant foods. Remember 1:1 Rule/Serv.



Yu, Edward Scd et al. JACC 2018; 72:914-16.

Outline

Topic 4

- Hazards of Cigarette Smoking and Secondhand Smoke
- Cardioprotective Medications
- Evidence-based Dietary Strategies
- Fitness/Physical Activity: Mortality, Heart Failure, Exercise Preconditioning, Training Goals, Combining Fitness + Statins, Medical Marvels
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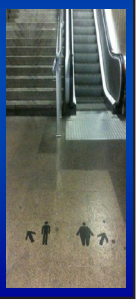
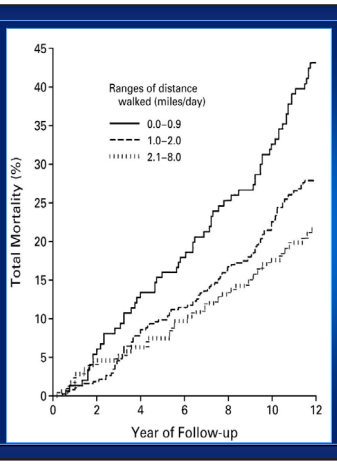


Effects of Walking on Mortality Among Non-Smoking Retired Men*

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



Hakim AA et al. NEJM 1998;338:94

How Fast does the Grim Reaper Walk? *

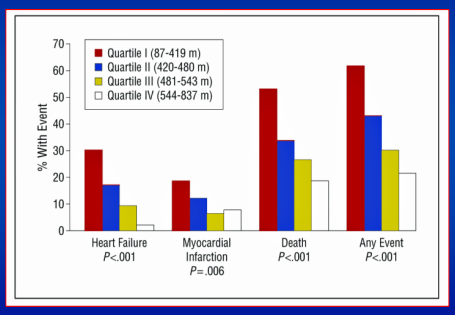
A walking speed of 0.82 m/s (2 mph) was most predictive of mortality.

Older men who walked at speeds greater than 0.82 m/s were 1.23 times less likely to encounter Death.

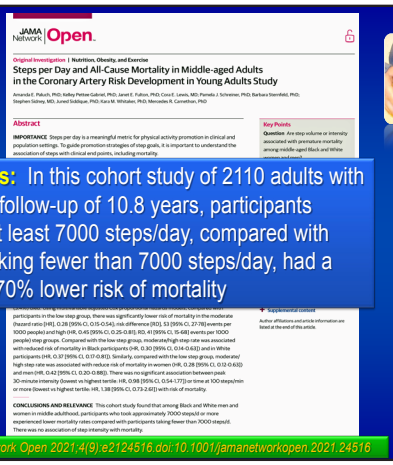
No men walking at speeds of 1.36 m/s (3 mph) or above were caught by Death (n=22, 1.4%), supporting the hypothesis that faster walking speeds are protective against mortality. Why? My hypothesis…

*Stanaway FF et al. BMJ 2011;343:d7679

HEART & SOUL STUDY: 556 Outpatients with stable CAD, 6-minute walk test, 8-year follow-up



Beatty AL et al. Arch Intern Med 2012;172(14):1096-1102


JAMA Network Open.

Original Investigation | Nutrition, Obesity, and Exercise

Steps per Day and All-Cause Mortality in Middle-aged Adults in the Coronary Artery Risk Development in Young Adults Study

Abstract

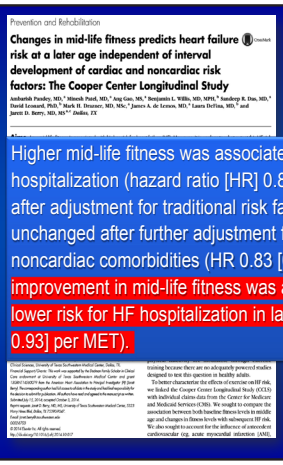
Key Points

Findings: In this cohort study of 2110 adults with a mean follow-up of 10.8 years, participants taking at least 7000 steps/day, compared with those taking fewer than 7000 steps/day, had a 50% to 70% lower risk of mortality

JAMA Network Open 2021;4(9):e2124516.doi:10.1001/jamanetworkopen.2021.24516

Risk Factors For Heart Failure*

* For individuals ≥ 65 years, HF is a common cause of mortality & the most frequent cause of hospitalization.

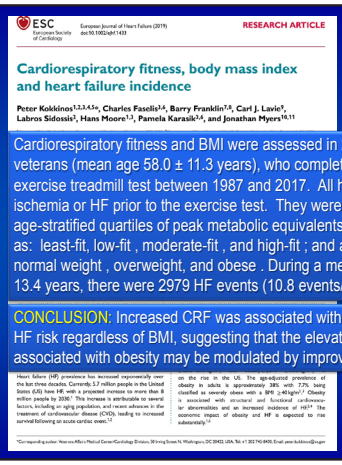

Prevention and Rehabilitation

Changes in mid-life fitness predicts heart failure risk at a later age independent of interval development of cardiac and noncardiac risk factors: The Cooper Center Longitudinal Study

Cardiorespiratory Fitness & Heart Failure : Recent Studies ?

Higher mid-life fitness was associated with a lower risk for HF hospitalization (hazard ratio [HR] 0.82 [0.76-0.87] per MET) after adjustment for traditional risk factors. This remained unchanged after further adjustment for cardiac and noncardiac comorbidities (HR 0.83 [0.78-0.89]). Each 1 MET improvement in mid-life fitness was associated with a 17% lower risk for HF hospitalization in later life (HR 0.83 [0.74-0.93] per MET).

Pandey A et al. Am Heart J 2015;169:290-297


ESC European Journal of Heart Failure (2019) doi:10.1002/ejhf.1433

RESEARCH ARTICLE

Cardiorespiratory fitness, body mass index and heart failure incidence

Peter Kokkinos[1,2,3,4,5]*, Charles Faselis[3,4], Barry Franklin[7,8], Carl J. Lavie[9], Labros Sidossis[5], Hans Moore[1,2], Pamela Karasik[3,4], and Jonathan Myers[10,11]

Cardiorespiratory fitness and BMI were assessed in 20,254 US male veterans (mean age 58.0 ± 11.3 years), who completed a maximal exercise treadmill test between 1987 and 2017. All had no evidence of ischemia or HF prior to the exercise test. They were classified based on age-stratified quartiles of peak metabolic equivalents (METs) achieved as: least-fit, low-fit , moderate-fit , and high-fit ; and according to BMI as normal weight , overweight, and obese . During a median follow-up of 13.4 years, there were 2979 HF events (10.8 events/1000 person-years).

CONCLUSION: Increased CRF was associated with progressively lower HF risk regardless of BMI, suggesting that the elevated HF risk associated with obesity may be modulated by improved CRF.

Kokkinos P et al. Eur Journal of Heart Failure (2019) doi:10.1002/ejhf.1433

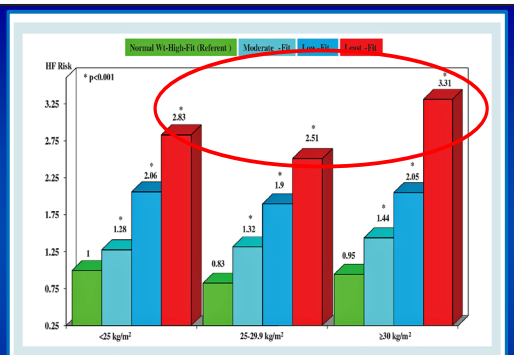


Figure 2 Risk of heart failure (HF) for cardiorespiratory fitness–body mass index interaction groups.

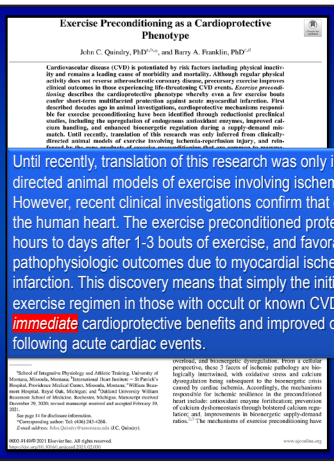
Kokkinos P et al. Eur J Heart Fail 2019

Exercise Preconditioning ? Physical Activity Status and Acute Coronary Syndromes (ACS) 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



Exercise Preconditioning as a Cardioprotective Phenotype

John C. Quindry, PhD[1,2,*], and Barry A. Franklin, PhD[3,4]

Cardiovascular disease (CVD) is potentiated by risk factors including physical inactivity and remains a leading cause of morbidity and mortality. Although regular physical activity does not reverse atherosclerotic coronary disease, precursory exercise improves clinical outcomes in those experiencing life-threatening CVD events. *Exercise preconditioning* describes the cardioprotective phenotype whereby even a few exercise bouts confer short-term multifaceted protection against acute myocardial infarction. First described decades ago in animal investigations, cardioprotective mechanisms responsible for exercise preconditioning have been identified through reductionist preclinical studies, including the upregulation of endogenous antioxidant enzymes, improved calcium handling, and enhanced bioenergetic regulation during a supply-demand mismatch. Until recently, translation of this research was only inferred from clinically-directed animal models of exercise involving ischemia-reperfusion injury, and rein-

Until recently, translation of this research was only inferred from clinically-directed animal models of exercise involving ischemia-reperfusion injury. However, recent clinical investigations confirm that exercise preconditions the human heart. The exercise preconditioned protection emerges within hours to days after 1-3 bouts of exercise, and favorably mitigates a host of pathophysiologic outcomes due to myocardial ischemia, injury, or infarction. This discovery means that simply the initiation of a remedial exercise regimen in those with occult or known CVD will provide *immediate* cardioprotective benefits and improved clinical outcomes following acute cardiac events.

Am J Cardiol 2021;148:8-15

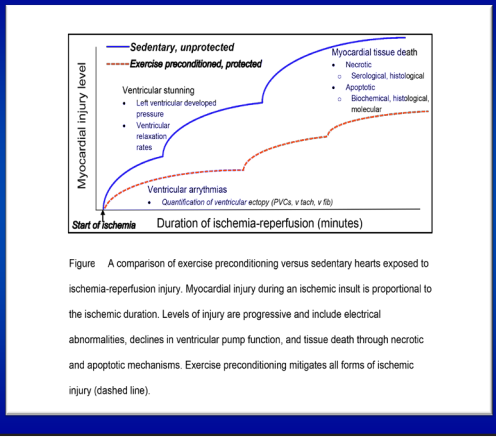
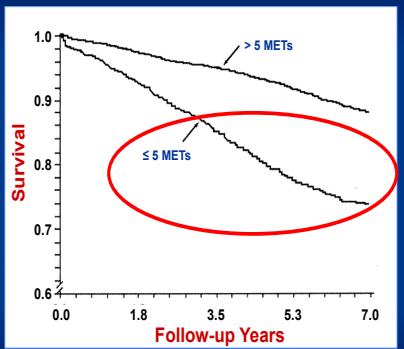


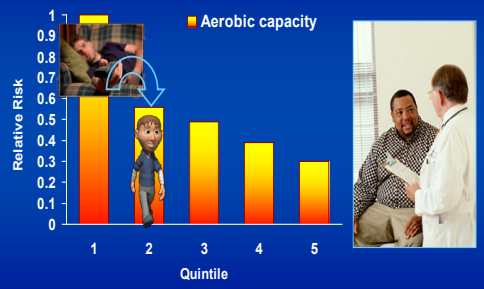
Figure A comparison of exercise preconditioning versus sedentary hearts exposed to ischemia-reperfusion injury. Myocardial injury during an ischemic insult is proportional to the ischemic duration. Levels of injury are progressive and include electrical abnormalities, declines in ventricular pump function, and tissue death through necrotic and apoptotic mechanisms. Exercise preconditioning mitigates all forms of ischemic injury (dashed line).

Exercise Training Goals



Myers J et al. Am J Med 2004;117:912

Implications for the Medical Community: Moving Patients Out of the Least Fit, "High-Risk" Cohort (Bottom 20%, < or =5 METs)



Blair SN et al. JAMA 1996;276:205
Williams PT Med Sci Sports Exerc 2001;33:754
Franklin B et al. Mayo Clin Proc 2013;88:431

Climbing Out of the Least Active, Least Fit "High Risk" Cohort (Bottom 20%)*

A key factor during the initial weeks of exercise training is to gradually increase the exercise intensity, so that, at a minimum, individuals get out of the least active, least fit segment of the population (i.e., the bottom 20%), which requires training above 3 METs. Why ? Fitness > 5 METs gets them out of this "high-risk" cohort.

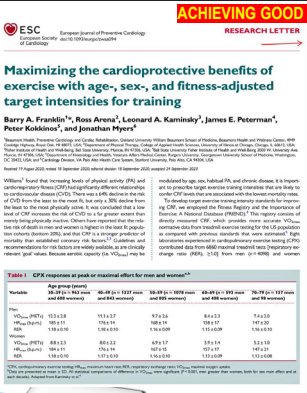
Corresponding treadmill workloads (> 3 METs) include . . .

- 2.0 mph, 3.5% grade, or
- 3.0 mph on the level

Franklin B et al. Circulation 2020;141:e705-e736

ACC.21

ACHIEVING GOOD FITNESS ?



ESC European Journal of Preventive Cardiology

RESEARCH LETTER

Maximizing the cardioprotective benefits of exercise with age-, sex-, and fitness-adjusted target intensities for training

Barry A. Franklin[1]*, Ross Arena[2], Leonard A. Kaminsky[3], James E. Peterman[4], Peter Kokkinos[5], and Jonathan Myers[6]

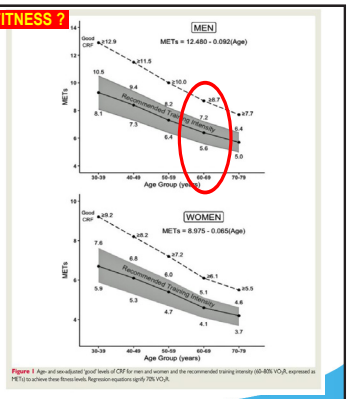
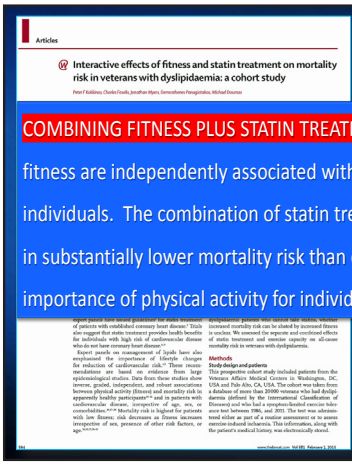


Figure 1 Age- and sex-adjusted 'good' levels of CRF for men and women and the recommended training intensity (60–80% VO_2R, expressed as METs) to achieve these fitness levels. Regression equations signify 70% VO_2R.

ACC.21

COMBINING FITNESS PLUS STATIN TREATMENT: Statin treatment and increased fitness are independently associated with low mortality among dyslipidaemic individuals. The combination of statin treatment and increased fitness resulted in substantially lower mortality risk than either alone, reinforcing the importance of physical activity for individuals with dyslipidaemia.

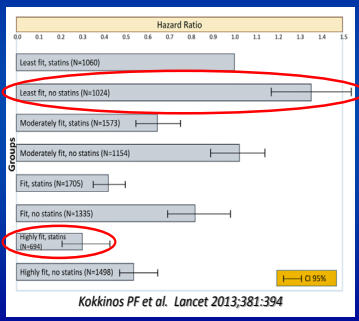


Articles

Interactive effects of fitness and statin treatment on mortality risk in veterans with dyslipidaemia: a cohort study

Kokkinos PF et al. Lancet 2013;381:394-99

Mortality Risk, Expressed as Adjusted Hazard Ratios ± 95 % CI, for Combined Fitness and Statin Categories (n=10,004; 10 Yr FU)

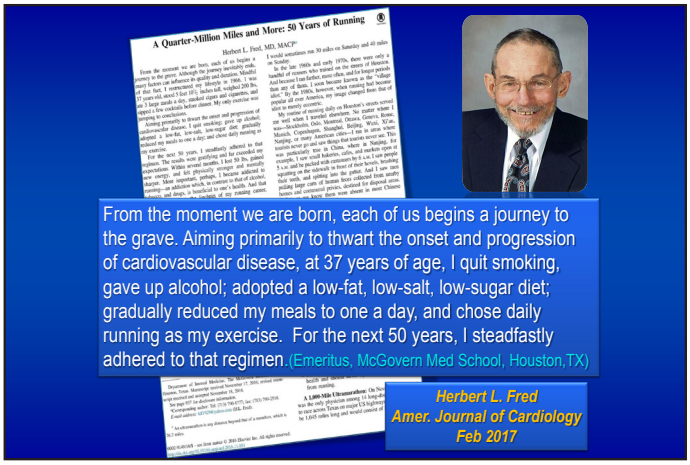


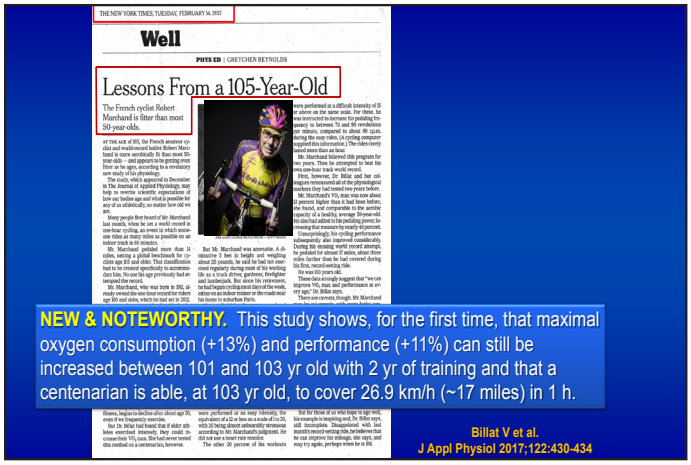
Kokkinos PF et al. Lancet 2013;381:394

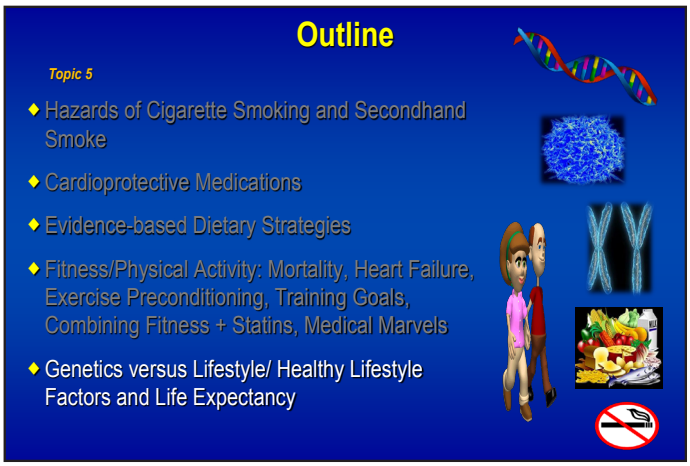
Case Studies: Medical Marvels

85-Year-Old Marathoner Is So Fast That Even Scientists Marvel

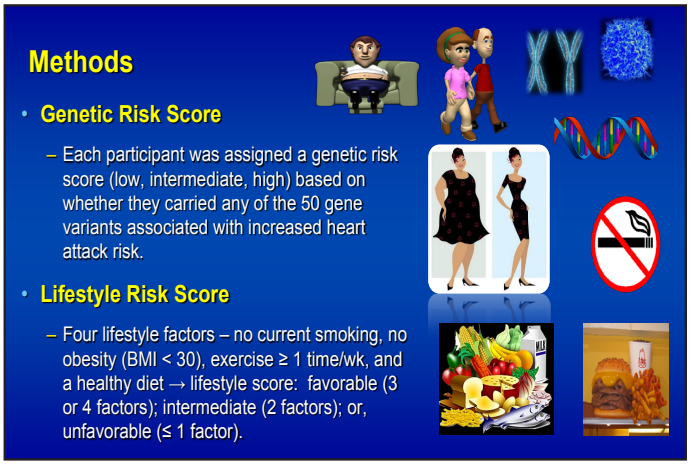
By JERÉ LONGMAN DEC. 28, 2016

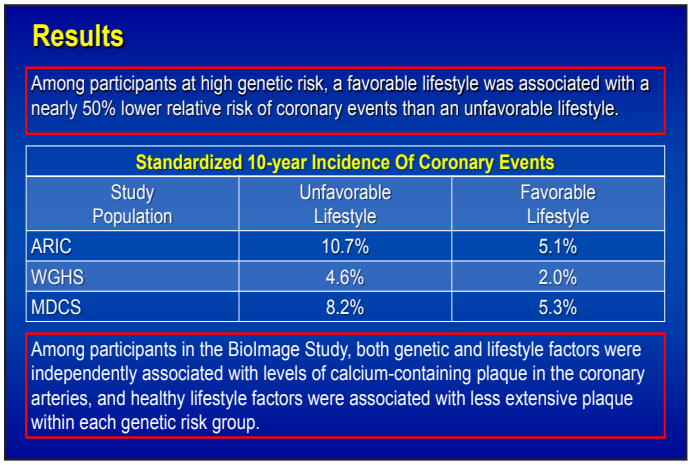

A Quarter-Million Miles and More: 50 Years of Running
Herbert L. Fred, MD, MACP
From the moment we are born, each of us begins a journey to the grave. Aiming primarily to thwart the onset and progression of cardiovascular disease, at 37 years of age, I quit smoking, gave up alcohol; adopted a low-fat, low-salt, low-sugar diet; gradually reduced my meals to one a day, and chose daily running as my exercise. For the next 50 years, I steadfastly adhered to that regimen.(Emeritus, McGovern Med School, Houston,TX)
Herbert L. Fred
Amer. Journal of Cardiology
Feb 2017

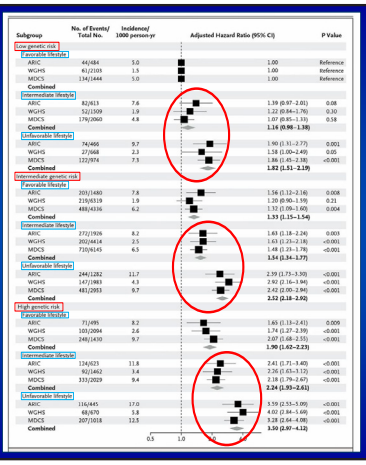

Well
Lessons From a 105-Year-Old
NEW & NOTEWORTHY. This study shows, for the first time, that maximal oxygen consumption (+13%) and performance (+11%) can still be increased between 101 and 103 yr old with 2 yr of training and that a centenarian is able, at 103 yr old, to cover 26.9 km/h (~17 miles) in 1 h.
Billat V et al.
J Appl Physiol 2017;122:430-434


Outline
Topic 5
Hazards of Cigarette Smoking and Secondhand Smoke
Cardioprotective Medications
Evidence-based Dietary Strategies
Fitness/Physical Activity: Mortality, Heart Failure, Exercise Preconditioning, Training Goals, Combining Fitness + Statins, Medical Marvels
Genetics versus Lifestyle/ Healthy Lifestyle Factors and Life Expectancy


Can Bad Genes be Offset by a Healthy Lifestyle ?
ORIGINAL ARTICLE
Genetic Risk, Adherence to a Healthy Lifestyle, and Coronary Disease
4 Large-Scale Studies which included extensive genetic and lifestyle information that have followed > 55,600 adults for up to 20 years
Khera AV et al.
NEJM 11/13/2016


Methods
Genetic Risk Score
Each participant was assigned a genetic risk score (low, intermediate, high) based on whether they carried any of the 50 gene variants associated with increased heart attack risk.
Lifestyle Risk Score
Four lifestyle factors – no current smoking, no obesity (BMI < 30), exercise ≥ 1 time/wk, and a healthy diet → lifestyle score: favorable (3 or 4 factors); intermediate (2 factors); or, unfavorable (≤ 1 factor).


Results
Among participants at high genetic risk, a favorable lifestyle was associated with a nearly 50% lower relative risk of coronary events than an unfavorable lifestyle.
Standardized 10-year Incidence Of Coronary Events
Study Population | Unfavorable Lifestyle | Favorable Lifestyle
ARIC | 10.7% | 5.1%
WGHS | 4.6% | 2.0%
MDCS | 8.2% | 5.3%
Among participants in the BioImage Study, both genetic and lifestyle factors were independently associated with levels of calcium-containing plaque in the coronary arteries, and healthy lifestyle factors were associated with less extensive plaque within each genetic risk group.

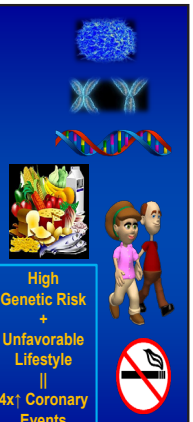


Regardless of the genetic risk [low, intermediate, or high], the biggest protective effect, by far, came from moving from an unfavorable lifestyle to one that was at least intermediate.

Khera AV et al.
NEJM 11/13/2016

Major Findings: Bad Genes ? Lifestyle Matters !

Bad genes can double the risk of heart disease, but a favorable lifestyle cuts it in half. An unfavorable or unhealthy lifestyle erases about half the benefits of good genetics. The 'deadliest combination' was when high genetic risk was paired with an unfavorable lifestyle= 4x increased risk of cardiac events.



High Genetic Risk + Unfavorable Lifestyle || 4x↑ Coronary Events

Circulation

ORIGINAL RESEARCH ARTICLE

Impact of Healthy Lifestyle Factors on Life Expectancies in the US Population

Background: Americans have a shorter life expectancy compared with residents of almost all other high-income countries. We aim to estimate the impact of 5 low-risk lifestyle factors (not smoking, normal BMI, > or = 30 min/day of moderate intensity physical activity, moderate alcohol consumption, healthy diet score) on premature mortality and life expectancy in the US population.

deaths. The multivariable-adjusted hazard ratios for mortality in adults with 5 compared with zero low-risk factors were 0.26 (95% confidence interval [CI], 0.22–0.31) for all-cause mortality, 0.35 (95% CI, 0.27–0.45) for cancer mortality, and 0.18 (95% CI, 0.12–0.26) for cardiovascular disease mortality. The population-attributable risk of nonadherence to 5 low-risk factors was 60.7% (95% CI, 53.6–66.7) for all-cause mortality, 51.7% (95% CI, 37.1–62.9) for cancer mortality, and 71.7% (95% CI, 58.1–81.0) for cardiovascular disease mortality. We estimated that the life expectancy at age 50 years was 29.0 years (95% CI, 28.3–29.8) for women and 25.5 years (95% CI, 24.7–26.2) for men who adopted zero low-risk lifestyle factors. In contrast, for those who adopted all 5 low-risk factors, we projected a life expectancy at age 50 years of 43.1 years (95% CI, 41.3–44.9) for women and 37.6 years (95% CI, 35.8–39.4) for men. The projected life expectancy at age 50 years was on average 14.0 years (95% CI, 11.8–16.2) longer among female Americans with 5 low-risk factors compared with those with zero low-risk factors; for men, the difference was 12.2 years (95% CI, 10.1–14.2).

CONCLUSIONS: Adopting a healthy lifestyle could substantially reduce premature mortality and prolong life expectancy in US adults.

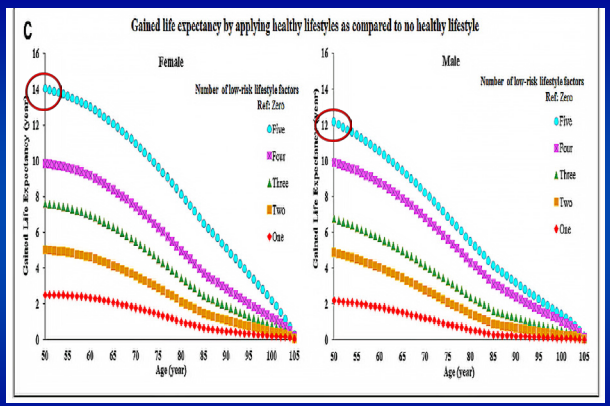
RECENT BLOCKBUSTER STUDY

Circulation 2018;137:00-00, DOI: 10.1161
Circulation/AHA, 117.032047

Results: Clinical Implications*

- During up to 34 years of follow-up, adherence to 5 low-risk lifestyle-related factors could prolong the life expectancy at age 50 years by 14.0 and 12.2 years for female and male U.S. adults compared with individuals who adopted zero low-risk lifestyle factors. The most physically active cohorts of men and women demonstrated 7-to-8 year gains in life expectancy.

Li Y et al. Circulation 2018



Li Y et al. Circulation 2018

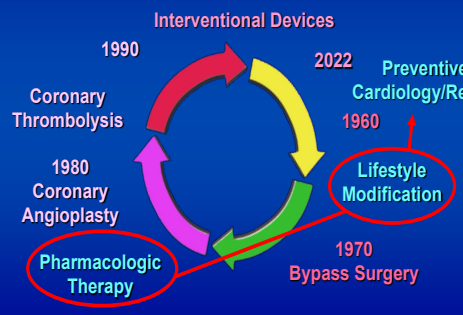
Practical Implications

- Americans could narrow the life-expectancy gap between the U.S. and other industrialized countries by adopting a healthier lifestyle
- Prevention should be a top priority for national health policy, and preventive care should be an indispensable part of the U.S. healthcare system.

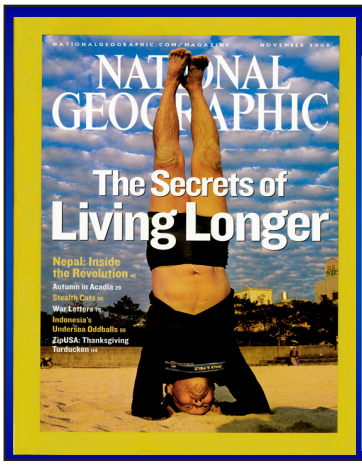
Conclusion

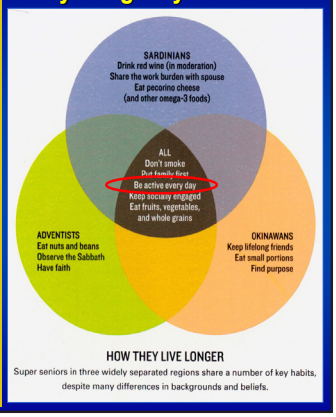
Last 5 slides

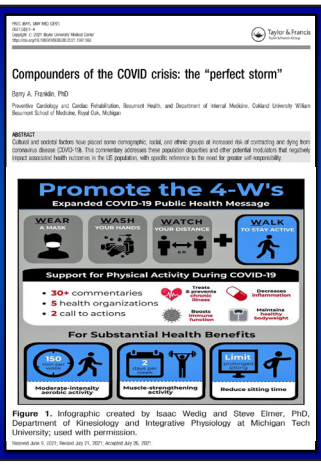
Evolutionary Treatment of Heart Disease: Value of Risk Reduction



5 Key Longevity Habits +1







- Consistently meeting physical activity guidelines is associated with a reduced likelihood for hospitalization, ICU admission, and death among patients with COVID-19.*
- Cardiorespiratory fitness is inversely associated with the likelihood of hospitalization due to COVID-19. The higher the fitness, the lower the risk of hospitalization.+

* Sallis R, et al. Br J Sports Med 2021
+ Brawner CA, et al. Mayo Clin Proc 2021

Moving from Our Reactive Sick Care Model to Proactive Health Care….

Health care will soon account for $1 out of every $5 spent in the U.S. If these trends continue, health care will soon become unaffordable, unless we find ways to implement effective preventive interventions.

Marvasti FF, et al. N Engl J Med 2012;367:889

The Challenge ? Beyond Acute and Palliative Care…

Contemporary healthcare providers need to become champions of achieving healthy lifestyle overhauls in the patients we serve---well beyond the acute and palliative care provided in our emergency centers, surgical suites, cath labs, hospital rooms, and physician offices. The "paradigm shift"needs to move from not only helping patients when they are ill, injured, or sick, to "helping patients help themselves (24/7) ." Compliance with prescribed cardioprotective medications and aggressive lifestyle modification, are the keys to achieving a healthy lifestyle. Bottom Line?

GREATER RESPONSIBILITY ON THE PATIENT !!!

SELF EVALUATION

Cardiovascular Disease Lifestyle Risk Factor and Behavioral Therapies

1. According to a landmark study (using intravascular ultrasound) from the Cleveland Clinic, _____% of individuals over the age of 50 have subclinical evidence of coronary atherosclerosis.

a. 10
b. 25
c. 60
d. 85

2. Which of the following is not considered a foundational lifestyle risk factor for coronary heart disease?

a. chronic stress
b. poor dietary habits
c. physical inactivity
d. smoking

3. Two landmark studies have shown that life expectancy was shortened by ~ ____ years among current smokers, as compared with those who had never smoked.

a. 5 – 7
b. 8 – 9
c. 10 – 12
d. 14 – 16

4. Regular exposure to secondhand smoke increases the risk of coronary heart disease and cardiac events by approximately _____%.

a. 10
b. 20
c. 30
d. 45

5. The American Heart Association recommends limiting the amount of trans fats you eat to less than _____% of your total daily calories.

a. 1
b. 3
c. 5
d. 10

6. According to recent cohort study of > 2,000 adults with a mean follow-up of nearly 11 years, participants taking at least _____ steps/day, compared with their less active counterparts, had a 50% to 70% lower risk of mortality.

a. 2,000
b. 4,000
c. 7,000
d. 10,000

7. Exercise training intensities >____ METs are needed to move clients/patients out of the least fit, least active “high risk” cohort?

a. 1
b. 3
c. 5
d. none of the above

8. According to a recent blockbuster study, during up to 34 years of follow-up, adherence to 5 low-risk lifestyle-related factors could prolong the life expectancy at age 50 years by ___ and ___ years for women and men, respectively, compared with their counterparts who adopted none of these lifestyle factors.

a. 8 & 6
b. 10 & 8
c. 12 & 10
d. 14 & 12

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

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Current Abortive and Preventive Treatment Options for Migraine

Migraine Rx Algorithm

Abortive Rx

Tier 1	NSAID	Timolol Ophthalmic
Tier 2	Triptan	
Tier 3	Gepant	Ditan

Prophylactic Rx

Tier 1	β-blocker (nadolol,* bisprolol,* propranolol*)
Tier 2	Anticonvulsant (topiramate*)
Tier 3	ARB (candesartan*) or ACE
Tier 4	CGRP-MAB
Tier 5+	CCB, TCA, Botox, Other, Other, Other

Why Migraine Management Should Be a PARTICULARLY POSITIVE Experience for You & Your Patient

Why You Should WELCOME A New Migraine Patient

- Often dissatisfied with current level of disease management (lots of room for improvement)
- Usually, substantial untapped resources
  - Prophylaxis
  - Abortives
- Strong likelihood of meaningful improvements

Migraine

Dx

Migraine without Aura (aka Common Migraine): IHS Criteria Require ≥ 5 attacks fulfilling criteria

- Duration 4-72 hrs
- ≥2 characteristics
  - Unilateral
  - Pulsating
  - Pain mod-severe
  - Aggravated by physical activity
- ≥ 1 of
  - Nausea and/or vomiting
  - Photophobia orphonophobia

Goldsmith CG, Kass JS *Ferri's Clinical Advisor* 2021:900-901

Migraine with Aura (aka Common Migraine): IHS Criteria Require ≥ 2 attacks fulfilling criteria

- Aura with ≥1 fully reversible non-motor characteristic
  - Visual Sx
  - Other sensory Sx
  - Disphasic speech disturbance
- ≥2 Aura aspects
  - Homonymous visual Sx
  - Unilateral sensory Sx
  - Sx develop gradually (>5 mins)
  - Sx last 5-60 mins
- Migraine within 60 mins of aura

Goldsmith CG, Kass JS *Ferri's Clinical Advisor* 2021:900-901

Migraine: Fast-Track Dx

"HA experts have suggested that to improve the recognition of migraine, patients with a stable pattern of episodic, disabling HA and a normal PE should be considered to have migraine in the absence of contradictory evidence."

Tepper SJ, Dahlof CGH, Dowson A, et al Headache 2004;44:856-864

Simple 3 Item Migraine Screen (any 2 of 3 is a POSITIVE Screen)

- Are your headaches
  - disabling (work or recreation)?
  - associated with nausea?
  - associated with photophobia

Sensitivity = 0.81; Specificity = 0.75

Lipton RB, et al Neurology 2003;61:375-382

Simple 3 Item Migraine Screen

"The current study demonstrates that the 3-item ID Migraine Screener, consisting of questions on disability, nausea, and photophobia, is a valid and reliable screening instrument for migraine headaches in the primary care setting."

Lipton RB, et al Neurology 2003;61:375-382

Migraine Workup

"In general, no additional investigation is needed with recurrent, typical attacks with usual age of onset, FHx, and a normal PE."

Goldsmith CG, Kass JS *Ferri's Clinical Advisor* 2021:900-901

Migraine

Red Flags

Headache Red Flags: SNOOP^{5}S

Systemic Sx (fever Wt loss)	Pregnancy
Neurologic Deficit	Postural
Onset Sudden (Thunderclap)	Papilledema
Older (>50) Onset	Precipitation by Valsalva
Pattern Change	Secondary Immunosuppression (e.g., CA)

Goldsmith CG, Kass JS *Ferri's Clinical Advisor* 2021:900-901

Migraine: Red Flags

INDICATIONS FOR NEUROIMAGING and/or CSF	
•Abrupt onset	•L.O.C.
•Awakens from sleep	•Trigger: exertion, sex, Valsalva
•Neuro Sx > 1hr	•1st/Worst HA
•New HA age <5, >50	•Abnormal PE/neurological XM
•Fundamental change or progression in HA pattern	
•New HA in CA, immunosuppressed, or pregnant patients	

Kaniecki R "Headache Assessment and Management" JAMA 2003;289(11):1430-1433

Migraine

Differential Dx

Migraine Vs Tension vs Cluster

	Migraine	Tension	Cluster
Location	Hemicranial*	Bilateral	Hemicranial
Nature	Throbbing*	Dull Ache	Icepick
Severity	Mod-Severe	Mild-Mod	Severe
Functionality	Disabling	Diminished	Disabling
Behavior	Passive Withdrawal	Irritable Participation	Agitation
Associated Sx	Phobias, N/V	None	Naso-oculo-orbital
Alcohol	Exacerbates	Mitigates	Exacerbates
Gender	F:M 3:1	F>M	M:F 5:1

*in ±50% of patients, at least at onset

adapted from Goldsmith CG, Kass JS *Ferri's Clinical Advisor* 2021:900-901

Migraine Rx

Abortive

Abortive Rxs

- Triptans
- Triptan/NSAID
- Gepants
- Ditans
- Ophthalmic Timolol
- DHE SQ
- Antiemetics

Should You Comply?

"Doc, I've tried everything for these migraines. The only things that really work are **Vicodin** or **Fioricet**…."

Migraine: Dubious Choices Opioids

"Opioids… should not be used for the Rx of migraine, except as a last resort."

Bajwa ZH, et al "Acute Rx of migraine in adults" UpToDate 2016 (August)

Migraine: Butalbital NOT

"There is no evidence to support the use of…butalbital compounds in migraine…."

Emphasis added

Kaniecki R "Headache Assessment and Management" *JAMA* 2003;289(11):1430-1433

Butalbital: Why Not?

"There is no high-quality evidence supporting the efficacy of barbiturates (i.e., butalbital-containing compounds) for acute migraine Rx."

Bajwa ZH, et al "Acute Rx of migraine in adults" UpToDate 2016 (August)

Abortive Rx: Basic Principles

- Early Rx more effective than late Rx
- Large single dose > repetitive small doses
- Oral agent efficacy may be compromised by migraine-related gastric stasis

Bajwa ZH, et al "Acute Rx of migraine in adults" UpToDate 2016 (August)

Abortive Rx: Basic Principles Mild-Moderate Severity Attacks

- NSAIDs
- Acetaminophen
- Aspirin

Alone or combination

- Nausea/vomiting:
  - Oral or rectal antiemetic

Bajwa ZH, et al "Acute Rx of migraine in adults" UpToDate 2016 (August)

Acute Migraine: NSAIDS, Acetaminophen

- Clinical trials: various NSAIDs efficacious
- No head-to-head NSAID comparator trials
- Indomethacin available PO and PR
- Worth trying more than one NSAID
- Acetaminophen
  - 1000 mg effective for mild-moderate migraine
  - Also effective +NSAID or + ASA/caffeine

Bajwa ZH, Sabahat A, "Acute Treatment of Migraine" UpToDate Acc 5/14/12

Migraine: Acetaminophen

"….a RDBPCT of 289 patients…found acetaminophen at a dose of 1000 mg to be highly effective for treating pain, functional disability, photophobia, and phonophobia."

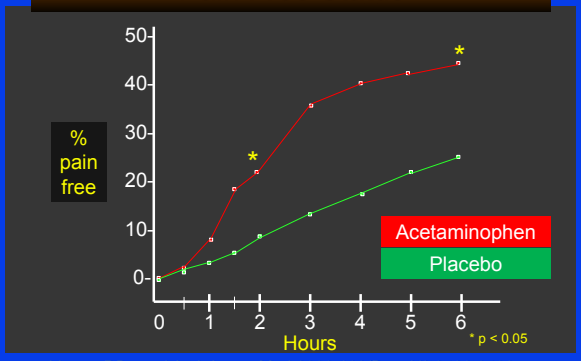
Bajwa ZH, et al "Acute Rx of migraine in adults" UpToDate 2016 (August)

Migraine: Acetaminophen

- Study: RDBPCT Adult Migraneurs (n=351)
- Inclusion:
  - <6 HA/month
  - ≥ Moderate intensity
- Exclusions:
  - HA Severely disabling >50% of episodes
  - Vomiting >20% of episodes
- Rx: acetaminophen 1 g vs placebo

Lipton RB, et al Arch Intern Med 2000;160(Dec 11):3486-3492

Acetaminophen for Migraine: Pain Free Status



Lipton RB, et al Arch Intern Med 2000;160(Dec 11):3486-3492

How 'About Just Excedrin

- FDA review 3 RDDBPC trials (n=1,220)
- Subjects: mod-severe migraine < 6 X/month
- Rx: 2 XS Excedrin at onset (= 65 mg caffeine, 250mg acetaminophen, 250 mg ASA)
- Results at 2 hrs: 59% = resolved/sig subsided (placebo = 33%)

Modern Medicine 1997; 65: 8

Migraine: NSAIDs

"….all NSAIDs may be beneficial in patients who have migraine, with or without aura."

Bajwa ZH, et al "Acute Rx of migraine in adults" UpToDate 2016 (August)

Triptans: MOA

- Serotonin 1b/1d agonists
- Inhibit release of vasoactive peptides
- Vasoconstriction
- Block brainstem pain pathways
- ↓ calcitonin gene related peptide (CGRP)

Bajwa ZH, et al "Acute Rx of migraine in adults" UpToDate 2016 (August)

Triptans: Any Difference?

- Study: 53 clinical trials (n=24,089)
- ORAL Triptans:
  - Almo
  - Frova
  - Riza
  - Zolmi
  - Ele
  - Nara
  - Suma
- Measured
  - Efficacy
  - Consistency

Ferrari MD, Roon KI, Lipton RB, Goadsby PJ "Oral triptans in acute migraine Rx: a meta-analysis of 53 trials" Lancet 2001;358:1668-75

Triptan Meta-analysis: Results

"…all oral triptans were effective and well tolerated."

Ferrari MD, Roon KI, Lipton RB, Goadsby PJ "Oral triptans in acute migraine Rx: a meta-analysis of 53 trials" *Lancet* 2001;358:1668-75

Triptans : Is There a Difference?

"We agree that in terms of safety and appropriate patient selection there appears to be no difference among the triptans…."

Mannix LK, Wang JT Response to LTE on Triptans and Chest Sx Am J Managed Care 2002;8(8):693-695

Triptan Timing : Earlier is Better

- STUDY: Migraneurs (n=2,074) for ± 21,000 headaches over 1 year
- Rx: zolmitriptan 2.5 mg (open label)
- 2 hour pain free rates as per baseline intensity
  - Mild = 84%
  - Moderate = 67%
  - Severe = 45%

Jancin B "Support Grows for Early Triptan Use in Migraine" Family Practice News 2002;June 15: p 20

Triptan Failure: Jump Ship?

- "Failure to respond to one triptan does not predict failure on another…supplementing triptan with an NSAID often speeds relief and reduces the need to redose…"

Marcus DA "Headaches" Conn's Current Therapy Rakel & Bope, Eds. Saunders (Philadelphia) 2003:988-994

Do We Really NEED New Migraine Meds?

"In a meta-analysis of migraine Rx with triptans, up to a third of all people with migraine and 40% of all migraine attacks did not respond…."

Edvinsson L, Linde M *Lancet* 2010;376:645-655

Do We Really NEED New Migraine Meds?

"…but… 20-30% of [attacks] develop a recurrent migraine attack requiring either re-dosing or a rescue medication…."

Bigal ME et al *Headache* 2013;53:1230-1244

Do We Need A New Abortive Rx?

"It has been estimated that 18.6% of women and 19.1% of men aged 22 years or older with episodic migraine have at least 3 CVD risk factors that contraindicate the use of triptans"

Lipton RB et al JAMA 2019;322(19):1887-1898

Triptans: The Tangled Web of CV Contraindications/Precautions

"… 5-HT1 agonists may cause coronary vasospasm, and therefore are contraindicated in patients with known or suspected CAD, angina……arteriosclerosis, silent myocardial ischemia, MI, or other significant cardiac disease."

Triptan Class Labeling 2019

Triptans: The Tangled Web of CV Contraindications/Precautions

"Patients with CAD risk factors (e.g. HBP, DM, hypercholesterolemia, obesity, tobacco, smoking, strong family Hx, menopause, or male > 40 years old) should not be given [a triptan] unless a cardiac evaluation determines they are reasonably free of CAD, myocardial ischemia, or other significant cardiac disease."

Triptan Class Labeling 2019

Why Dexamethasone?

"When added to standard abortive therapy for migraine headache, single dose parenteral dexamethasone is associated with a 26% relative reduction in headache recurrence (NNT =9) within 72 hours."

Colman I et al "Parenteral dexamethasone for acute severe migraine headache" BMJ 2008;336:1359-1366

Nonpharmacologic Rx

Up to 25% of migraine sufferers can manage their attacks without drugs, or with minimal medication, by eliminating triggers such as dietary change, and environmental stimuli.

Edmeads J. "Four steps in managing migraine" Postgrad Med 1989;85:121-134

JAMA | Original Investigation

Effect of Ubrogepant vs Placebo on Pain and the Most Bothersome Associated Symptom in the Acute Treatment of Migraine
The ACHIEVE II Randomized Clinical Trial

Richard B. Lipton, MD; David W. Dodick, MD; Jessica Ailani, MD; Kaifeng Lu; Armin Szegedi, MD; Joel M. Trugman, MD

Oral CGRP-R Antagonist

IMPORTANCE Ubrogepant is an oral calcitonin gene-related peptide receptor antagonist under investigation for acute treatment of migraine.

Supplemental con
CME Quiz at jamanetwork.com

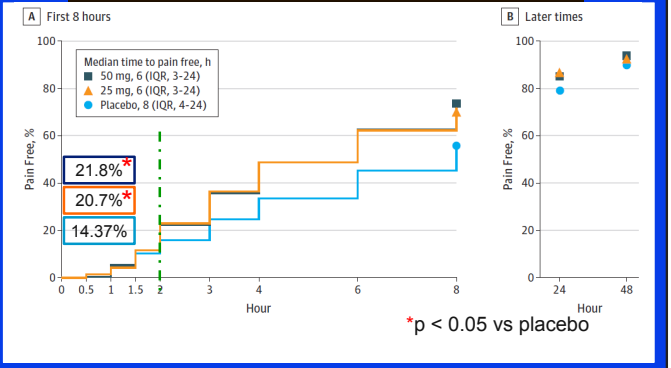
Lipton RB et al JAMA 2019;322(19):1887-1898

Ubrogepant: Migraine Abortive

- Study: RDBPCT single migraine attack
- Rx: ubrogepant (25mg or 50mg) vs placebo
- Inclusion (n=1,686):
  - Classic or common migraine
  - 2-8 attacks/month
- Outcomes
  - Pain free at 2 hours
  - Absence of most bothersome Sx at 2 hrs

Lipton RB et al JAMA 2019;322(19):1887-1898

Ubrogepant: % Pain Free



*p < 0.05 vs placebo

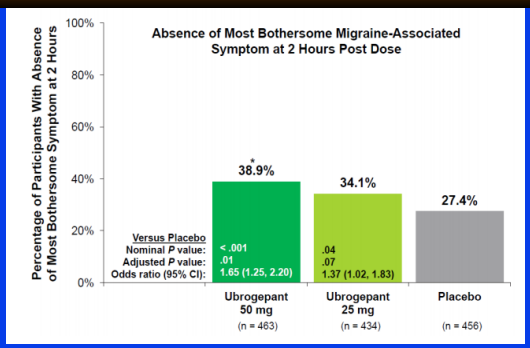
Lipton RB et al JAMA 2019;322(19):1887-1898

Ubrogepant: Most Bothersome Sx

	Ubrogepant N(%) 25 mg	50 mg	Placebo N(%)
Photophobia	257 (59.1)	265 (57.1)	245 (53.7)
Phonophobia	102 (23.4)	115 (24.8)	136 (29.8)
Nausea	75 (17.2)	83 (17.9)	75 (16.4)

Lipton RB et al JAMA 2019;322(19):1887-1898

Ubrogepant: *Most Bothersome* Sx Freedom at 2 Hours



Lipton RB et al JAMA 2019;322(19) e-Supplement 2:1887-1898

Lasmiditan: The Beginning of the Story

"Lasmiditan is a novel, highly selective and potent agonist at 5-HT_{1F} receptors that lacks vasoconstrictor activity….antimigraine efficacy…is mediated through a non-vascular, primarily neural, mechanism."

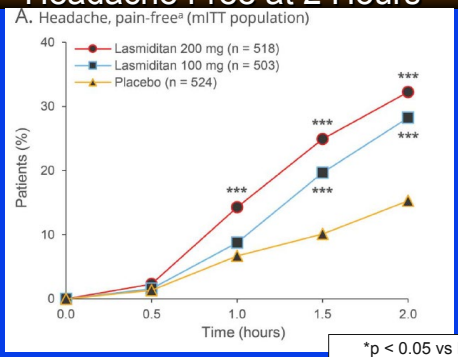
Ferrari MD et al *Cephalalgia* 2010;30(1):1170-1178

Lasmiditan: Migraine Abortive

- Study: RDBPCT migraneurs (n= 1,856)
- Rx: lasmitidan 100mg or 200 mg (1 dose)
- Inclusion:
  - age ≥18, classic or common migraine
  - 3-8 migraines/month
- Outcomes:
  - 1^0: Headache-free at 2 hours
  - 2^0: Most bothersome Sx-free at 2 hours

Kuca B et al *Neurology* 2018:91(24):e1-e11

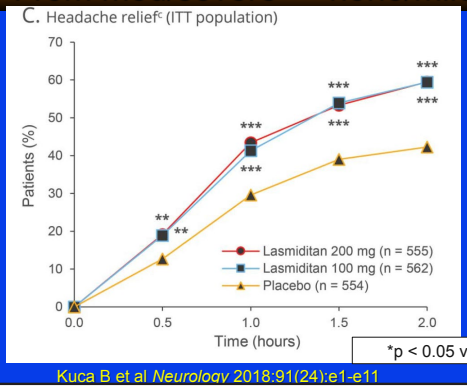
Lasmitidan Headache Free at 2 Hours



*p < 0.05 vs PBO

Kuca B et al *Neurology* 2018:91(24):e1-e11

Headache Responder Rate (= From mod/severe → none/mild



*p < 0.05 vs PBO

Kuca B et al *Neurology* 2018:91(24):e1-e11

Lasmiditan Tolerability (%)

	Placebo	100 mg	200 mg
Dizziness	3.4	12.5	16.3
Paresthesia	2.1	5.7	7.9
Somnolence	2.3	5.7	5.4
Nausea	1.9	3.0	5.3
Fatigue	0.3	4.1	3.1
Lethargy	2.5	1.9	0.3

Kuca B et al *Neurology* 2018:91(24):e1-e11

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use REYVOW safely and effectively. See full prescribing information for REYVOW.

REYVOW (lasmiditan) tablets, for oral use, CV
Initial U.S. Approval: 2020

---------- INDICATIONS AND USAGE ----------

REYVOW™ is a serotonin (5-HT) 1F receptor agonist indicated for the acute treatment of migraine with or without aura in adults. (1)

Limitations of Use

REYVOW is not indicated for the preventive treatment of migraine. (1)

----------DOSAGE AND ADMINISTRATION----------

- The recommended dose is 50 mg, 100 mg, or 200 mg taken orally, as needed. (2)
- No more than one dose should be taken in 24 hours. (2, 5.1)

----------DOSAGE FORMS AND STRENGTHS----------

Tablets: 50 mg, 100 mg (3)

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use REYVOW safely and effectively. See full prescribing information for REYVOW.

REYVOW (lasmiditan) tablets, for oral use, CV
Initial U.S. Approval: 2020

----------WARNINGS AND PRECAUTIONS ----------

- Driving Impairment: Advise patients not to drive or operate machinery until at least 8 hours after taking each dose of REYVOW. Patients who cannot follow this advice should not take REYVOW. Patients may not be able to assess their own driving competence and the degree of impairment caused by REYVOW. (5.1)

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use REYVOW safely and effectively. See full prescribing information for REYVOW.

REYVOW (lasmiditan) tablets, for oral use, CV
Initial U.S. Approval: 2020

7.3 Heart Rate Lowering Drugs

REVOW has been associated with a lowering of heart rate. In a drug interaction study, addition of a single 200 mg dose of REYVOW to propranolol ↓heart rate by an additional 5 bpm compared to propranolol alone, for a mean maximum of 19 bpm. Use REVOW with caution in patients taking concomitant meds that lower heart rate if this magnitude of heart rate decrease may pose a concern.

Why is Lasmitidan Controlled (Schedule V)?

9.2 Abuse

In a human abuse potential study in recreational poly-drug users (n=58), single oral therapeutic doses (100 and 200 mg) and a supratherapeutic dose (400 mg) of REYVOW were compared to alprazolam (2 mg) and placebo. With all doses of REYVOW, subjects reported statistically significantly higher 'drug liking' scores than placebo, indicating that REVOW has abuse potential….

Why is Lasmitidan Controlled (Schedule V)?

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use REYVOW safely and effectively. See full prescribing information for REYVOW.

REYVOW (lasmiditan) tablets, for oral use, CV
Initial U.S. Approval: 2020

9.2 Abuse

…[in the trial with poly-substance users] euphoric mood occurred to a similar extent with REYVOW 200 mg, REYVOW 400 mg, and alprazolam 2 mg (43-49%)….

Lasmiditan PO: Conclusions

"Oral lasmiditan seems to be safe and effective in the acute Rx of migraine."

Farkkila M et al Lancet Neurol 2012;11:405-413

And 1
'migraine upgrade'

Research

JAMA Ophthalmology | Original Investigation

Short-term Efficacy and Safety of Topical β-Blockers (Timolol Maleate Ophthalmic Solution, 0.5%) in Acute Migraine
A Randomized Crossover Trial

Abraham Kurian, MS, DO; Iodine Reghunadhan, DNB; Pratibha Thilak, MBBS, DNB; Indulekha Soman, MBBS, DNB; Unnikrishnan Nair, MS

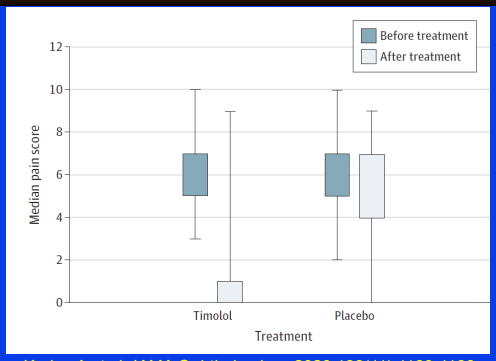
JAMA Ophthalmology 2020;138(11):1160-1166

Migraine Abortive:
Ophthalmic Beta Blocker (timolol maleate 0.5%)

- Study: RDBPCT migraneurs (n=50)
- Rx:
  - timolol 0.5% ophthalmic solution 1gtt each eye at headache onset
  - may repeat at 10 mins
- Outcome: Pain score at 20 mins

Kurian A et al *JAMA Ophthalmology* 2020;138(11):1160-1166

Migraine Abortive:
Ophthalmic Beta Blocker (timolol maleate 0.5%)



Kurian A et al *JAMA Ophthalmology* 2020;138(11):1160-1166

Migraine

PROPHYLAXIS

Initiating *Prophylactic* Pharmacotherapy

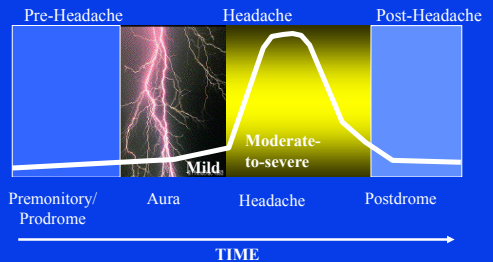
The "Literature View"

"Prophylactic Rx is generally indicated when HA are disabling >5 days/mo or when Sx Rxs are contraindicated or not effective."

Goldsmith CG, Kass JS *Ferri's Clinical Advisor* 2021:900-901

My View
Whenever the informed patient prefers

The "Process" of Headache in Migraine



Cady RK. *Headache* Q. 2001

Migraine : The Broader Picture

PRODROME	Aura ±1 hour	POSTDROME
• ↓activity • mood Δ's • Cravings • Fluid retention	HA	• Fatigue • Concentration Δ's • Food intolerance • Myalgias
12-36 hrs	≤72 hrs	≤ 24 hrs

Diamond S. "A fresh look at migraine therapy" Postgraduate Medicine 2001;109(1):49-60

Pharmacologic Rx : Prevention

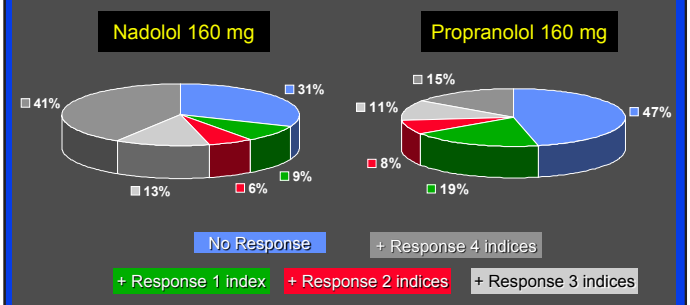
- Beta Blockers
- TCAs
- CCB's
- SSRI's
- Clonidine
- Cyproheptadine
- Methysergide
- ACEs
- ARBs
- Riboflavin
- Coenzyme Q
- Feverfew
- Montelukast
- Topiramate

Which Beta Blocker?

- Study: DBRCT migraneurs (n=140)
- Rx: nadolol 80 mg or 160 mg qd vs propranolol 80 mg bid X 12 weeks
- Outcomes:
  - 4 indices: frequency, intensity, # days headache, need for backup meds
  - Success defined as ≥50% improvement
  - Tolerability

Sudilovsky A, Elkind AH, Ryan RE, et al "Comparative Efficacy of Nadolol and Propranolol in the Management of Migraine" Headache 1987;27:421-26

Nadolol 160 mg/d vs Propranolol 160 mg/d at 2 months



Sudilovsky A, Elkind AH, Ryan RE, et al "Comparative Efficacy of Nadolol and Propranolol in the Management of Migraine" Headache 1987;27:421-26

Nadolol v Propranolol: AEs

- Adverse Events → D/C
  - Propranolol 80 mg bid: 9.1%
  - Nadolol 160 mg qd: 4.1%

Sudilovsky A, Elkind AH, Ryan RE, et al "Comparative Efficacy of Nadolol and Propranolol in the Management of Migraine" Headache 1987;27:421-26

Migraine Prophylaxis: ARB?

- Study: RDBPCT adult migraneurs (n=60)
- Inclusion: 2-6 attacks/month
- Rx: Candesartan 16mg qd vs Placebo X 12 weeks with 12 week XO design
- Primary Endpoint: # days with HA

Tronvik E, Stovner LJ, Helde G, et al "Prophylactic Rx of Migraine with an ARB" JAMA 2003;289:65-69

Candesartan Migraine Prophylaxis: Results

Endpoint	Candesartan	Placebo	P value
# HA days	13.6	18.5	0.001
# hours with HA	95	139	<0.001
HA severity index	191	293	<0.001
Disability Score	14.1	20.6	<0.001
Days of sick leave	1.4	3.9	0.01

Tronvik E et al JAMA 2003;289:65-69

Candesartan Migraine Prophylaxis

CONCLUSION

"…the ARB candesartan provided effective migraine prophylaxis, with a tolerability profile comparable with that of placebo."

Tronvik E et al JAMA 2003;289:65-69

Migraine Prophylaxis: ACEi

- Study: RDBPCT adult migraneurs (n=60)
- Inclusion: typical migraine, 2-6 X/m
- Rx: lisinopril 20 mg/d X 12 weeks (1 week titration at 10 mg/d) plus XO for 12 weeks
- Primary Outcome (ITT analysis): # days with migraine, #hours with migraine

Schrader H, Stovner IJ, Helde G, et al "Prophylactic Rx of migraine with ACEi lisinopril" BMJ 2001;322:19-22

ACEi Migraine Prophylaxis: Results

- Mean reduction in #HA hours: 15%
- #Days with headache ↓ 16%
- 50% ↓ HA days: 25%

Schrader H, Stovner IJ, Helde G, et al "Prophylactic Rx of migraine with ACEi lisinopril" BMJ 2001;322:19-22

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Controlled Trial of Erenumab for Episodic Migraine

Peter J. Goadsby, M.D., Ph.D., Uwe Reuter, M.D., Yngve Hallström, M.D., Gregor Broessner, M.D., Jo H. Bonner, M.D., Feng Zhang, M.S., Sandhya Sapra, Ph.D., Hernan Picard, M.D., Ph.D., Daniel D. Mikol, M.D., Ph.D., and Robert A. Lenz, M.D., Ph.D.

NEJM 2017;377(22):2123-2132

Episodic Migraine: Erenumab

- Study: RDBPCT migraine (n=955)
- Inclusion:
  - Age 18-65 yrs
  - Common or Classic
  - ≥4 headache days/month (and <15)
  - ≥80% adherence during baseline
- Rx: erenumab SQ 70mg or 140mg q month vs placebo X 6 months

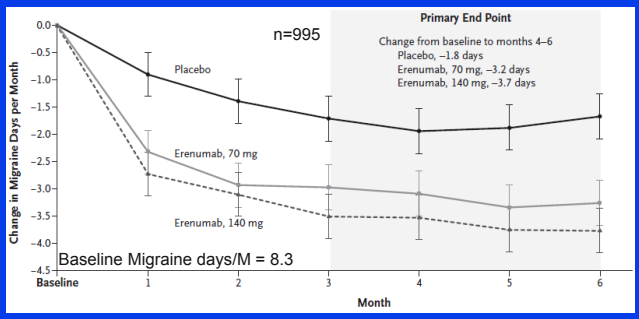
Goadsby PJ et al *N Engl J Med* 2017;377(22):2123-32

Episodic Migraine: Erenumab

- 1^0 Outcome: Δ from baseline to months 4-6 in mean # migraine days/month
- 2^0 Outcomes
  - Per cent with ≥ 50% ↓ migraine days/month
  - Days using acute migraine Rx
  - Migraine Physical Function Impact Diary Score

Goadsby PJ et al *N Engl J Med* 2017;377(22)2123-32

Episodic Migraine: Erenumab Δ Migraine Days/M



Goadsby PJ et al *N Engl J Med* 2017;377(22):2123-32

Migraine Rx Algorithm

Abortive Rx

Tier 1	NSAID	Timolol Ophthalmic
Tier 2	Triptan	
Tier 3	Gepant	Ditan

Prophylactic Rx

Tier 1	β-blocker (nadolol,* bisprolol,* propranolol*)
Tier 2	ARB (candesartan*) or ACE
Tier 3	Anticonvulsant (topiramate*)
Tier 4	CGRP-MAB
Tier 5+	CCB, TCA, Botox, Other, Other, Other

SCIENTIFIC REPORTS

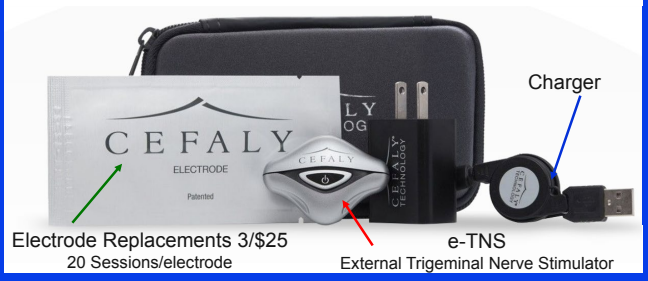
OPEN

The safety and preventive effects of a supraorbital transcutaneous stimulator in Japanese migraine patients

Received: 22 October 2018
Accepted: 20 June 2019
Published online: 09 July 2019

Danno D et al *Nature.com Scientific Reports* 2019;9:990:2-7

$499 (COVID Sale $399)



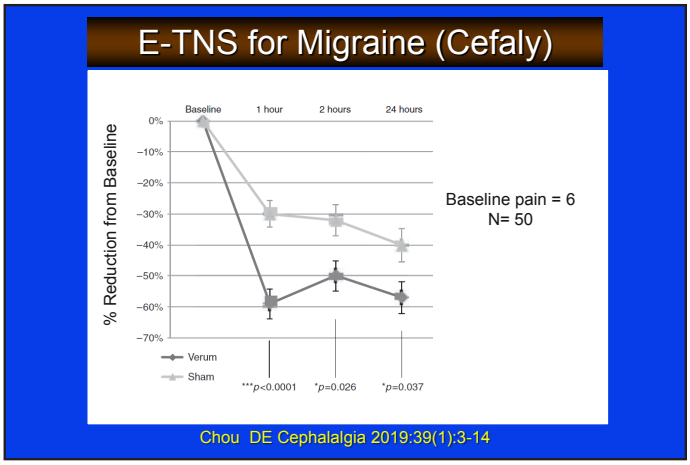
Electrode Replacements 3/$25
20 Sessions/electrode

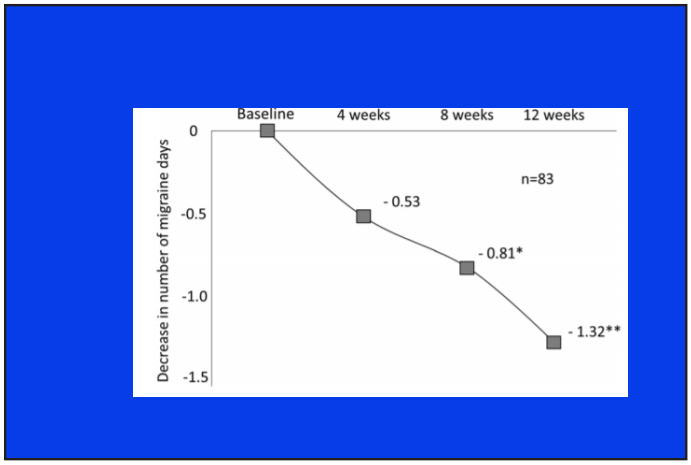
e-TNS
External Trigeminal Nerve Stimulator

Cefaly.com Website
Accessed January 10, 2021

Cefaly Device In Place

Cefaly.com Website
Accessed January 10, 2021





SELF EVALUATION

Current Abortive and Preventive Treatment Options for Migraine

1. Amongst the class of triptans for migraine abortive treatment, the most effective agent is

a. frovatriptan
b. sumatriptan
c. rizatriptan
d. Essentially all triptans are comparably effective

2. The role of butalbital-containing migraine medication is best described as:

a. Butalbital should be a 'last resort' consideration, and not routinely used because of potential for misuse, addiction, and the stark absence of efficacy for migraine
b. Butalbital is an appropriate 1st line treatment
c. Butalbital has numerous positive clinical trials demonstrating excellent efficacy
d. Because the dose of butalbital in current meds is so small, misuse is not an issue

3. Erenumab, fremanezumab and galcanezumab are all representative of a migraine prophylaxis class of

a. Parenteral CGRP Monoclonal Antibody drugs
b. Oral CGRP Antagonists
c. Oral Delta-Gated Calcium Channel Blockers
d. Oral Serotonin 1G receptor antagonists

4. Which recently approved migraine abortive is limited by the need to not drive within 8 hours of dosing

a. The CGRP MAB erenumab
b. The CGRP MAB fremanezumab
c. The 'gepant' ubrogepant
d. The 'ditan' lasmiditan

5. Beta blockers are a well recognized 1st line PROPHYLACTIC treatment for migraine. Which agent below has been demonstrated to have favorable effects as an acute ABORTIVE agent for migraine?

a. Oral pindolol
b. Intravenous labetolol
c. Ophthalmic timolol
d. Rectal sotalol

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

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Frederick M. Cummings, Esq., of Phoenix, Arizona, is a trial attorney with the law firm of Gust Rosenfeld with extensive experience in the areas of healthcare, medical malpractice, and medical products liability defense litigation. He has represented more than 1,000 physicians and dentists in malpractice suits before federal and state courts and in state disciplinary and licensing proceedings, and has also defended major Arizona hospitals, medical products manufacturers, distributors and retailers. Mr. Cummings is a frequent speaker and writer on topics related to medical and dental liability issues and has been featured on numerous local and national "Best Lawyers" lists including the current 28th edition of "Best Lawyers in America".

You may contact Mr. Cummings with your questions or comments at FCummings@GustLaw.com, or by phone at 602-615-0488.

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Anatomy of a Malpractice Lawsuit – Parts 1 & 2

Legal Disclaimer

(you should have expected this)

This is a general description of common problems. It is not a substitute for legal advice. Consult your own qualified attorneys in your state for advice. These are just my opinions.

GUST ROSENFELD PLC 1

Ten Notable Physician – Related Malpractice Statistics

1. Most physicians will face a malpractice lawsuit at some point in their careers.
2. Failure to diagnose is a leading driver of malpractice allegations.
3. General Surgery and Obstetrics and Gynecology physicians are most likely to be sued.
4. Pediatricians and Psychiatrists are least likely to be sued.
5. More malpractice payouts are made to female patients.
6. Patients aged 40-59 years account for the highest number of malpractice payouts.
7. Physicians often win malpractice lawsuits.
8. Malpractice payouts are costing less.
9. Most payouts are due to settlements, not judgments.
10. Five states in the USA continue to have the highest payouts rates. These are Florida, New Jersey, California, Pennsylvania and New York.

GUST ROSENFELD PLC 2

How common are medical malpractice suits among medical professionals?

- According to the New England Journal of Medicine, 99% of physicians face at least one lawsuit by age 65.
- According to data from the Rand Corporation, the average physician spends over ten percent of his or her career dealing with litigation.

GUST ROSENFELD PLC 3

4

5

6

As many as four in ten people believe they have been subject to certain medical malpractice in the past. Some of the most common medical errors are diagnostic failure, surgical error, and medication error.

GUST ROSENFELD PLC 7

The number one reason for medical malpractice is misdiagnosis or delayed diagnosis, **medical malpractice statistics** confirm. Due to misdiagnosis or delayed diagnosis, patients miss the chance to get treatment at the right time and put themselves at a higher risk of long-term injuries or even death.

GUST ROSENFELD PLC 8

Up to 73% of patients who have been subject to medical malpractice were directly injured by the error.

However, even though the number of medical errors is so high, only 1% of those will end up in a lawsuit.

GUST ROSENFELD PLC 9

- 41% of people claim they've been victims of medical malpractice.
- 48% of the malpractice cases include more than one person.
- Surgeons are the most likely medical professional to get into a lawsuit – 85%
- 78% of all medical malpractice claims don't result in any payment.
- 25% of physicians have lost faith in their patients because of medical malpractice lawsuits.

GUST ROSENFELD PLC 10

How many cases of medical malpractice are there?

There have been on average 12, 414 cases of medical malpractice reported to the NPDB annually for the past decade (2009-2018).

GUST ROSENFELD PLC 11

Have medical malpractice reports increased or decreased in recent years?

From 2009-2018, the number of medical malpractice reports has decreased from 14,017 to 11,429 – an 18.5% decrease.

GUST ROSENFELD PLC 12

What state had the most reports of medical malpractice?

- According to NPDB data, New York had the largest amount of medical malpractice reports from 2009-2018, with 16,688 – followed by California and Florida with 1, 157 and 10,788 reports, respectively.
- North Dakota only had 126 total reports of medical malpractice – the lowest by far within the continental United States.

GUST ROSENFELD PLC 13

How much is the average medical malpractice settlement?

According to NPDB data, the average payout for a medical malpractice claim for 2009-2018 was approximately $309,908.

GUST ROSENFELD PLC 14

How many people are killed by medical mistakes?

According to a study by John Hopkins University, more than 250,000 people in the U.S. die every year from medical errors and negligence. This makes medical malpractice the third-leading cause of death in the United States.

GUST ROSENFELD PLC 15

This number includes:

- 12,000 deaths each year due to unnecessary surgical procedures
- 7,000 deaths each year caused by medication errors in hospitals
- 20,000 deaths each year from other hospital errors
- 80,000 deaths each year from infections contracted in hospitals
- 106,000 deaths each year from adverse side effects of or reactions to medications

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Who Can Be Held Accountable for Medical Malpractice?

Generally speaking, a medical malpractice claim may be pursued against those who provided medical or health care to a patient, including physician, registered nurses, hospitals, dentists, nursing homes, and pharmacists. Medical malpractice claims may be brought about against individuals, partnerships, professional associations and corporations.

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How long does a medical malpractice lawsuit take?

- The time spent on a medical malpractice suit may vary. A 2006 study by the New England Journal of Medicine found that the average time for a medical malpractice suit took five years from the moment of the injury/damage to the closing of the case.
- However, a 2017 Medscape survey of physicians indicates that the majority of medical malpractice lawsuits took one to two years.

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38% of lawsuit plaintiffs have received a monetary award of $500,000 or less.

(Source: Medscape Malpractice Report 2019)

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What are some of the largest medical malpractice payouts in U.S. History?

- $216.7 million – awarded to Allan Navarro by a Florida jury for a misdiagnosis of stroke symptoms.
- $190 million – awarded to 8,000 plaintiffs by Johns Hopkins Hospital in 2014 on behalf of Dr. Nikita Levy, a gynecologist who had been secretly taking photos and recording videos of his patients.
- $172 million – awarded to Tiffany Applegate by a Bronx jury in 2014 for improper care and advice by paramedics, leading to severe brain damage and paralysis.

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A 2017 survey of more than 4000 physicians gave insight into some interesting questions from the perspective of the medical industry.

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- 58% of physicians who were sued stated they were "very surprised" by the lawsuit.
- 89% of physicians who were named in a malpractice suit believed that the suit was unwarranted.
- 49% of physicians surveyed stated they were named in 2-5 lawsuits.
- 49% of physicians said that there was no event that sparked the lawsuit or would have.

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Some Legal Terms You Should Know

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Litigation

Is the act or process of bringing about or contesting a lawsuit or all lawsuits collectively.

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Sue

To undertake legal proceedings or to take legal action against somebody to obtain something, usually compensation for a wrong.

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Medical Malpractice

Is professional negligence by act or omission by a health care provider in which care provided deviates from accepted standards of practice in the medical community and causes injury to the patient.

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Negligence

Refers to the failure of a person to exercise sufficient care in his or her conduct. When a person's conduct falls below the reasonable expectation of society and causes foreseeable harm to another, the person has acted negligently.

A professional who injures a client by providing care that is below the standard for that profession commits the tort of malpractice. A physician who is not able to cure a patient has not committed malpractice. However, a physician who removes the wrong lung or ovary during a surgery has committed malpractice. Most cases of medical malpractice proceed under the rules of common law, the body of legal judicial opinion derived from precedent cases rather than statutory or legislative rules. Alleged acts of medical malpractice are almost always tried as torts, governed by the rules of common law.

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Tort

Wrongful act that causes injury to a person or property and for which the law allows a claim by the injured party to recover damages (usually money).

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Torts, in the context of medical malpractice, can be intentional, unintentional (or negligent).

i) **Intentional torts:** Most intentional tors in the context of medical practice are clams of **battery**. However, even these are rare in the physician-patient context. **Battery** is broadly defined as unwanted, harmful, or offensive bodily contact that occurs without consent.

ii) **Unintentional torts (Torts based on negligence):** Most malpractice claims in the medical context are filed as **unintentional torts (negligence).** These claims are based on allegations that damages resulted from the violation of one or more standards of care.

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In such negligence torts, legal responsibility is established by proving 4 elements:

- **Duty**
- **Breach of duty**
- **Causation**
- **Damages**

GUST ROSENFELD PLC 30

Duty and the Breach of Duty

The duty of the physician is the legal responsibility to cause no harm and to act in accordance with established standards of care. **A breach of duty** occurs when the physician does not adhere to established methods of diagnosis and treatment or to applicable standards of care.

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Causation

Is the link or proximate cause between a breach of duty and the injury sustained by the patient. Unless there is proof of causation, no liability exists. Proving causation in obstetric cases is often problematic and almost invariably complex.

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Damages

The final component in a negligence suit is damages, or the harm(s) suffered by the patient. Damage must be discernible injury in order for the plaintiff to recover compensation.

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Damages can either be:

- Economic (medical expenses, lost wages, etc.) or
- Noneconomic (emotional distress, loss of consortium, pain and suffering, etc.)

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The Summons and Complaint

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Your Participation:

1. Notice to carrier
2. Meeting with attorney
3. Preparing an answer
4. Disclosure statements
5. Settlement conference
6. Your deposition
   a) Preparation
   b) Testimony
7. Expert selection
8. Jury Trial
9. Appeal

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Notice to Carrier

1. Required
2. Prompt time limits on response
3. Appointment of Counsel
4. Assignment to claims representative

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Your Attorney

- Duty to you
- Payment by carrier
- Deductibles
- Expertise

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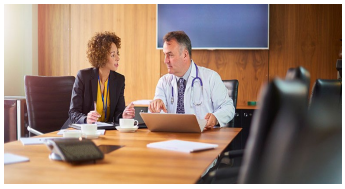
Educating Your Attorney

- Medical records
- Literature
- Expertise



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What Must Be Shown to Prevail in A Medical Practice Case?

While there are various types of medical malpractice claims generally speaking, a claimant must usually show the following:

- The health care providers owed a duty to the patient;
- The health care provider breached that duty;
- The patient suffered an injury; and
- The patient's injury was a proximate cause of the health care provider's breach.

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A physician owes a duty to a patient once a "doctor-patient" relationship has been formed. Such a relationship is usually formed when the physician agrees to care for the patient. Nonetheless, even if it is established that a duty existed and the health care provider breached that duty (e.g. failed to meet the requisite standard of care), a claimant may not recover unless the claimant suffered injuries that were a direct result of the breach. If the breach resulted in no harm to the patient a claimant generally has no right to recovery.

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Burden of Proof

- In a civil lawsuit, the burden of proof rests on the plaintiff – the person or entity bringing the lawsuit.
- The plaintiff must prove the allegations are true and that the defendant caused damages.

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In a medical negligence lawsuit, the plaintiff must usually prove the allegations by a preponderance of the evidence.

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What does the plaintiff have to prove to meet the preponderance of the evidence standard?

- The standard is met if the proposition is more likely to be true than not.

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In other words, the standard is satisfied if there is a greater than 50% chance that the proposition is true.
In other words, more probable than not.

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In medical negligence cases, the legal standard is to a reasonable degree of medical probability.

GUST ROSENFELD PLC 46

It is <u>not</u> beyond a reasonable doubt.
Medical malpractice is not a crime.

GUST ROSENFELD PLC 47

In some states, in some instances, a plaintiff must meet a higher burden of proof than preponderance of the evidence.

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Clear and Convincing

- Clear and convincing means the evidence is highly and substantially more likely to be true than not true.
- The jury or fact finder must be convinced that the contention is highly probable.

GUST ROSENFELD PLC 49

Examples of cases which require higher burden of proof

- Good Samaritans
- Emergency Care
- Baby delivery

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Punitive Damages

1. Defendant's conduct was outrageous, including acts done with malice, bad motives or "an evil mind".
2. Evidenced reckless indifference to the interest of another person.

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Most states require plaintiffs to prove a claim of punitive damages by clear and convincing evidence.

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Colorado requires plaintiff to prove allegations supporting punitive damages beyond a reasonable doubt.

Colorado
§13-25-127(2)
§13-64-302.5

GUST ROSENFELD PLC 53

Most states do not impose caps on punitive damages even if they do so for other types of claims for damages.

8 states cap punitive damages:

- Monetary cap
- % net worth

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Some states prohibit insurance companies covering punitive damage awards as against public policy.

GUST ROSENFELD PLC 55

7 states prohibit punitive damage awards or allow only when authorized specifically by statute such as for wrongful death.

- Contrarian Colorado allows punitive damage awards except for wrongful death.

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7 states require partial payment of a punitive damages award go to the state general fund.

- Utah takes 50% of punitive damages award.

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Your Defense

You
Your Attorney
Your Experts
*Support your care
*Rebut plaintiff expert
*Provide proof of fault of others or of a disease process

Support Personnel
*Nurses
*Paralegals
*I.T.

GUST ROSENFELD PLC 58

What is the statute of limitations on medical malpractice?

The statute of limitations on medical malpractice cases generally varies by state, and may include two separate deadlines:

1. The standard deadline to file a claim starts from the moment the malpractice actually occurred.
2. However, most states have a discovery exception deadline in which the time limit starts when the patient discovers the malpractice – or reasonably should have discovered the malpractice.

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The conduct of the physician is to be judged based on the medical information current at the time.

- Subsequent surgical or therapeutic breakthroughs are not be considered.

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A bad result, a negative outcome, foreseeable complications typically do not presume malpractice.

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Other actors not a party to the lawsuit are at fault.

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EXPERT WITNESS TESTIMONY

GUST ROSENFELD PLC 63

Plaintiff required to meet burden of proof

Almost all states require a plaintiff to meet the burden of proof through expert witness testimony in a medical malpractice case "unless the malpractice is so obvious that a jury does not need an expert to understand the facts". (i.e., scalpel left in patient, amputate wrong leg.)

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Most states require the expert to be a specialist in the same field as the health care provider.

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Many states require the expert to have a combination of academic and/or practical experience or through board certification.

Some states have special rules designated to prevent "career" experts who spend most of their time testifying by requiring the majority of the expert's time be devoted to practicing medicine.

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Expert Witness Services
American Medical
Forensic Specialists
Technical Advisory Service
for Attorneys (TASA)
JurisPro
Seak, Inc.

GUST ROSENFELD PLC 67

Typical Defenses Where Defendant Carries the Burden of Proof

Two Schools of Thought:

- A physician is free to pursue any reasonable course of treatment that another physician would have chosen a different path is not a sufficient reason to find malpractice
- Statute of limitations
- Most states have a statutory time limit as to when a case against a health care provider must be brought
- Your care was not a cause of the patient's alleged harm

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Discovery

- Interrogatories
- Request for Production of Documents
- Disclosure Statements

GUST ROSENFELD PLC 69

Deposition of Defendant

GUST ROSENFELD PLC 70

Preparation

Meeting with your counsel well in advance of deposition.

- Review issues in case thoroughly
- Get background on attorney(s) asking you questions
- Determine problem areas and how to meet them
- Learn what to emphasize, what to downplay, what to avoid
- Practice cross-examination
- Most important deposition in case
- Likeability and bedside manner
- Knowledge of subject matter
- Experience counts

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DO

- Be courteous
- Be direct
- Know your audience
- Testify like you would before peers
- Experts
- Other parties' lawyers
- Review your deposition transcript

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DON'T

- Be rude or condescending
- Argumentative
- Impatient
- Object to questions
- Answer questions with a question
- Read literature to prepare for your deposition
- Criticize your patient
- Exaggerate your expertise or boast about your care

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How are depositions used at trial?

1. To refresh your recollection
2. To impeach trial testimony inconsistent with deposition testimony
3. To question your expert
4. To question the other side's expert
5. To impeach or corroborate other witnesses' testimony
6. To prove elements of case without your explanation

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"Opening the Door"

1. Materials reviewed to prepare for the deposition
2. Medical literature review
3. Conversations with others
4. Conversations with 3rd parties in presence of counsel
5. Criticisms of others

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Considerations

1. Testimony critical of other doctors
2. Testimony critical of patient

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Raise Barriers to Bringing Lawsuits or Reaching Trial

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Statutes of Limitation and Repose

These statutes limit the amount of time that a patient has to file a malpractice claim after discovering an injury or being injured.

New England Journal of Medicine

GUST ROSENFELD PLC 78

Pretrial Screening Panels

Expert panels review malpractice cases at an early stage and provide opinions about whether claims have sufficient merit to proceed.

Typically, a negative opinion does not bar a case from going forward, but to proceed a plaintiff may be required to post a bond and the negative opinion will be admissible evidence at the trial.

New England Journal of Medicine

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Certificate of Merit Requirements

The plaintiff must present, at the time of filing a malpractice claim or soon thereafter, an affidavit certifying that a qualified medical expert believes that there is reasonable and meritorious cause for the suit.

New England Journal of Medicine

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Expert Witness Certification Requirements

Expert witnesses in malpractice suits must have certain credentials, such as licensure in the state where the suit is brought, board certification in a specialty relevant to the lawsuit, or training in the same specialty as the defendant.

New England Journal of Medicine

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Limits on Attorneys' Fees

A limitation is typically expressed as a percentage of the award, but it may also incorporate a maximum dollar value.

New England Journal of Medicine

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Limit the Compensation Plaintiffs May Recover in Lawsuits Caps on Damages

Limitations are placed on the monetary compensation that can be awarded in a malpractice trial for noneconomic losses ("pain and suffering"), economic losses, or both.

A cap may apply to the plaintiff, limiting the amount that the plaintiff may receive, or to a defendant, limiting the total amount that the defendant may be required to pay.

New England Journal of Medicine

GUST ROSENFELD PLC 83

Which states have caps on compensatory damages in medical malpractice?

Six states have caps on total damages in medical malpractice cases – this includes both economic and non-economic damages:

- Colorado
- Indiana
- Louisiana
- Nebraska
- New Mexico
- Virginia

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24 states have caps on non-economic damages:

- Alaska
- California
- Colorado
- Hawaii
- Iowa
- Idaho
- Maryland
- Massachusetts
- Michigan
- Mississippi
- Missouri
- Montana
- North Carolina
- North Dakota
- Nevada
- Ohio
- Oregon
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- West Virginia
- Wisconsin

GUST ROSENFELD PLC 85

20 states have no caps on damages:

- Alabama
- Arizona
- Arkansas
- Connecticut
- Washington D.C.
- Delaware
- Florida
- Georgia
- Illinois
- Maine
- Minnesota
- New Hampshire
- New Jersey
- New York
- Oklahoma
- Pennsylvania
- Rhode Island
- Vermont

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Colorado is the only state in the country with caps on both total damages and non-economic damages. It claims a $1 million "umbrella" cap, while also enforcing a $300,000 limit on non-economic damages.

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Collateral-Source Rule Reform

This reform eliminates a traditional rule stipulating that even if an injured plaintiff has received compensation from other sources (e.g., health insurance), the amount of that compensation should not be deducted from the amount that a defendant who is found liable must pay.

New England Journal of Medicine

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Change How Damages Awards Are Paid Periodic Payment

Insurers are allowed or required to pay malpractice awards over a long period of time rather than in a lump sum.

Insurers may be able to retain any amount that is not collected during a plaintiff's lifetime.

New England Journal of Medicine

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Joint and Several Liability Reform

In malpractice trials involving multiple defendants, the financial liability of each defendant is limited to the percentage of fault that the jury allocates to that defendant.

Without this statutory reform, a plaintiff may collect the entire judgement from one defendant regardless of that defendant's extent of fault in the case.

New England Journal of Medicine

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Nontraditional Approaches to Medical Liability Reform

Communication and Resolution Programs

What is it?

- A program where practitioners openly discuss adverse outcomes with patients and seek solutions, including offering an apology, an explanation of what happened, and if the standard of care was not met, compensation.
- Rather than avoid discussion, expressions of remorse and responsibility may address misunderstandings proactively offering compensation early. Avoid a lawsuit altogether.

Mandatory Presuit Notification Laws

- Some states require plaintiffs to give notice in advance of filing a lawsuit..
- Allows practitioners and the insurers to investigate what happened and attempt to resolve the matter before a lawsuit.

Apology Laws

- "Sorry" Laws protect statements of apology, or fault made to patients by doctors and forbid those statements from being used in malpractice suits against the doctor.
- This encourages care and candid communication with patients that can diffuse misunderstandings and emotions that lead to lawsuit.

Judge-Directed Negotiations/Settlement Conference

- Some courts require malpractice litigants to meet the judge to discuss settlement.
- Judges may nudge parties toward settlement but retain responsibility for the case through trial.

Medical Liability Review Administration Compensation Systems Panels

- An alternative process that uses specialized panels to prescreen liability and damages.
- More reliable than juries.
- Findings may be admissible at trial.

SETTLEMENT CONFERENCE

Mandatory
Voluntary
Consents to Settle

Considerations:

- Economic Risk
- Impact on Practice
- Credentialing
- National Practitioner Data Bank
- Licensing Boards

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TRIAL

Preparation
Attendance
Testimony
Verdict

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APPEAL?

Considerations

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2020 and Beyond . . .

Unknown

- *Could liability immunity
- *Delayed care
- *Telemedicine
- *More complex diagnosis

Trends likely to ↑ medical malpractice claims

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SELF EVALUATION

Anatomy of a Malpractice Lawsuit – Parts 1 & 2

1. T/F - The number one reason for a medical malpractice lawsuit is misdiagnosis or delayed diagnosis?

2. T/F - If you are unable to cure the patient of their disease or injury, you have committed malpractice?

3. T/F - Unless the patient can prove that the injury sustained was caused by your care, you will not have liability for the patient's claim.

4. If you are served with a lawsuit alleging you have committed malpractice, which of the following choices are true?

a. You should put it in your desk drawer and forget about it.
b. You need to call the lawyer you saw on a television ad for help.
c. You should call your malpractice insurance carrier and immediately give notice of the lawsuit you received.
d. You should call the patient's lawyer and try to convince him that you did not commit malpractice.

5. T/F - Your care in a malpractice lawsuit is judged by current standards, even if a medical breakthrough occurred after you have cared for the patient?

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

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TOM VIOLA
PHARMACOLOGY DECLASSIFIED

Cannabis and Terpenes Parts 1 & 2

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 2

Program Learning Objectives

Upon successful completion of this program, participants should be able to:

- Discuss the history of and various types of cannabis, as well as its current legal status available formulations and proposed uses in dentistry.
- Describe the pharmacology of cannabis, including its mechanism of action, routes of administration, adverse reactions, drug interactions and contraindications.

 3

Program Learning Objectives

Upon successful completion of this program, participants should be able to:

- Identify the pharmacologic effects of cannabis on major organ systems.
- Explore the dental considerations of cannabis, including effects on dental treatment, potential treatment modifications, and patient care planning.

 4

Current Legal Status

 5

Controlled Substances

The Controlled Substances Act of 1970 empowered the DEA to regulate the manufacture and distribution of substances with abuse potential.

- Termed "controlled substances", these substances can only be prescribed and dispensed when there is a currently accepted medical use.
- Substances are placed in assigned "schedules" based on abuse potential and accepted uses.

 6

Controlled Substances

- Schedule I
  - Highest potential for abuse
  - Not considered safe for use
  - No accepted medical indication in the U.S.
    - Illegal to possess (on the federal level)
  - Types
    - Heroin
    - LSD
    - Marijuana

 7

Controlled Substances

- Schedule II
  - High potential for abuse
  - High potential for physical and psychological dependence
  - Accepted medical indication (strong restrictions)
  - Types
    - Morphine
    - Oxycodone, hydrocodone
    - Cocaine

 8

Controlled Substances

- Schedule III
  - Some potential for abuse
  - Moderate to low risk of physical dependence
  - High risk of psychological dependence
  - Accepted medical indication (some restrictions)
  - Types
    - Codeine
    - Anabolic steroids

 9

Controlled Substances

- Schedule IV
  - Low potential for abuse
  - Low risk of physical and psychological dependence
  - Accepted medical indication (some restrictions)
  - Types
    - Valium (diazepam)
    - Xanax (alprazolam)

 10

Controlled Substances

- Schedule V
  - Low potential for abuse
  - Limited risk of physical and psychological dependence when used inappropriately
  - Accepted medical indication (few restrictions and available OTC in some states)
  - Types
    - Robitussin with codeine
    - Lyrica (pregabalin)

 11

Access to Cannabis

 12

Access to Cannabis

- Access Varies By State
  - Medical Use
    - Persons meeting the minimum age requirement may use medical marijuana for the treatment of only those qualifying conditions established by legislation
  - Recreational Use
    - Persons meeting the minimum age requirement may use cannabis for recreational purposes.

 13

Access to Cannabis

- Access Varies By State
  - Decriminalized
    - Persons meeting the minimum age requirement can possess a certain amount of cannabis as established by legislation.
  - Public Consumption
    - The ability to consume cannabis in public.
  - Home Cultivation
    - The ability to grow cannabis for personal use.

 14

Medical Marijuana Programs

 15

Medical Marijuana Programs

- Medical Use Legislation Varies By State
  - Standardization
  - Quality Control
  - Labeling
  - Zoning and Location of Dispensaries
  - Qualifying Conditions

 16

Medicial Marijuana Programs

- Most Common Qualifying Conditions
  - ALS
  - Alzheimer's disease
  - Arthritis
  - Cachexia
  - Cancer
  - Crohn's disease
  - Irritable Bowel Syndrome (IBS)
  - Epilepsy/seizures
  - Glaucoma
  - Hepatitis C

 17

Medicial Marijuana Programs

- Most Common Qualifying Conditions
  - HIV/AIDS
  - Nausea
  - Neuropathies
  - Pain
  - Parkinson's disease
  - Persistent muscle spasms (including MS)
  - PTSD
  - Sickle cell disease
  - Terminal illness

 18

Medicial Marijuana Programs

- Most Common Qualifying Conditions
  - Opioid Use Disorder
    - Allows for the use of medical cannabis as an adjunct to Medication Assisted Treatment (MAT).
    - For all patients that suffer from opioid dependence and addiction, not only those with chronic pain.

 19

Is There Any Evidence of Cannabis Therapeutic Efficacy?

 20

"*The Health Effects of Cannabis and Cannabinoids*"
- National Academy of Sciences, 2017

 21

Is There Any Evidence of Efficacy?

The committee creating this National Academy report was tasked with conducting a comprehensive review of the current evidence of the health effects of cannabis.

- The strongest evidence was in reducing nausea and vomiting, treating pain, and relieving subjective spasticity associated with multiple sclerosis.
- A lower level of confidence supported efficacy for improving short term sleep outcomes.

 22

Is There Any Evidence of Efficacy?

- Substantial or Conclusive Evidence:
  - Cachexia
  - Chronic pain
  - Chemotherapy-induced nausea and vomiting
  - Multiple sclerosis related spasticity
  - Neuropathy

 23

Is There Any Evidence of Efficacy?

- Moderate Evidence:
  - Short term sleep disturbance
    - Obstructive sleep apnea, etc.
  - Reduction of seizure frequency
    - Dravet syndrome
    - Lennox-Gastaut syndrome
  - Improvement in symptoms of Tourette syndrome

 24

Is There Any Evidence of Efficacy?

- Limited Evidence:
  - Increasing appetite and decreasing weight loss
  - Anxiety
  - Post-Traumatic Stress Disorder (PTSD)
  - Traumatic brain injury or intracerebral hemorrhage

 25

Is There Any Evidence of Efficacy?

- Insufficient Evidence or Lack of Efficacy:
  - Dementia
  - Intraocular pressure associated with glaucoma
  - Depression
  - Cancer
  - Irritable Bowel Syndrome
  - Parkinson's Disease

 26

Proposed Uses in Dentistry (& Medicine)

 27

Proposed Uses in Dentistry (& Medicine)

- THC
  - Proposed Uses
    - Post-Operative Pain Control
      - Replace NSAIDs
      - Replace Opioids
    - Peri-Operative Anxiety and Pain Control
      - Replace Nitrous Oxide
        - However, high doses of THC may cause anxiety and paranoia

 28

Proposed Uses in Dentistry (& Medicine)

- CBD
  - Proposed Uses
    - Smoking cessation
    - Treatment of mucositis
    - Treatment of chemotherapy adverse effects
      - Anti-emetic
      - Appetite stimulant

 29

Types of Cannabis

 30

Types of Cannabis

- Hybrids
  - There has been much cross-breeding, in-breeding and blending of strains to produce hybrids
  - Thus, strain "names" have essentially become meaningless

 31

Types of Cannabis

- Hemp
  - Cannabis plant of the sativa species
  - THC content less than 0.3%
  - Grown for its seed and fiber
  - Used commercially to make
    - Canvas
    - Biofuel
    - CBD (cannabidiol)

 32

The Anatomy of the Cannabis Plant

 33

The Anatomy of the Cannabis Plant

- The Leaf
  - Allows for identification of strains
  - Allows for photosynthesis and plant growth
  - Does not produce the majority of the actives

 34

The Anatomy of the Cannabis Plant

- The Cola
  - Actives are isolated from flowers of female plants
  - The flower is then dried to produce "buds"
  - Male plants pollinate female plants

 35

The Anatomy of the Cannabis Plant

- Trichomes
  - Tiny hair-like projections on the flowers and leaves
  - Used to differentiate each strain of cannabis
  - Contain hundreds of cannabinoids, terpenes
    - Terpenes are essential oils found in the cannabis plant and other plants

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Cannabis Active Compounds

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Cannabinoids

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Cannabis Active Compounds

- Phytocannabinoids
  - Cannabis contains over 500 compounds and 66 known cannabinoids
    - Major cannabinoids
      - Tetrahydrocannabinol (THC)
      - Cannabidiol (CBD)
    - Minor cannabinoids
      - Cannabinol (CBN)
      - Cannabigerol (CBG)
      - Cannabichromene (CBC)

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Terpenes

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Cannabis Active Compounds

- Terpenoids (terpenes)
  - In addition to cannabinoids, cannabis also contains terpenoids
    - Organic compounds found in plants:
      - Beta-caryophyllene
      - Limonene
      - Linalool
      - Myrcene
      - Pinene

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Terpenes

- Beta-caryophyllene (BCP)
  - Proposed Effects
    - Anti-bacterial
      - Effective against streptococcus mutans
    - Analgesic
      - Current research for treatment of dental pain
  - Also found in black pepper, cloves, hops, oregano

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Terpenes

- Limonene
  - Proposed Effects
    - Anti-anxiety
    - Antifungal
    - Antibacterial
    - Carminative
  - Also found in grapefruit, lemons, oranges

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Terpenes

- Linalool
  - Proposed Effects
    - Anti-anxiety
    - Anti-inflammatory
    - Antibacterial
  - Also found in cinnamon, lavender, jasmine, rosewood

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Terpenes

- Myrcene
  - Proposed Effects
    - Anti-inflammatory
    - Sedative
    - Muscle relaxant
      - Contributes to “couch-lock”
  - Also found in bay leaves, eucalyptus, hops, lemongrass, mango

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Terpenes

- Pinene
  - Proposed Effects
    - Anti-inflammatory
    - Bronchodilation
    - Promotes alertness
  - Also found in pine cones

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Mechanism of Action

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Endocannabinoids

- Endogenous cannabinoids
  - Synthesized by the body
    - Anandamide (AEA)
    - 2-arachidonoylglycerol (2-AG)
  - Metabolites of arachidonic acid
    - Proposed link with the prostaglandin system

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Endocannabinoids

- Mechanism of Action
  - –Cannabis works in the endocannabinoid system
    - Two receptors govern this system
      - CB1 Receptors
        - Primarily found in the CNS
        - Altered perception and mood
        - Disturbed memory function
        - Impaired judgement
        - Slowed cognition
        - Psychosis
        - Loss of time perception
        - Impaired coordination

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Endocannabinoids

- Mechanism of Action
  - –Cannabis works in the endocannabinoid system
    - Two receptors govern this system
      - CB2 Receptors
        - Found in the GI
          - CHS
        - Found in the immune system
          - Effects on immunity

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Cannabis Preparations

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Routes of Administration

Routes of Administration

- Oral
  - Edibles, tinctures, oils
  - Advantages
    - Delayed onset, longer duration of action
  - Disadvantages
    - Inconsistent bioavailability
    - Extensive first-pass metabolism
    - Greater potential for overdose

Routes of Administration

- Sublingual/Buccal
  - Sprays, strips, oils
  - Gums, lozenges, mints, toothpicks
  - Advantages
    - Immediate onset, shorter duration of action
  - Disadvantages
    - Adverse effects on oral mucosa from consistent exposure

Routes of Administration

- Smoking (combustion)
  - Plant material
    - Joints, blunts, pipes
  - Advantages
    - Simple and effective
  - Disadvantages
    - Inhalation of combustion products
    - More than 2000 compounds are produced during smoking with mostly unknown effects

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Routes of Administration

- Water pipes
  - Plant material (bongs, hookah)
  - Advantages
    - Removes toxins in smoke
  - Disadvantages
    - Doesn't remove particulates
    - Might remove THC

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Routes of Administration

- Vaping
  - Concentrates, resins (chips, oils, budders)
  - Advantages
    - More efficient delivery of actives
    - Target temperature of specific cannabinoids
    - No odor
  - Disadvantages
    - Need special equipment
    - Presence of residual solvents

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Routes of Administration

- Other Routes of Administration
  - Oral Inhalers
  - Topicals
    - Creams, ointments, balms, lotions, patches
    - Eye drops
  - Suppositories
    - Vaginal, rectal
  - Tampons

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Adverse Reactions

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Adverse Reactions

- Neurological and behavioral effects
  - Immediate effects
    - Cognitive and psychomotor impairment.
  - Chronic effects
    - Addiction
    - Disruption of brain development
    - Psychotic disorders

Source: ADA Oral Health Topics, Cannabis: Oral Health Effects (1/18)

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Adverse Reactions

- Immediate cardiovascular effects
  - Tachycardia
  - Hypertension
  - Myocardial Infarction
- Immunosuppressive effects
  - Increased risk of opportunistic infection

Source: ADA Oral Health Topics, Cannabis: Oral Health Effects (1/18)

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Cannabis Dental Considerations

 68

Cannabis Dental Considerations

- Use of cannabis has been associated with:
  - Poor quality of oral health
    - –Frequently complicated by associated factors
      - –High tobacco, alcohol, and other drug use
      - –Poor oral hygiene practices
    - –Use of cannabis causes xerostomia
    - –Use of cannabis causes appetite stimulation and consumption of cariogenic snack foods

Source: ADA Oral Health Topics, Cannabis: Oral Health Effects (1/18)

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Cannabis Dental Considerations

- Use of cannabis has been associated with:
  - Poor quality of oral health (continued)
    - –Smoking cannabis is associated with similar oral pathologies as tobacco smoking including leukoedema
    - –Smoking cannabis is associated with gingival enlargement, erythroplakia and chronic inflammation of the oral mucosa with hyperkeratosis and leukoplakia.

Source: ADA Oral Health Topics, Cannabis: Oral Health Effects (1/18)

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Cannabis Dental/Medical) Considerations

- Use of cannabis has been associated with:
  - Increased risk of cancer
    - –Synergistic effects between tobacco and cannabis smoke may increase oral and neck cancer risk for people who smoke both.
    - –Immunosuppressive effects of cannabis, especially in association with oral papillomavirus in smokers, may contribute to these increased risks of cancer

Source: ADA Oral Health Topics, Cannabis: Oral Health Effects (1/18)

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Cannabis Dental/Medical Considerations

- Use of cannabis has been associated with:
  - Increased risk of opportunistic infection
    - –The immunosuppressive effects of cannabis may contribute as well to a higher prevalence of oral candidiasis compared to non-users.
    - –Recent research has suggested that viable microbiota may be transmitted from contaminated cannabis.

Source: ADA Oral Health Topics, Cannabis: Oral Health Effects (1/18)

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Cannabis Dental/Medical Considerations

- Use of cannabis presents several clinical challenges for the dental practitioner
  - Increased anxiety, paranoia and hyperactivity may heighten the stress experience of a dental visit.
  - Increased heart rate and other cardiorespiratory effects of cannabis make the use of epinephrine potentially life-threatening.

Source: ADA Oral Health Topics, Cannabis: Oral Health Effects (1/18)

 73

Cannabis Dental/Medical Considerations

- Use of cannabis presents several ethical challenges for the dental practitioner
  - "Intoxicated users" and informed consent
  - "Impaired" practitioners and potential malpractice

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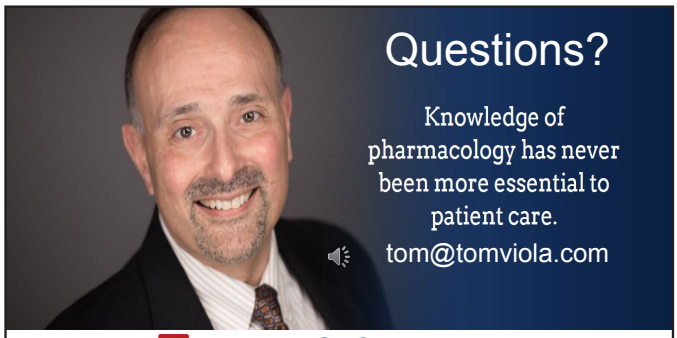

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SELF EVALUATION

Cannabis and Terpenes Parts 1 & 2

1. As a result of recent changes in legislation across 33 states, cannabis has now been designated nationwide as a:
   a. Schedule I controlled substance
   b. Schedule II controlled substance
   c. Schedule III controlled substance
   d. Schedule IV controlled substance
   e. Schedule V controlled substance

2. Which of the following is a qualifying condition for the use of medical marijuana in some states?
   a. Alzheimer's Disease
   b. Cachexia
   c. Cancer
   d. Parkinson's Disease
   e. All of the above

3. T/F - Based on federal law, hemp may contain a THC content of greater than 0.3%

4. Proposed uses of cannabis in dentistry include all of the following except:
   a. Replace NSAIDs for post-operative pain control
   b. Replace opioids for post-operative pain control
   c. Replace nitrous oxide for peri-operative pain control
   d. Replace local anesthetics for peri-operative pain control
   e. Replace nitrous oxide for peri-operative anxiety control

5. T/F - There is substantial or conclusive evidence that cannabis may be useful in managing short-term sleep disturbances.

6. Potential adverse effects of cannabis include which of the following?
   a. tachycardia
   b. mycocardial infarction
   c. stroke
   d. hypertension
   e. all of the above

7. T/F - CB1 receptors are found primarily in CNS.

8. Which of the following is a terpene found in cannabis plants?
   a. Beta-caryophyllene
   b. Limonene
   c. Linalool
   d. Myrcene
   e. All of the above

9. Potential adverse effects of cannabis include which of the following?
   a. tachycardia
   b. myocardial infarction
   c. stroke
   d. hypertension
   e. all of the above

10. T/F - CB1 receptors are found primarily in immune system.

11. Which of the following is a terpene found in cannabis plants?
   a. Beta-caryophyllene
   b. Limonene
   c. Linalool
   d. Myrcene
   e. All of the above

12. T/F - Trichomes are tiny hair-like projections on the flowers and leaves of the cannabis plant that contain most of the active compounds.

13. Which of the following is not a cannabis extraction?
   a. Budder
   b. Shatter
   c. Bolt
   d. Distillate
   e. Crumble

Answer Key: 1. A, 2. E, 3. F, 4. D, 5. F, 6. E, 7. T, 8. E, 9. E, 10. F, 11. E, 12. T, 13. C

Dennis Wichern

Dennis Wichern, of Indianapolis, Indiana, is a partner in Prescription Drug Consulting LLC, where he focuses his efforts on risk mitigation and compliance initiatives to protect healthcare organizations, pharmacies and providers nationwide. His experience includes 30 years of public service as a DEA Special Agent, Special Agent in Charge of the Chicago Field Division where he directed all criminal enforcement and diversion control operations in the states of Illinois, Indiana, Wisconsin, Minnesota and North Dakota with a team of approximately 550 employees.

Mr. Wichern is a recognized expert on the dangers of heroin and the prescription drug epidemic and routinely speaks to healthcare organizations, pharmacies and providers to identify methods to better safeguard their practices and reduce the professional and operational risks emanating from these threats. He was the first to develop CME programs addressing MAT and pain prescribing safeguards, federal regulatory and DEA compliance, credentialing and drug destruction. Mr. Wichern has been a guest lecturer on medical prescriber safeguards to audiences nationwide.

You may contact Mr. Wichern with your questions or comments at Dennis.Wichern@prescriptiondrugconsulting.com or by phone at 312-859-2430.

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Medically Assisted Treatment of Opioid Abuse Disorder

Dennis Wichern

Who I Am

- Retired DEA Special Agent in Charge - Chicago.
- 30 years of experience.
- Worked through the Indiana "pill mill" crisis during 2005 through 2014.
- Have been partnering with medical community/prescribers for last 10 years through CS programs.
- Developer of CME and CLE prescription drug risk mitigation programs focusing on prescriber safeguards, DEA compliance, MAT, pain and drug destruction.
- I am not an attorney.
- Zero medical training.

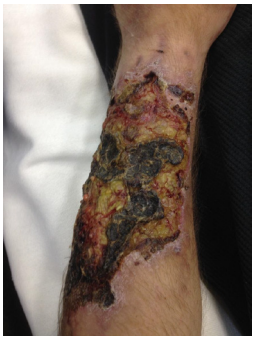
Disclosure Statement

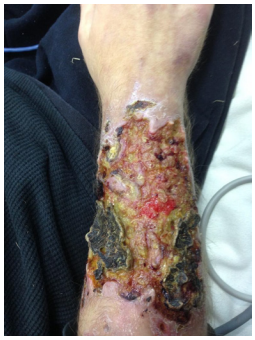
- This is not a promotional talk for any pharmaceutical company.
- I will not discuss off-label/investigative use of any commercial product.

Presentation Outline

- HHS/SAMHSA Authority - MAT
- DEA Authority
- DATA Waived Requirements & Recordkeeping
- Recent Federal Legislation
- Case Studies & Red Flags
- MAT Studies
- Buprenorphine Diversion
- Emerging MAT Issues
- DEA Resources
- MAT Practice Safeguards

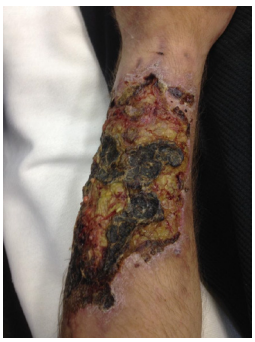
What Drug Causes This?

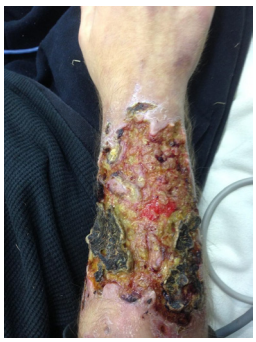




Extreme Heroin Use

Heroin Addiction and Needle Use





Heroin User Photographs

Seven Months Apart

https://www.wthr.com/article/these-pictures-were-taken-7-months-apart-mom-shares-photos-son-bring-awareness-addiction

Chicago AM Heroin Line

Medically Assisted Treatment (MAT) of Opioid Use Disorder (OUD)

Authorities

HHS/SAMHSA

- Medical practice
- The drugs used
- ASAM

DEA

- Security of the drugs
- Recordkeeping requirements

DEA's Role with Medical Providers

DEA's authority under the CSA is not equivalent to that of a State medical board. DEA does not regulate the general practice of medicine.

The responsibility for educating and training physicians so that they make sound medical decisions in treating pain (or any other ailment) lies primarily with medical schools, post-graduate training facilities, State accrediting bodies, and other organizations with medical expertise.

DEA's authority is limited to controlled substances only.

DEA's Role with Controlled Substances

DEA's statutory responsibility under the Controlled Substance Act (CSA) is two-fold:

1) prevent diversion and abuse of drugs
2) ensure an adequate and uninterrupted supply is available to meet the country's legitimate medical, scientific, and research needs.

DEA has no medical doctors on staff.

DATA Waived & Office Based Opioid Treatment (OBOT)

Drug Abuse Treatment Act (DATA) of 2000

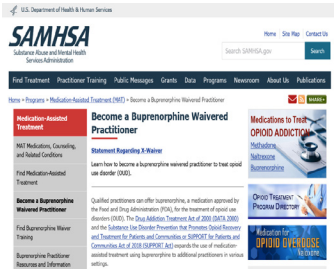
Provider Licensing

1. State Medical License
2. State Controlled Substance Registration
3. Federal Controlled Substance Registration (DEA) $888 fee for three years.
4. X-Number (DEA & HHS) License to treat substance users. Must have license from SAMHSA. No additional fee.
5. All federal licenses contingent on state licenses

Obtaining a DATA Waiver

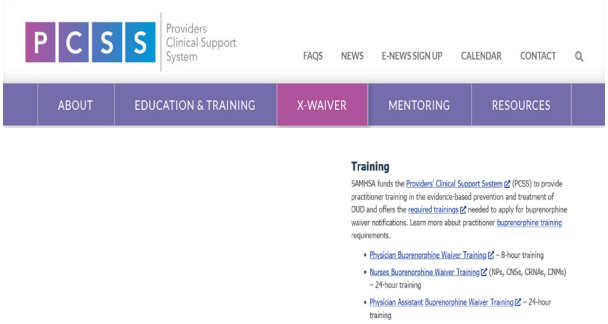
1. • Provider takes 8 hour MAT training class from SAMHSA
   • NP's and PA's take 24 hour class
   • SAMHSA verifies provider requirements & notifies DEA
2. • DEA assigns a special identification number in addition to a provider regular DEA number (X number)
3. • Year 1: up to 30 patients
   • Year 2: up to 100 patients
   • Year 2: Can go to 275 patients if or earlier?

Obtaining a DATA Waiver



https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner

MAT Training



https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner

275 Patient Requirements

Two Options

1) By holding additional credentialing ; or

2) By practicing in a qualified practice setting

- "Board certification in addiction medicine or addiction psychiatry by the American Board of Addiction Medicine or the American Board of Medical Specialties, or certification by the American Board of Addiction Medicine or the American Society of Addiction Medicine."

- **"Qualified Practice Setting"**
  1) Provides professional coverage for patient medical emergencies during hours when the practice is closed.
  2) Provides access to case management services for patients, including referral and follow-up services for programs that provide or financially support medical, behavioral, social, housing, employment, educational, or other related services.
  3) Uses health information technology if it is already required in the practice setting.
  4) Is registered for their state prescription drug monitoring program where operational and in accordance with federal and state law.
  5) Accepts third-party payment for some services, though not necessarily for buprenorphine-related services and not necessarily all third-party payers.

https://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/understanding-patient-limit275.pdf

Medications to Treat Opioid Addiction

- Methadone
  NTP's/OTP's/Methadone Clinics
  - Can also be prescribed for pain & three day rule
- Naltrexone
  - not a CS
- Buprenorphine
  - DATA Waived

https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner

Common Forms of Buprenorphine

- Suboxone
- Subutex
- Zubsolv
- Sublocade
- Probuphine
- Generics

Differences Between DATA - Waived/OBOT/MAT Practice & Opioid Treatment Program

DATA Waived/OBOT

- SAMHSA approved
- Patient limits
- Cannot prescribe or dispense methadone
- Allowed to prescribe and dispense buprenorphine
- Counselors onsite not required
- Flexible guidelines

OTP Treatment Programs

- Federal, state & SAMHSA approved
- No patient limits
- Allowed to dispense liquid methadone
- Allowed to dispense buprenorphine
- Counselors onsite
- Fairly rigid guidelines

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Opiate Treatment Programs (OTPs)
Methadone Clinics
Narcotic Treatment Programs (NTPs)

- Established in 1972
- Pros and cons
- Public/private
- Dispense liquid methadone for addiction & bup
- Also provide counseling
- Highly regulated

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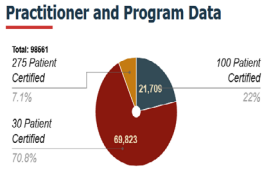
Inside a Opioid Treatment Program

Prescription Drug Consulting LLC — Protecting Healthcare Organizations and Providers Nationwide

Nationwide Numbers

98,561 DATA/OBOT's
(as of 4/5/2021)

1,823 OTP's
(as of 4/5/2021)



https://www.samhsa.gov/medication-assisted-treatment/practitioner-resources/DATA-program-data

https://dpt2.samhsa.gov/treatment/

Prescription Drug Consulting LLC — Protecting Healthcare Organizations and Providers Nationwide

The Latest Numbers

DEA Registrants – 2021

- Approximately 1.10 million MD's & DO's
  - 200,000 Dentists
  - 73,000 Vets
  - 453,000 NP's & PA's
- 18,764 hospitals/clinics
- 70,681 Pharmacies
- Approximately 330,000 pharmacists
- Approximately 400,000 pharmacy techs

Prescription Drug Consulting LLC — Protecting Healthcare Organizations and Providers Nationwide

2016 CARA Highlights & FAQ's

Comprehensive Addiction and Recovery Act (CARA)

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Comprehensive Addiction and Recovery Act (CARA) Highlights

- In effect since July 22, 2016
- Qualifying physicians can treat up to 30, 100 or 275 patients (Board Certification for those treating 275)
- Qualifying NP's and PA's can treat up to 30 or 100 – forever.
- Revised SAMHSA guidelines TIP 63 published February 15, 2018.
- When in doubt – email SAMHSA.
- About 6% of total are waivered.

Data Waived Physicians as of 4/2021 - SAMHSA	
30 patient limit	69,823
100 patient limit	21,709
275 patient limit	7,029
Total	98,561

CARA Highlights

Final Rule - 42 CFR Part 8

- "The final rule also includes requirements to ensure that patients receive the full array of services that comprise evidence-based MAT and minimize the risk that the medications provided for treatment are misused or diverted."
- "HHS has changed the highest patient limit from 200 to 275."
- "With respect to the comments suggesting that no limit apply to patients treated with new formulations, HHS does not believe that raising the limit beyond that specified in this rule is warranted at this time."

https://www.deadiversion.usdoj.gov/pubs/docs/SAMHSA_Regulations_275.pdf

CARA Highlights

Final Rule - 42 CFR Part 8

- "HHS received comments stating that the proposed rule does not address the many reasons why providers are not prescribing MAT to the fullest extent of their current waivers, including concerns about public and private insurer reimbursement for the additional reporting, documentation, and counseling as well as concerns about on-site DEA inspections."

https://www.deadiversion.usdoj.gov/pubs/docs/SAMHSA_Regulations_275.pdf

DEA MAT Support

December 2019


DEA Supports the Use of Medication Assisted Treatment for Opioid Use Disorder: Message for DATA Waived Practitioners And Those Eligible To Become DATA Waived

September 2020 with AMA

https://www.deadiversion.usdoj.gov/pubs/docs/mat.htm

CARA Highlights

Final Rule - 42 CFR Part 8

- "Under the final rule, practitioners authorized to treat up to 275 patients will be required to meet infrastructure requirements that exceed those required for practitioners who have a waiver to treat 100 or fewer patients. HHS proposed additional criteria and responsibilities for practitioners to be able to treat up to the higher patient limit with the specific aims of ensuring quality of care and minimizing diversion."
- "HHS has determined that increasing the patient limit to 275 balances the pressing need to expand access to MAT with the desire to ensure the provision of high-quality, evidence- based MAT while limiting the risk of diversion."

https://www.deadiversion.usdoj.gov/pubs/docs/SAMHSA_Regulations_275.pdf

CARA Highlights

Final Rule - 42 CFR Part 8

- "Given the significant responsibility associated with prescribing buprenorphine, HHS believes that practitioners should be board certified or practicing in a qualified practice setting to safely and appropriately provide this treatment to up to 275 patients."
- "HHS believes that in order to ensure quality care, providing behavioral health support services is a key component to delivering effective MAT and encourages all practitioners prescribing covered medications to ensure that their patients receive it. The selection of behavioral health support services is a clinical decision to be made between the practitioner and the patient."

https://www.deadiversion.usdoj.gov/pubs/docs/SAMHSA_Regulations_275.pdf

CARA Highlights

Final Rule - 42 CFR Part 8

Third-Party Payment Comment

Comment: HHS received numerous comments expressing concerns with the requirement that practitioners prescribe in a setting that accepts third-party payment.

Response: This requirement was created to minimize the public health and safety risks, such as diversion, that are associated with dispensing or prescribing medications that are not supported by an appropriate medical diagnosis and assessment of medical need. Such risks are often associated with "cash only: entities that do not accept any third-party payment for services. Using third-party payment provides a record that buprenorphine has been provided to an individual and thus allows for more accountability, lowering the risk of diversion.

https://www.deadiversion.usdoj.gov/pubs/docs/SAMHSA_Regulations_275.pdf

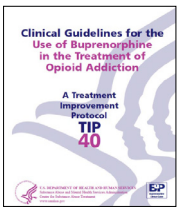
Anecdotal Information on Why Data Waived Physicians Do Not Use Their X Numbers

It is estimated that about half of those certified do not treat drug users

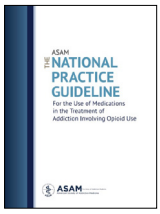
- Do not like nor want patient base
- Small practice providers lack counseling support and expertise
- Some do not believe in replacing one opioid for another opioid
- Addiction treatment is difficult and time consuming
- Success rate is poor, expect 7 to 8 relapses or higher

MAT Guidelines

HHS/SAMHSA Guidelines
2004



ASAM Guidelines
June 1, 2015



HHS/SAMHSA Guidelines
February 2018

Requirements of a OBOT Provider per 2018 Guidelines

- The law requires buprenorphine prescribers to be able to refer patients taking OUD medication to counseling and ancillary services. Buprenorphine prescribers may meet this requirement by keeping a list of referrals or by providing counseling themselves. Section 4-5, page 217

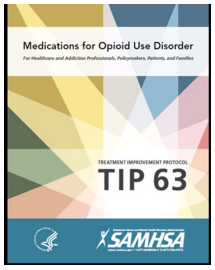
Requirements of a OBOT Provider per 2018 Guidelines

"Office-Based Induction Providers can perform office-based induction by ordering and storing induction doses in the office or by prescribing medication and instructing patients to bring it to the office on the day of induction."

Section 3-60, page 146

2108 SAMHSA Guidelines

(Multiple Forms in Appendix)



- Appendix
  - Diversion Plan 5-29
  - Bup Office Policy 5-45
  - Treatment Agreement 5-50

Emergency Narcotic Addiction Treatment "The Three Day Rule"
21CFR1306.07(b)

"An exception to the registration requirement, known as the "three day rule" (Title 21, Code of Federal Regulations, Part 1306.07(b)), allows a practitioner who is not separately registered as a narcotic treatment program, to administer (but not prescribe) narcotic drugs to a patient for the purpose of relieving acute withdrawal symptoms while arranging for the patient's referral for treatment, under the following conditions:

- Not more than one day's medication may be administered or given to a patient at one time
- This treatment may not be carried out for more than 72 hours and;
- This 72-hour period cannot be renewed or extended

The intent of 21 CFR 1306.07(b) is to provide practitioner flexibility in emergency situations where he may be confronted with a patient undergoing withdrawal. In such emergencies, it is impractical to require practitioners to obtain a separate registration. The 72-hour exception offers an opioid dependent individual relief from experiencing acute withdrawal symptoms, while the physician arranges placement in a maintenance/detoxification treatment program. This provision was established to augment, not to circumvent the separate registration requirement."
https://www.deadiversion.usdoj.gov/pubs/advisories/emerg_treat.htm

What About DEA MAT Inspections?

.

DATA 2000 Regulations

"Under the authority of the Controlled Substances Act (21 U.S.C. 822 (f)), DEA is authorized to conduct periodic on-site inspections of all registrants. DWPs are also subject to on-site inspections to ensure compliance with the DATA and its implementing regulations."

https://www.deadiversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm

The History of DEA MAT Inspections

- Federal law back in 1970's gave DEA authority to inspect those registered to maintain drugs on a routine basis. DEA routinely inspects all drug manufacturers, wholesalers & distributors.
- SAMHSA TIP 40 (2004) had OBOT providers maintaining buprenorphine for induction.
- Federal law requires security and extensive recordkeeping for all controlled drugs.
- Most OBOTs failed to keep accurate records of their buprenorphine due to lack of knowledge.
- Most if not all inspections lead to benign "Letter of Admonition" to keep better records in future.
- DEA has changed OBOT visits to once every 15 years as of 2016.
- Best Practice: Prescribe for induction and never maintain drugs if possible in office setting. Never worry about DEA and records again.

What are the criteria when DEA completes an audit on a MAT Provider?

DEA's Authority is Limited to Controlled Substances Only.

- DEA's focus during an audit will be on the controlled substance records – bup on hand.
- DEA will also check patient limits 30, 100 or 275.
- Most recordkeeping violations result in only a letter of admonition.

Prescriber Advice & Counsel

- If possible, don't maintain any CS's/bup at office and write only prescriptions.
- DEA cannot find a violation if you don't maintains any CS's/bup.
- If you maintain CS's/bup keep good records that are all in one place. Think checkbook register.

Required Records – Controlled Substances
CFR Part 1304

- POA's for II's – not needed for buprenorphine (III)
- Initial Inventory
- Biennial Inventory
- Closing Inventory
- Receiving Records, 222's or invoices – 2 year federal retention
- Distribution Records
- Theft and Loss – DEA Form 106 Report to LE
- Drug Destruction – DEA Form 41 – Reverse Distributors – Return to Manufacturer
- Prescriptions vs Dispensing (*Must keep dispensing records*)

The DEA Audit Process

- Two diversion investigators or more
- Two to four hour process
- Starts with a DEA form 82 "Notice of Inspection"
- You have right to refuse
- Administrative search warrant option
- Records need to be "readily retrievable"

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The Key Records in a DEA Audit Process that Will be Checked

1. Executed and unexecuted official order forms (DEA Form 222) or the electronic equivalent
2. Power of Attorney authorization to sign order forms (II's only)
3. Receipts and/or invoices for schedules III, IV, and V controlled substances
4. All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business
5. Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)

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The Key Records in a DEA Audit Process that Will be Checked

6. Records of controlled substances dispensed (i.e., prescriptions, schedule V logbook)
7. Reports of Theft or Significant Loss (DEA Form 106), if applicable
8. Inventory of Drugs Surrendered for Disposal (DEA Form 41), if applicable
9. Records of transfers of controlled substances
10. DEA registration certificate

Will also count and confirm several drug inventories

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The DEA Audit Form

1	2	3	4	5	6	7	8	9
Names & Strength of Drugs	Initial Inventory as _____	Total Purchased (same time frame)	Total Accountable For (2 +3)	Closing Inventory as of _____	Total Dispensed	Total Can Account For (5+6)	Difference Over= Short = (7-4)	Percentage Difference (8/4 x100)

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Providers Who Maintain Office Buprenorphine (bup) for Induction Must Keep the Following Records

- Maintain all bup purchase invoices for two years.
- Conduct a bup inventory audit every two years.
- Maintain a bup dispensing log comprised of patient name, date, amount of bup used and providers initials.
- Keep bup secured in locked cabinet.
- Think checkbook register!

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Sample Dispensing Log

Administered/Dispensing Log

Organization and address: _____

Drug Name:_____, Form: _____, Strength:_____

Date	Patient Name & Address	Initials of Person Dispensing	Witness Initials (optional)	Current Balance	Amount Dispensed or Purchased	New Balance

(Works Like Bank Check Register)

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Sample Drug Inventory

Drug Inventory

(Must be taken at least every two years, at beginning of drug acquisition and maintained for two years)
(Keep this executed form with drug records)

Organization: _____ Date: _____ (start or end of day)

Address: _____

DEA#: _____

Persons (2) Taking Inventory_____

Signatures (2) _____

Drug Name	Dosage Form	Strength	Quantity on Hand

(Compare against perpetual inventory – numbers should match)

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Sample Perpetual Inventory

Controlled Substance Perpetual Inventory

Date: _____

Drug Name:_____, Strength: _____, Form:_____

Purchases			Prescriptions			Inventory Balance or Balance Forward	Pharmacist's Signature	
Invoice #	Date Received	Quantity Received	RX Number	Date Filled	Quantity Dispensed	Current Inventory		

(Form to Know Exact Quantities Daily)

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Can I Prepare for a DEA Audit?

YES

1. Assign one person ahead of time for the poc.
2. Keep all your buprenorphine records easily accessible for review. (See previous slides)
3. Keep copies of your licenses in same place.
4. Do not maintain bup and your recordkeeping requirements go away.
5. Keep a log of your patient numbers, 30, 100 or 275.
6. Audits will occur once every 15 years or more
7. Remember to notify SAMHSA when your year is up and you want to raise your patient limit at https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/apply-for-practitioner-waiver.

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I Want to Know More

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MAT Providers by Zip Code

https://www.samhsa.gov/medication-assisted-treatment/practitioner-program-data/treatm

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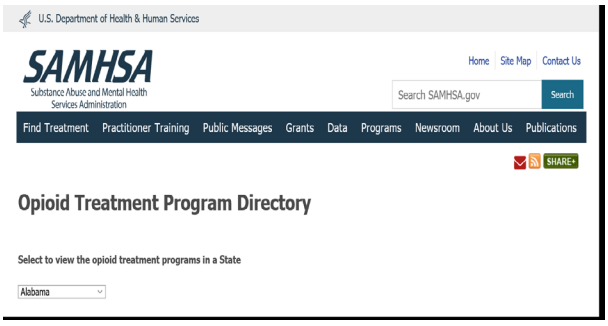
OTP's by State



https://dpt2.samhsa.gov/treatment/

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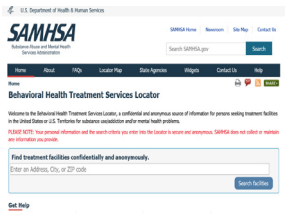
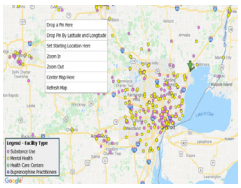
Behavioral Health Treatment Services Locator by Zip Code





https://findtreatment.samhsa.gov/

SAMHSA MAT Main Page

https://www.samhsa.gov/medication-assisted-treatment

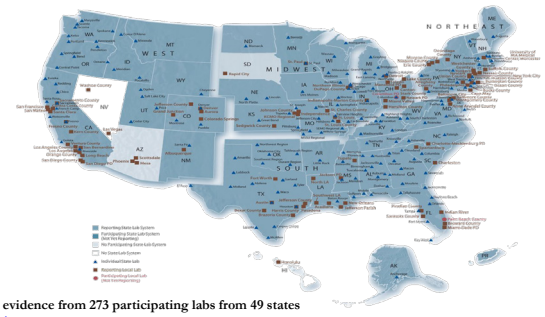
DEA DATA Waived Main Page

https://www.deadiversion.usdoj.gov/pubs/docs/index.html

Who Decides the MAT Patient Caps?

Most Commonly Abused Pharmaceutical Drugs

National Forensic Laboratory Information System NFLIS



91% all evidence from 273 participating labs from 49 states
https://www.nflis.deadiversion.usdoj.gov

Top Seized Opioids Analgesics

Table 2.1 *Narcotic Analgesics*
Number and percentage of narcotic analgesic reports in the United States, 2019[1]

Narcotic Analgesic Reports	Number	Percent
Fentanyl	98,954	49.74%
Oxycodone	22,470	11.30%
Buprenorphine	20,552	10.33%
Hydrocodone	12,747	6.41%
Acetyl fentanyl	12,190	6.13%
Tramadol	8,196	4.12%
ANPP[2]	5,798	2.91%
Carfentanil	3,288	1.65%
Morphine	3,003	1.51%
Codeine	2,210	1.11%
Valeryl fentanyl	2,042	1.03%
Methadone	1,839	0.92%
Hydromorphone	1,582	0.80%
Oxymorphone	565	0.28%
Thiomisobutyryl fentanyl	436	0.22%
Other narcotic analgesics	3,056	1.54%
Total Narcotic Analgesic Reports[3]	198,929	100.00%
Total Drug Reports	1,521,360	

https://www.nflis.deadiversion.usdoj.gov/DesktopModules/ReportDownloads/Reports/NFLIS-Drug-AR2019.pdf

Top Three Benzodiazepines Submitted to Crime Laboratories

Alprazolam (Xanax)	47%
Clonazepam (Klonopin)	14%
Diazepam (Valium)	5%

https://www.nflis.deadiversion.usdoj.gov/DesktopModules/ReportDownloads/Reports/NFLIS-Drug-AR2019.pdf

Drug Blogs

(Research Tool)

- Erowid.org
- Bluelight.org
- Drugs-Forum.com
- Opiophile.org

Walk me through some MAT case studies

MAT Medical Office?

Types of Investigations & Examples

Types	**Examples**
• Administrative	• Provider self-abuse
• Civil	• Recordkeeping violations – Manufacturers – Dispensers – Handlers of CS's – Significant fines possible
• Criminal	• Pill Mills, Billing fraud & other

Federal Law – Definition of a Legitimate Prescription

Title 21 Code of Federal Regulations (CFR) 1306.04

Section 1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (**21 U.S.C. 829**) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Section 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.

Source: www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_04.htm
www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_05.htm

MAT Civil Fine Only #1

Boston, MA August 8, 2018
(Might have been charged criminally for fraud in other district?)

- Dr. Hung K. Do and his addiction treatment clinic, H.K.D. Treatment Options, have agreed to pay $23,000 to settle claims of improper billing of medical services under the Controlled Substances Act and the False Claims Act. Dr. Vasumathi Brown, a physician employed by H.K.D., has agreed to pay a $12,500 civil penalty for issuing invalid prescriptions for controlled substances under the Controlled Substances Act.
- It is alleged that, at Dr. Do's direction, Dr. Brown signed hundreds of blank prescriptions for use by unsupervised non-physician staff while Dr. Brown was on vacation abroad in December 2016. Ultimately, unsupervised non-physician staff issued over 600 prescriptions for controlled substances using the pre-signed blank prescriptions. It is further alleged that Dr. Do subsequently billed Medicare improperly for services related to the prescriptions that non-physician staff provided in Dr. Brown's absence, and that Dr. Do falsely reported to Medicare that Dr. Brown supervised those services.

https://www.justice.gov/usao-mapr/lowell-physicians-settle-drug-diversion-allegations

MAT Civil Fine #2

Syracuse, NY June 8, 2017

"Physician Accepted Payment in Marijuana at Appointments Where Controlled Substances Were Prescribed – Agreed to $50,000 Civil Judgment

The government alleged that, over an approximately year and a half time period, Dr. Blake issued twenty-three Suboxone prescriptions to a patient and was paid by the patient in small quantities of marijuana for at least twelve of the corresponding medical appointments. Dr. Blake admitted to being paid in marijuana but asserted that it was fewer than twelve times. The government also alleged that Dr. Blake created a medical record in only four of the twenty-three visits.

The CSA and its implementing regulations make it unlawful for a physician registered with the Drug Enforcement Administration (DEA) to dispense a controlled substance unless the prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of her professional practice. Violations of this requirement create civil penalty exposure of up to $25,000 per violation."

https://www.justice.gov/usao-ndny/pr/syracuse-area-physician-agrees-pay-financial-penalty-resolve-allegations-she-violated

MAT Criminal Charges #1

Albany, NY July 19, 2018

"Adrian Morris, age 61, a Clifton Park, New York, psychiatrist specializing in addiction recovery, was arrested today and charged with distributing controlled substances outside the course of professional practice and for no legitimate medical purpose.

According to a criminal complaint, Morris dispensed Xanax, Adderall, and Suboxone to patients for no legitimate medical purpose, and to at least one patient in exchange for sex. In addition to writing unjustified prescriptions to patients, Morris also wrote prescriptions for individuals he never treated."

https://www.justice.gov/usao-ndny/pr/clifton-park-doctor-arrested-unlawful-drug-distribution

MAT Criminal Charges #2

Jury Convicts Doctor of Health Care Fraud, Distributing Controlled Substances through Pain Cream Scheme and Suboxone Clinic
May 2, 2019

- COLUMBUS, Ohio – A jury has convicted a Central Ohio doctor with charges related to a health care fraud scheme that included marketing prescription creams in Sav-a-Lot and low-income neighborhoods and persistently mailing those creams to Medicaid customers, as well as prescribing and distributing Suboxone without medical necessity.
- Bernard Oppong, 60, of Blacklick, Ohio was convicted on five counts following a trial that began on April 22 before U.S. District Judge Algenon L. Marbley.

https://www.justice.gov/usao-sdoh/pr/jury-convicts-doctor-health-care-fraud-distributing-controlled-substances-through-pain

MAT Criminal Charges #2

Jury Convicts Doctor of Health Care Fraud, Distributing Controlled Substances through Pain Cream Scheme and Suboxone Clinic
May 2, 2019

- Oppong was registered through the DEA to prescribe the drug addiction treatment Suboxone to up to 275 patients at any one given time.
- Health and Wellness Medical Center submitted fraudulent claims to Medicaid for psychotherapy services that were never rendered to patients.
- Specifically, patients indicated they would sit in a room with a timer. When the timer went off, they were allowed to leave and receive their Suboxone prescription, which was written by Oppong and co-conspirators. No counseling services were provided during this time. Some patients reported coloring in coloring books during the time they were in the room.
- Oppong pre-signed prescriptions for Suboxone and left them at the medical center for anyone to distribute. Prescriptions were issued to patients who had repeatedly failed urine tests.
- The medical center treated patients paying with cash differently than those with insurance. The patients paying with cash only had appointments every two weeks or once a month, and paid $300. Insured patients had appointments three times a week. Cash-paying patients were only required to attend 15 to 30 minutes of counseling, while insured patients were required to stay for one hour.
- Oppong and co-defendants averaged more than 150 patients per day.

https://www.justice.gov/usao-sdoh/pr/jury-convicts-doctor-health-care-fraud-distributing-controlled-substances-through-pain

MAT Criminal Charges #3
Former Suboxone Clinic Doctor Sentenced for Illegal Prescribing and Health Care Fraud
October 16, 2019

"Bummer and other doctors at Redirections would routinely pre-sign blank prescriptions for buprenorphine, which is a scheduled controlled substance under federal law. The pre-signed prescriptions were then given to other medically-unlicensed employees at Redirections who completed the prescription and provided it to the patients in exchange for cash. On numerous occasions, the doctors were not physically present at Redirections and did not exam their patients when prescriptions bearing their names were issued.

Because the prescriptions were illegally issued, Medicare and Medicaid were defrauded when Redirections' patients used their insurance to fill the prescriptions.

https://www.justice.gov/usao-wdpa/pr/former-suboxone-clinic-doctor-sentenced-illegal-prescribing-and-health-care-fraud

Common MAT Problem Areas & Red Flags

- Non-provider owner/manager
- Non-provider owner/manager has access to blank prescriptions/pre-signed prescriptions
- No insurance accepted (cash only)
- Irregular business hours
- Use of contract and part-time doctors
- Patient visits lasting 5 minutes or less

Common MAT Problem Areas & Red Flags

- Counseling optional or use of non-licensed counselors.
- Questionable use of PDMP's if any
- Complaints from patients, pharmacies, and from other providers
- Poor maintenance of patient counts & significant exceeding of counts
- Overall non-adherence to recognized MAT protocols.
- Limited if any medical history and exams

Common MAT Problem Areas & Red Flags

- Providers pre-signing prescriptions and filled out by employees
- Lack of or non-use of urine screens
- Provider payment tied to number of patients seen
- Drive thru clinic
- Provider trusting clinic director
- Providers getting paid while not on-site
- Usually a combination of many things

What About Urine Drug Screens?

What About Urine Drug Screens?
(No federal law on UDSs)
Do You have a policy or contract in place?

Positive Screens

- Using MAT – good thing
- Using other drugs – expected and for how long?
- Terminate?
- Expect relapses
- How often and how many?
- Methadone in screen?
  - VA
  - NTP/OTP
  - Importance of PMP use
- Other?
- Importance of following guidelines

Negative Screens

- Not good
- Indicates diversion?
- Terminate patient?

Drug Testing:
A White Paper of the American Society of Addiction Medicine
(ASAM)
October 26, 2013

"1.2. Responding to Positive Tests During Various Phases of Treatment A fundamental goal of addiction treatment is for patients to achieve abstinence from the use of alcohol and other drugs of abuse. In this context, an unexpected positive test result signals continued use of non-prescribed drugs of abuse by tested patients. In medication assisted treatment (MAT), a test result that fails to confirm the patient's use of the prescribed medicine (e.g. methadone or buprenorphine) (an unexpected negative test result) also is a significant finding because it signals non-compliance and possible diversion. In the context of MAT, the identification of prescribed medications is not a violation of the abstinence standard.

Ignoring positive test results undermines treatment goals. Discharging a patient from treatment for an initial positive test is seldom, if ever, appropriate. Positive test results signal the need to intensify or alter current care. There are many options to consider in response to positive test results, including more frequent testing and specialized interventions for non-compliant patients. In MAT, a positive test for opioid use may reflect the need for a higher dose of medication.

Continued positive test results, after the intensification of treatment, raise the question of the value of treatment and may justify discharging the patient from treatment. Each patient's situation should be taken into account as a clinician determines what changes should be made to the treatment plan in the patient's best interests in response to positive test results. "

Source: https://www.asam.org/docs/default-source/public-policy-statements/drug-testing-a-white-paper-by-asam.pdf
page 49

Buprenorphine Studies

Buprenorphine Studies

- University of Kentucky
  - - 1,674 addicts interviewed
  - - 985 reported taking Suboxone at some point
  - - 6% got it by legitimate prescription
  - - 62% received it by illegal means
  - - 32% received both ways
  - Nearly 8 in 10 or approximately 80% who got it both ways - admitted selling - trading or giving away what was prescribed.
  - More than three quarters admitted mixing Suboxone with other drugs or alcohol to get high.

https://www.in.gov/bitterpill/files/Quintin%20Chipley.pdf

- John Hopkins
  - - Analyzed 38,000 buprenorphine users
  - - Most stopped use within 3 months
  - - 43% also received different opiate during treatment
  - - 67% received an opioid prescription within 12 months after treatment

http://www.jhsph.edu/news/news-releases/2017/many-patients-receive-prescription-opioids-during-medication-assisted-treatment-for-opioid-addiction.html

Buprenorphine Study

Medicaid Study

- Their findings arose from a study of 2013-2015 insurance claims data from the MarketScan multi-state Medicaid database. The study sample included 17,329 individuals aged 18 to 64 years with a diagnosis of OUD in the 6 months prior to buprenorphine initiation.
- The majority of patients with opioid use disorder (OUD) who receive buprenorphine for their symptoms likely discontinue the medication within 6 months of receipt, according to new findings.
- Results of the study indicated that 28.4% (n = 4928) of patients in the sample had discontinued buprenorphine within the first month of treatment, and 64.6% (n = 11,189) had discontinued it before 180 days.

https://www.consultant360.com/article/consultant360/mental-health/most-who-receive-buprenorphine-discontinue-it-quickly

Buprenorphine Study

Lancet

Researchers found that 52 percent of those who started on Vivitrol relapsed during the 24-week study, compared with 56 percent of those who started on Suboxone.

But the study, conducted with 570 adults addicted mostly to heroin, also found a substantial hurdle for Vivitrol. Because the medication can be started only after a person is completely detoxed from opioids — a process that can take over a week — more than a quarter of the study participants assigned to Vivitrol dropped out before being able to take their first dose.

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)32812-X/fulltext

Buprenorphine Diversion

NPR Maryland Article

2016

- Maryland effective July 1, 2016 stopped allowing Suboxone strips under Medicaid but allowing tablet forms.
- "State officials say the change was made to stop the illicit flow of the drug into jails and prisons. "Those Suboxone strips were diverted and smuggled into jails and later were sold or traded in criminal activity that was happening in jails," says Shannon McMahon, deputy secretary of Maryland's Department of Health and Mental Hygiene. "The numbers were frankly staggering, the amount of diversion that was happening in the jails."

https://www.npr.org/sections/health-shots/2016/07/19/486419277/maryland-switches-opioid-treatments-and-some-patients-cry-foul

Buprenorphine Diversion/Smuggling

AP Article

2016

In the state's prisons, officials say it's the type of drug, not the volume, that's changed. Suboxone, used to treat opioid addiction but also producing a high of its own, in the form of a breath strip is the latest drug of choice, Hammer said. Inmates smuggle it in by sticking it to their bodies or swallowing balloons filled with dozens of strips. On the street, strips or pills of Suboxone sell for $10 to $20. Within prison, a strip can sell for hundreds of dollars. "The value once you're in the state prison increases dramatically," Hammer said. Suboxone smuggling has posed problems in county jails in New Mexico and Virginia, where inmates were receiving photographs soaked in a liquid form of Suboxone that they could chew on to get high. In 2014, California officials reported a significant increase in drug smuggling in jails and the state prison system brought in drug-sniffing dogs and implementing airport-style hand swabs for visitors and staff.

https://www.seacoastonline.com/news/20160619/keeping-drugs-out-jails-prisons-find-steep-challenge

Columbus, Ohio Dispatch

2017

"Behind prison walls in Ohio, inmates regularly are abusing an opioid normally used to wean people off drugs. Inmates, many of whom are in prison on drug charges in the first place, are sneaking in Suboxone, which is legally prescribed to treat people recovering from heroin addiction. The drug is vying to become the most common contraband drug brought into state prisons — neck-and-neck with marijuana. Prison officials say a strip of Suboxone the size of a postage stamp, which melts on the tongue, goes for about $100 or more in a lucrative prison black market. The Suboxone strips are similar to small mouthwash strips but contain a slow-acting opioid."

https://www.dispatch.com/news/20170416/addiction-drug-suboxone-is-popular-prison-contraband

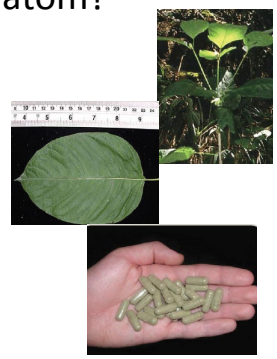
Emergence of State MAT Laws

- West Virginia 2016
- Kentucky 2017
- Tennessee 2017
- Ohio 2017
  - Most new state laws deter cash businesses, must be owned or lead by MD, must be licensed & registered with state, and will be inspected by state authorities. New regs/laws similar to methadone clinic oversight requirements

What else should I know?

What is Kratom?

- Leaves from a southeast Asia tree
- Used to self–treat pain, anxiety and depression,
- Smoked or put in tea
- Stimulant at low doses
- Sedative at higher doses
- DEA action - 2016
- FDA advisories
  - 2017 – 36 deaths
  - 2018 – 44 deaths
  - 2019 – 91 deaths
- Illegal in states of AL, AR, IN, VT & WI



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2014 & 2018 Federal Farm Bill's, Hemp & CBD

- Defined hemp as marijuana containing 0.3 or less of THC. (2014)
- Under this definition, hemp with less 0.3 or less is not a schedule I drug. (2018)

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FDA's View on CBD

- New approved drug for epilepsy – Epidiolex
- Schedule V
- Yearly cost is $32,500
- Contains less than 0.1% THC
- FDA's view and laws – supersede 2018 hemp law & CBD

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DEA Press Release

August 26, 2019

Hemp CBD is not a Controlled Substance

"This notice also announces that, as the result of a recent amendment to federal law, certain forms of cannabis no longer require DEA registration to grow or manufacture. The Agriculture Improvement Act of 2018, which was signed into law on Dec. 20, 2018, changed the definition of marijuana to exclude "hemp"—plant material that contains 0.3 percent or less delta-9 THC on a dry weight basis. Accordingly, hemp, including hemp plants and cannabidiol (CBD) preparations at or below the 0.3 percent delta-9 THC threshold, is not a controlled substance, and a DEA registration is not required to grow or research it."

https://www.dea.gov/press-releases/2019/08/26/dea-announces-steps-necessary-improve-access-marijuana-research

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Law Enforcement & Treatment Partnerships 55+ in Michigan

Develop "A Way Out" Program with Law Enforcement & Treatment Providers?

- "A Way Out" is a Law Enforcement Assisted Diversion pilot program, designed to fast-track users to substance abuse programs and services. This program is available 24 hours a day, 7 days a week at participating police departments and ensures no criminal charges will be sought for those that may be in possession of narcotics or paraphernalia, as long as assistance is sought out by the prospective program participant.
- Also known as a "Angel Program" or Police Assisted Addiction & Recovery Initiative (PAARI)
- http://awayoutlc.org/
- http://paariusa.org/

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Online DEA Resources

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Registration Assistance

- **HQ Registration Call Center**
  - (800) 882-9539
    8:30 am-5:50 pm EST
    DEA.Registration.Help@usdoj.gov ($888 fee for three year license)
  - ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES
    EPCS@usdoj.gov
  - IINTERPRETATION AND GUIDANCE ON DEA POLICIES AND REGULATIONS
    ODLP@usdoj.gov

Practitioner Diversion Awareness Conferences

https://www.deadiversion.usdoj.gov/mtgs/pract_awareness/index.html

Wrap it Up

Specific MAT Prescriber Protection & Safeguards

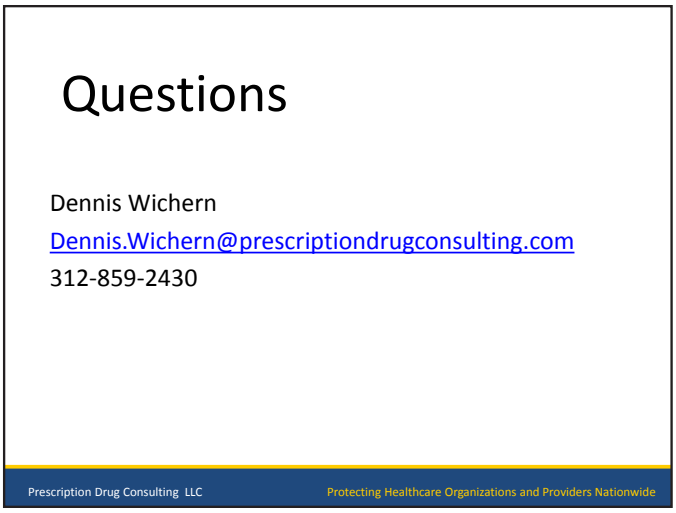
- Follow a general and accepted MAT guideline
- Ensure a counseling component
- Practice due diligence
- No one expects you to be perfect all the time
- Use your PDMP
- Conduct UDS's
- Prescribe only for induction in office/out patient setting

Specific MAT Prescriber Protection & Safeguards

- DEA recognizes that addiction treatment is tough, grey and evolving
- Keep a list of terminated patients – (just in case)
- Use all of the tools in your toolbox?
  - Film versus pill?
  - Taper down or not?
  - Change to Vivitriol?
  - Change to injectable form?
  - Wean off?
  - Other?
  - Keep log of such actions

Key Takeaways to Zero-Out Risk

- Treat your prescription pad like your checkbook & secure other pads.
- Never sign prescription blanks in advance.
- Use the PDMP more - than less.
- Prescribe over dispense in office setting (in-patient & hospital settings are different).
- Practice the way you were taught in medical school.
- 99.9% of all medical providers never have an interaction with DEA.



SELF EVALUATION

Medically Assisted Treatment of Opioid Abuse Disorder

True/False

1.___ There is no limit on the total number of opioid dependent patients a provider can treat according to SAMHSA regulations.

2.___ The responsibility for educating and training physicians so that they make sound medical decisions in treating pain, addiction (or any other ailment) lies primarily with medical schools, post-graduate training facilities, State accrediting bodies, and other organizations with medical expertise.

3.___ DEA's authority is limited to controlled substances only.

4.___ Pursuant to recent federal law, Advanced Practice Nurses and Physician Assistants are not allowed to prescribe buprenorphine medications to opioid dependent patients.

5.___ Methadone used for opiate use disorder treatment can only be dispensed by Opioid Treatment Programs.

6.___ The total hours of SAMHSA Data-Waived training is the same for physicians, advanced practice nurses and physician assistants.

7.___ In the majority of instances, first-year DATA-Waived providers can only treat up to 50 patients.

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

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Low Dose CT Screening of Lung Cancer

Objectives

- Become familiar with current (2021) USPSTF recommendations on lung cancer screening
- Recognize the risks and benefits of screening for lung cancer
- Engage appropriate patients in the lung cancer screening process

Pretest Question

- The USPSTF recommends screening adults aged 50-80 years old with a 20 p/y smoking hx (or who have quit within the past 15 years) with

a) A Chest X-ray
b) One Low-dose Chest CT
c) Annual Low-dose Chest CT X 3
d) Annual Low-dose Chest CT through age 80

Pretest Question

- The SECOND most common cause of lung cancer in the US is

a) Asbestos
b) Air Pollution
c) Radon
d) e-cigarettes

Pretest Question

- The percent of FALSE POSITIVE low-dose CT lung scans in the National Lung Screening Trial (n=53,000) was

a) <10%
b) 10-30%
c) 40-60%
d) >90%

Pretest Question

- The *absolute* risk reduction in lung CA mortality found in the National Lung Screening Trial with Low-Dose CT was

a) <1%
b) 20%
c) 40%
d) >60%

Screening for Lung Cancer:
US Preventive Services Task Force Recommendation Statement
2004
INSUFFICIENT EVIDENCE (I)

Moyer VA et al *Ann Int Med* 2014;160:330-338

Screening for Lung Cancer:

US Preventive Services Task Force Recommendation Statement

2013

YES (B)

Moyer VA et al *Ann Int Med* 2014;160:330-338

USPSTF Recommendation Grading 2014

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial	Offer or provide this service
B	The USPSTF recommends this service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial	Offer or provide this service
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is a least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits	Discourage the use of this service
I	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

www.uspreventiveservicestaskforce.org

USPSTF Recommendation Grading 2014

Grade	Definition	Suggestions
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial	Offer or provide this service
B	The USPSTF recommends this service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial	Offer or provide this service

www.uspreventiveservicestaskforce.org

USPSTF: The Latest Greatest 2021

Clinical Review & Education

JAMA | US Preventive Services Task Force | RECOMMENDATION STATEMENT

Screening for Lung Cancer

US Preventive Services Task Force Recommendation Statement

US Preventive Services Task Force *JAMA* 2021;325(10):962-970

USPSTF: The Latest Greatest 2021

Clinical Review & Education

JAMA | US Preventive Services Task Force | RECOMMENDATION STATEMENT

Screening for Lung Cancer

US Preventive Services Task Force Recommendation Statement

US Preventive Services Task Force *JAMA* 2021;325(10):962-970

What does the USPSTF recommend?	Adults aged 50 to 80 years who have a 20 pack-year smoking history and currently smoke or have quit within the past 15 years: • Screen for lung cancer with low-dose computed tomography (CT) every year. • Stop screening once a person has not smoked for 15 years or has a health problem that limits life expectancy or the ability to have lung surgery. Grade: B

Clinical Review & Education

JAMA | US Preventive Services Task Force | RECOMMENDATION STATEMENT

Screening for Lung Cancer

US Preventive Services Task Force Recommendation Statement

US Preventive Services Task Force *JAMA* 2021;325(10):962-970

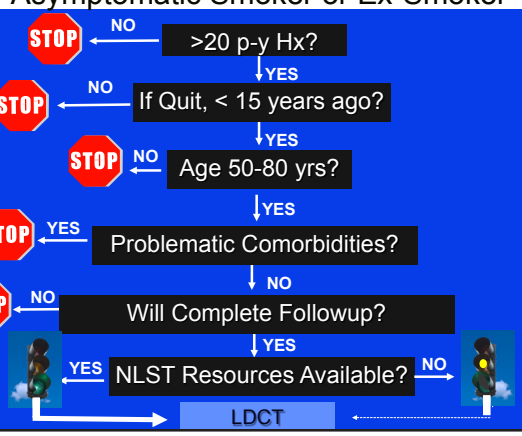
WHO

- Age 50-80
- 20 p-y Hx
- Currently smoke or stopped <15 yrs prior

HOW

- LDCT annually age 50-80
- Stop if
  - smoking cessation >15 yrs
  - heath problem limits life expectancy
  - health problem precludes lung surgery

Asymptomatic Smoker or Ex-Smoker



LUNG CA
Epidemiologic Burden

Lung CA: Current Burden

- 2nd most common CA
- #1 cause of CA death
- Overall 5-year survival = 20.5%

US Preventive Services Task Force *JAMA* 2021;325(10):962-970

Estimated NEW CASES 2021

			Males	Females			
Prostate	248,530	26%			Breast	281,550	30%
Lung & bronchus	119,100	12%			Lung & bronchus	116,660	13%
Colon & rectum	79,520	8%			Colon & rectum	69,980	8%
Urinary bladder	64,280	7%			Uterine corpus	66,570	7%
Melanoma of the skin	62,260	6%			Melanoma of the skin	43,850	5%
Kidney & renal pelvis	48,780	5%			Non-Hodgkin lymphoma	35,930	4%
Non-Hodgkin lymphoma	45,630	5%			Thyroid	32,130	3%
Oral cavity & pharynx	38,800	4%			Pancreas	28,480	3%
Leukemia	35,530	4%			Kidney & renal pelvis	27,300	3%
Pancreas	31,950	3%			Leukemia	25,560	3%
All Sites	**970,250**	**100%**			**All Sites**	**927,910**	**100%**

Siegel RL, et al CA Cancer J Clin 2021;71:7-33

Estimated DEATHS 2021

			Males	Females			
Lung & bronchus	69,410	22%			Lung & bronchus	62,470	22%
Prostate	34,130	11%			Breast	43,600	15%
Colon & rectum	28,520	9%			Colon & rectum	24,460	8%
Pancreas	25,270	8%			Pancreas	22,950	8%
Liver & intrahepatic bile duct	20,300	6%			Ovary	22,950	5%
Leukemia	13,900	4%			Uterine corpus	12,940	4%
Esophagus	12,410	4%			Liver & intrahepatic bile duct	9,930	3%
Urinary bladder	12,260	4%			Leukemia	9,760	3%
Non-Hodgkin lymphoma	12,170	4%			Non-Hodgkin lymphoma	8,550	3%
Brain & other nervous system	10,500	3%			Brain & other nervous system	8,100	3%
All Sites	**319,420**	**100%**			**All Sites**	**289,150**	**100%**

Siegel RL, et al CA Cancer J Clin 2021;71:7-33

Lung CA: The Global Picture

"The most common causes of cancer in 2020 were:
- lung (1.80 million deaths);
- colon and rectum (935 000 deaths);
- liver (830 000 deaths);
- stomach (769 000 deaths); and
- breast (685 000 deaths)."

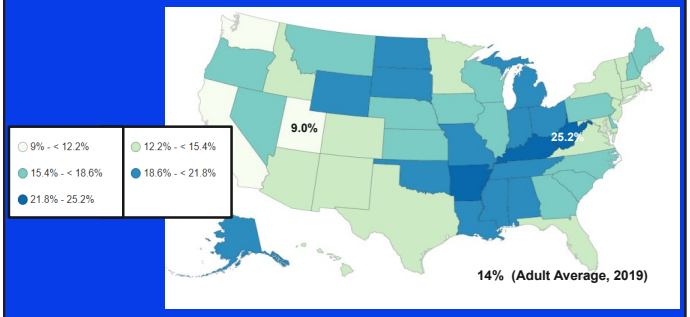
WHO accessed May 3, 2021 https://www.who.int/news-room/fact-heets/detail/cancer

Light At the End of the Tunnel? China

- Current Smokers:
  - >50% adult men
  - 26.5% of all adults over age ≥15

WHO accessed May 3, 2021 https://www.who.int/china/health-topics/tobacco

Current US Smoking Prevalence



CDC.Gov accessed May-3-2021 (Updated December 2020)
/www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm

Lung CA: Risk Factors

- Smoking (→ 85% of all lung cancer)
  - Cigarettes
  - Pipe
  - Cigars
- Radon

NOT

- Marijuana

American Cancer Society. *Cancer Facts & Figures 2013*. Atlanta: ACS; 2013.

Marijuana ↔ Chronic Lung Disease? NOT

"We systematically reviewed 34 studies…. these studies fail to report a consistent association between long-term marijuana smoking and FEV_1/FVC ratio, DL_{CO}, or airway hyperreactivity."

Tetrault JM et al Effects of Marijuana Smoking on Pulmonary Function and Respiratory Complications" Arch Intern Med 2007;167:221-228

Marijuana ↔ Lung Cancer? NOT

"A systematic review assessing 19 studies …concluded that observational studies failed to demonstrate statistically significant associations between marijuana inhalation and lung cancer after adjusting for tobacco use."

NCI Cannabis and Cannabinoids PDQ Health Professional Version Last Modified 11/21/2013 www.cancer.gov accessed 014/Feb-2

Lung CA Risk Factors: Radon?

"Exposure to radon gas released from soil and building materials is estimated to be the second leading cause of lung cancer in Europe and North America."

American Cancer Society. *Cancer Facts & Figures 2013*. Atlanta: ACS; 2013.

Lung CA: 'Tier 2' Risk Factors

- Asbestos
- Chromium
- Cadmium
- Arsenic
- Radiation
- Air pollution
- Diesel exhaust
- Paint

American Cancer Society. *Cancer Facts & Figures 2013*. Atlanta: ACS; 2013.

Lung CA: Occupational Risk Factors

- Rubber manufacturing
- Paving
- Roofing
- Chimney Sweeping

American Cancer Society. *Cancer Facts & Figures 2013*. Atlanta: ACS; 2013.

Lung CA: The Language

- AIS: adenocarcinoma in situ
  - small solitary lesion; *pure* lepidic growth
- MIA: minimally invasive carcinoma
  - Small solitary lesion with *predominantly* lepidic growth with ≤5 mm invasion

Akin A, et al CA Cancer J Clin 2012;62(6):364-393

Lung CA: The Language

Lepidic (lĕ-pid´ik) [Gr *lepis* scale]

1) Pertaining to scales

2) pertaining to embryonic layers

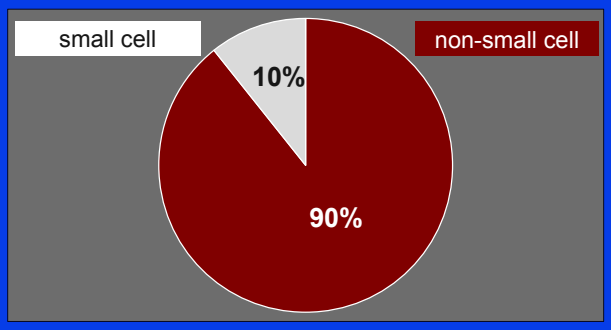
Dorland's Illustrated Medical Dictionary 26th Edition 1974

Lung CA: The Language

"For resection specimens…AIS and MIA… define patients who, if they undergo complete resection, will have 100% or near 100% disease-specific survival."

Akin A, et al CA Cancer J Clin 2012;62(6):364-393

Lung CA Classification



The First Prominent Message

Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening

The National Lung Screening Trial Research Team
N Engl J Med 2011;365(5):395-409

NLST: Step 1

- STUDY: aSx participants enrolled at 33 US centers (n=53,454)
- INCLUSION:
  - Age 55-74 with 30 p-y smoking Hx
  - If quit, ≤15 years ago
- RANDOMIZATION (q1y X 3)
  - Low Dose CT (n=26,722)
  - Single PA CXR (n=26,732)
- PRIMARY OUTCOME: Lung CA mortality

NLST Research Team N Eng J Med 2011;365(5):395-409

NLST: Step 1

PREMISES

- RCT of CXR: no mortality risk reduction
- Molecular Markers: NRFPT
- CT advances allow lower radiation dose
- H2H CT vs CXR: CT superior for detecting nodules and cancers

NLST Research Team N Eng J Med 2011;365(5):395-409

NLST: Why Wasn't This a PLACEBO Controlled Trial?

"Radiographic screening…was chosen... because [CXR vs community care] was being evaluated in the PLCO trial at the time the NLST was designed."

BECAUSE

- IF, in PLCO: CXR > community care (NOT)
- THEN: NLST would have had to prove LDCT >CXR

NLST Research Team N Eng J Med 2011;365(5):395-409

NLST: Exclusions

- Previous Dx Lung CA
- CT Chest ≤ 18 months prior to enrollment
- Hemoptysis
- Unexplained Weight loss > 15# in prior 12 months

NLST Research Team N Eng J Med 2011;365(5):395-409

NLST: Radiation Burden Compared

Exposure	Radiation
Annual Background Radiation (US)	2.4 mSv
LDCT Chest	1.5 mSv
'Standard' CT Chest	8 mSv
Mammography	0.7 mSv
Head CT	1.7 mSv

Moyer VA, et al Ann Int Med online accessed 013-Dec-30
NLST Research Team N Eng J Med 2011;365(5):395-409

"Typical" Effective Doses from X-ray

Radiographic Study	Dose (mSv)	Equivalent #CXR
Chest PA	0.013	1
L-spine AP	0.44	30
Mammogram (4 view)	0.2	15
Dental Panorama	0.012	1
BE	5	350
CT L-spine	7	550
CT Abdomen	10	750
CT Chest	10	750
LDCT Chest	1.5	113

Adapted from Linet MS et al CA Cancer J Clin 2012;62:75-100

Estimated Radiation-Related Cancers from Repeated Screening

Test	Frequency	Age (years)	X-ray related CA/100,000
Lung LDCT	Q1Y	50-70	230 (♂)
			850 (♀)
Coronary Ca++	Q1Y	45-70	40 (♂)
		55-70	60 (♀)
Mammography	Q1Y <55	45-74	90
	Q2Y >55		

Linet MS et al CA Cancer J Clin 2012;62:75-100

NLST: Defining "+" Findings

- LDCT: Any non-calcified nodule > 4mm
- CXR: any non-calcified nodule or mass
- BOTH:
  - Adenopathy
  - Effusion

NLST Research Team N Eng J Med 2011;365(5):395-409

Baseline Characteristics

Characteristic	LDCT (n=26,722)	CXR (n=26,732)
Age at Randomization		
<55	2 (<0.1%)	4 (<0.1%)
55-60	11,440 (42.8%)	11,420 (42.7%)
60-64	8,170 (30.6%)	8,198 (30.7%)
65-69	4,756 (17.8%)	4,762 (17.8%)
70-74	2,353 (8.8%)	2,345 (8.8%)
>75	1 (<0.1%)	3(<0.1%)
Males	15,770 (59%)	15,762 (59.0%)
Females	10, 952 (41%)	10,970 (41%)

NLST Research Team N Eng J Med 2011;365(5):395-409

Screening Rounds: +Findings

	LDCT		CXR	
	#	+	#	+
T0	26,309	?	26,035	?
T1	24,715	?	24,089	?
T2	24,102	?	23,346	?

NLST Research Team N Eng J Med 2011;365(5):395-409

Screening Rounds: +Findings

	LDCT		CXR	
	#	+	#	+
T0	26,309	7,191 (27.3%)	26,035	2,387 (9.2%)
T1	24,715	6,901 (27.9%)	24,089	1,482 (6.2%)
T2	24,102	4,054 (16.8%)	23,346	1,174 (5.0%)

NLST Research Team N Eng J Med 2011;365(5):395-409

NLST Limitations: How Much Unwanted 'Noise'*?

	+ Screen	% +Screens that were FALSE+
LDCT	24.2%	96.4%
CXR	6.9%	94.5%

*Includes all three sequential screens

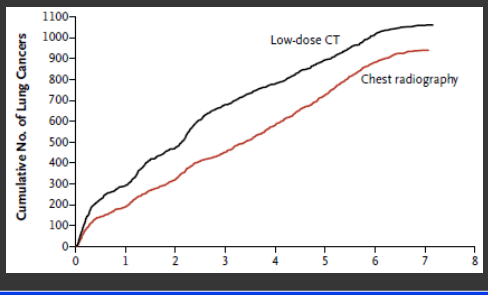
NLST Research Team N Eng J Med 2011;365(5):395-409

LDCT Screening: Adverse Events

PROCEDURE	COMPLICATION (%)				
	Any	Major	Intermediate	Minor	Death
Thoracotomy Thoracoscopy Mediastinoscopy	165 (32.4)	71 (13.9)	81 (15.9)	13 (2.6)	5 (1.0)
Bronchoscopy	7 (9.2)	2 (2.6)	5 (6.6)	0	4 (5.3)
Needle Bx	7 (21.2)	0	7 (21.2)	0	1 (3.0)
Non-Invasive	5 (16.1)	5 (16.1)	2 (6.5)	1 (3.2)	0

NLST Research Team N Eng J Med 2011;365(5):395-409

NLST: Lung CA Incidence



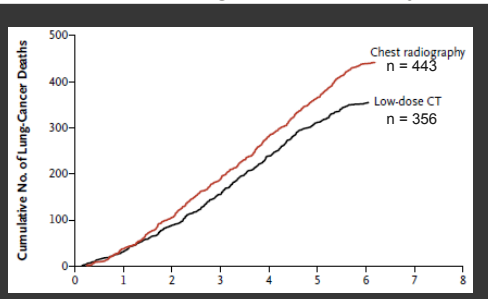
NLST Research Team N Eng J Med 2011;365(5):395-409

NLST: Primary Outcome

	Lung CA Mortality (n)	Lung CA Mortality (rate/100K-y)	RR	NNT
LDCT	356	247/100K-y	0.8 (6.8-26.7) p = 0.004	320
CXR	443	309/100K-y		

NLST Research Team N Eng J Med 2011;365(5):395-409

NLST: Lung CA Mortality



NLST Research Team N Eng J Med 2011;365(5):395-409

NLST: ALL-CAUSE Mortality

	Mortality (n)	RR
LDCT	1,877	0.93 p = 0.02
CXR	2,000	

NLST Research Team N Eng J Med 2011;365(5):395-409

NLST Primary Outcome: Simpler

	Lung CA Mortality (n)	Rate (%)	Absolute RR
LDCT	356/26,309	1.3%	0.348%
CXR	443/26,035	1.7%	

NLST Research Team N Eng J Med 2011;365(5):395-409

NLST Limitations: Remarkably Low Surgical Mortality

"…one of the most important factors determining the success of screening will be the mortality associated with surgical resection, which was much lower in NLST than has been reported previously in the general US population (1% vs 4%)

? How 'bout OUR house? ?

NLST Research Team N Eng J Med 2011;365(5):395-409

NLST Limitations: How Much Unwanted 'Noise'*?

	+ Screen	% +Screens that were FALSE+
LDCT	24.2%	96.4%
CXR	6.9%	94.5%

*Includes all three sequential screens

NLST Research Team N Eng J Med 2011;365(5):395-409

NLST: How Much 'Unsolicited Signal'?

"The NLST reported that 7.5% of non-lung cancer abnormalities were clinically significant."

Moyer VA, USPSTF Ann Int Med 2013;Dec 31 (Online)

NLST Incidentalomas: Impact?

"None of the studies reported data on the evaluations…in response to the incidental findings, therefore, the harms and benefits…cannot currently be determined."

Moyer VA, USPSTF Ann Int Med 2013;Dec 31 (Online)

Limitations of NLST: Generalizability

- Exclusions
  - Unlikely to complete curative surgery
  - Competing comorbidities posing risk for death during 8-yr trial
- Healthy sample
- Age: <10% over age 70

USPSTF Lung CA Screening Limitations: Comorbidities

"The NLST, the largest RCT (n > 50K)… enrolled generally healthy persons, and the findings may not accurately reflect the balance of benefits and harms in those with comorbid conditions."

Moyer VA, et al Ann Int Med online accessed 013-Dec-30

USPSTF Lung CA Screening Limitations: Generalizability

"The evidence for the effectiveness…comes from…large academic medical centers with expertise in using LDCT…and managing abnormal lung lesions."

?? How well might MY local resources compare??

Moyer VA, et al Ann Int Med online accessed 013-Dec-30

HARMS of Lung CA Screening: Summary Recommendation

"The harms associated with LDCT screening include false- and false+ results, incidental findings, overDx, and radiation exposure.

Moyer VA, et al Ann Int Med online accessed 013-Dec-30

HARMS of Lung CA Screening: OverDx

"A modeling study performed for the USPSTF estimated that 10%-12% of screen-detected cancer cases are over diagnosed—that is, they would not have been detected in the patient's lifetime without screening."

Moyer VA, et al Ann Int Med online accessed 013-Dec-30

HARMS of Lung CA Screening: False Positives

"…95% of all positive results do not lead to a Dx of cancer."

Moyer VA, et al Ann Int Med online accessed 013-Dec-30

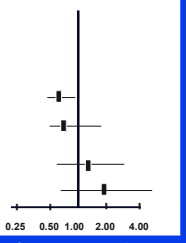
LDCT Screening HARMS: Did They Miss Any?

- False +/-
- Radiation
- Incidentalomas
- OverDx (≠False+)

- $$
- Resource Utilization
- -LDCT = Permission to Keep Smoking?
- Reinforcement: "I can do this now 'cause they can fix it later."

Lung CA **MORTALITY**
Comparing OTHER LDCT Lung CA Screening Trials

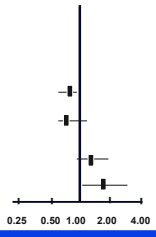
Trial (n)	Men %	F/U yrs	Lung CA Mortality RR (CI)
NLST (53,454)	59	6.5	0.80 (0.73-0.93)
DANTE (2,472)	100	2.8	0.83 (0.45- 1.54)
DLCST (4,104)	56	4.8	1.37 (0.63-2.97)
MILD (4,099)	66	4.4	1.99 (0.80-4.96)



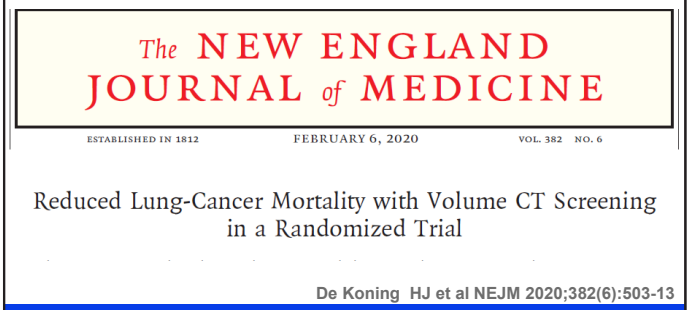
Moyer VA, et al Ann Int Med online accessed 013-Dec-30

ALL-CAUSE MORTALITY
Comparing OTHER LDCT Lung CA Screening Trials

Trial (n)	Men %	F/U yrs	All-Cause Mortality RR (CI)
NLST (53,454)	59	6.5	0.93 (0.86-0.99)
DANTE (2,472)	100	2.8	0.85 (0.56-1.27)
DLCST (4,104)	56	4.8	1.46 (0.99-2.15)
MILD (4,099)	66	4.4	1.80 (1.03-3.13)



Moyer VA, et al Ann Int Med online accessed 013-Dec-30



De Koning HJ et al NEJM 2020;382(6):503-13

Lung CA Screening: LDCT the NELSON Trial

- Study: RDBPCT ♂ (n=13,195), ♀ (n= 2,594), and unknown (n=3)
- Inclusion (Current or Ex-smokers):
  - Adults ≥15 p-y smoking Hx
  - If quit, ≤10 yrs prior
  - Wt <140 kg
  - No breast CA, kidney CA or melanoma
  - No lung CA within 5 years

De Koning HJ et al NEJM 2020;382(6):503-13

Lung CA Screening: LDCT the NELSON Trial

- Intervention: Low Dose CT vs placebo
  - T-0
  - Year 1
  - Year 3
  - Year 5.5
- Outcomes (at 10 years)
  - Lung CA incidence
  - Lung CA mortality
  - All-cause mortality (males)

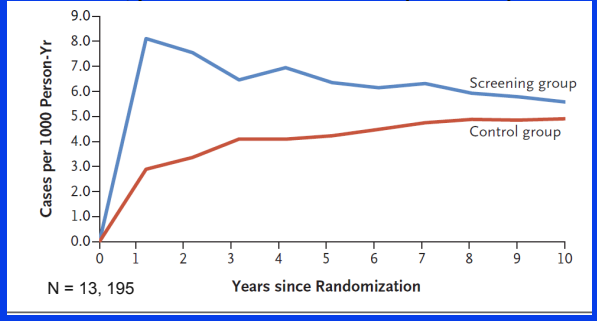
De Koning HJ et al NEJM 2020;382(6):503-13

LDCT Lung CA Screening: the NELSON Trial
Baseline Demographics

	LDCT	PBO
Age (median)	58	58
Smoking P-Yr median	38	38
Former Smoker	44.5	45.2

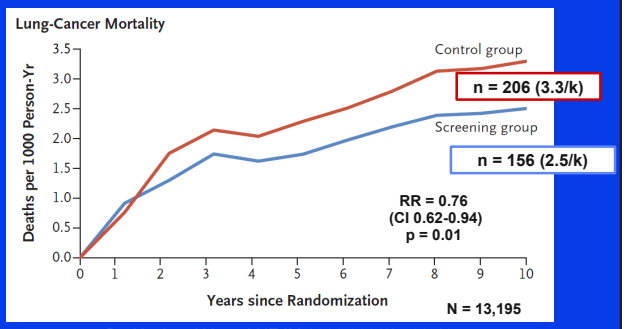
De Koning HJ et al NEJM 2020;382(6):503-13

LDCT Lung CA Screening: the NELSON Trial
Lung CA INCIDENCE (Males)



De Koning HJ et al NEJM 2020;382(6):503-13

LDCT Lung CA Screening: the NELSON Trial
Lung CA MORTALITY (Males)



De Koning HJ et al NEJM 2020;382(6):503-13

LDCT Lung CA Screening: the NELSON Trial
The 'Less Cheery News"

10 yr Outcomes	RR	p
Lung CA Mortality (Females)	0.67 (CI 0.38-1.14)	NS
All-cause mortality (Males)	1.01 (CI 0.98-1.11)	NS

De Koning HJ et al NEJM 2020;382(6):503-13

Lung CA Screening
The LUSI Trial

IJC
International Journal of Cancer

Lung cancer mortality reduction by LDCT screening—Results from the randomized German LUSI trial

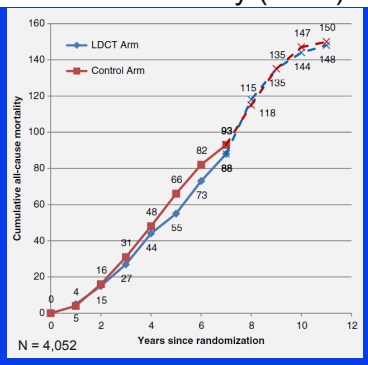
Becker N et al *Int J Cancer* 2020;146:1503-1513

Lung CA LDCT Screening: Germany
LUSI (Lung Cancer Screening Intervention)

- Study: RCT adult smokers (n= 4,042)
- Inclusion:
  - Age 50-69
  - ± 15-19 p-y Hx (10/d x30 yrs, 15/d x 25 yrs)
  - If stopped, <10 yrs
- Intervention: LDCT X 5 years vs control

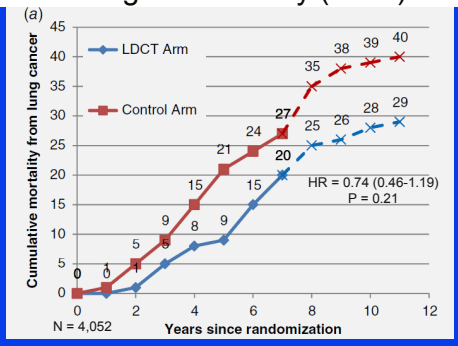
Becker N et al *Int J Cancer* 2020;146:1503-1513

Lung CA LDCT Screening All-Cause Mortality (LUSI)



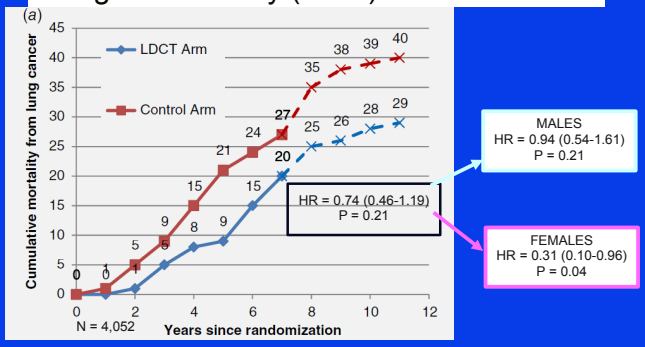
Becker N et al *Int J Cancer* 2020;146:1503-1513

Lung CA LDCT Screening Lung CA Mortality (LUSI)



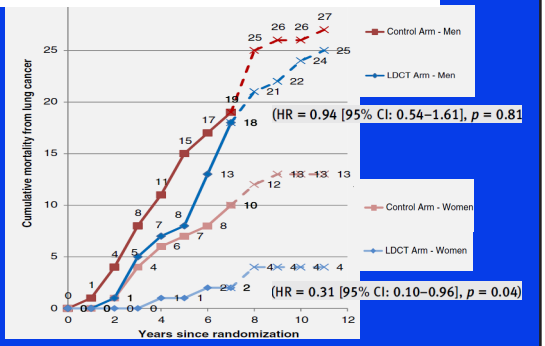
Becker N et al *Int J Cancer* 2020;146:1503-1513

Lung CA LDCT Screening Lung CA Mortality (LUSI): The 'Fine Print'



Becker N et al *Int J Cancer* 2020;146:1503-1513

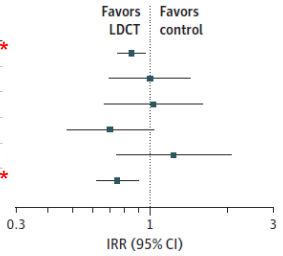
Lung CA Mortality



Becker N et al *Int J Cancer* 2020;146:1503-1513

Lung Cancer Mortality

Study, y	Follow-up, y	IRR (95% CI)
NLST,[29-37] 2011-2019	6.5	0.85 (0.75-0.96)*
DANTE,[12-14] 2008-2015	8.4	1.00 (0.69-1.44)
DLCST,[15,16] 2012-2016	9.8	1.03 (0.66-1.61)
ITALUNG,[17] 2017	9.3	0.70 (0.47-1.03)
LSS,[18-20] 2004-2018	5.2	1.24 (0.74-2.07)
NELSON,[24-28] 2006-2020	10	0.75 (0.61-0.90)*

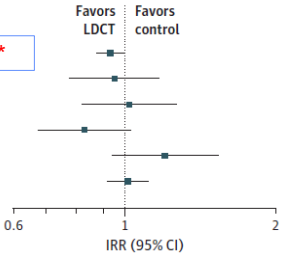


* p < 0.05

US Preventive Services Task Force *JAMA* 2021;325(10):962-970

All-Cause Cancer Mortality

Study, y	Follow-up,	IRR (95% CI)
NLST,[29-37] 2011-2019	6.5	0.93 (0.88-0.99)*
DANTE,[12-14] 2008-2015	8.4	0.95 (0.77-1.17)
DLCST,[15,16] 2012-2016	9.8	1.02 (0.82-1.26)
ITALUNG,[17] 2017	9.3	0.83 (0.67-1.03)
LSS,[18-20] 2004-2018	5.2	1.20 (0.94-1.53)
NELSON,[24-28] 2006-2020	10	1.01 (0.92-1.11)



* p < 0.05

US Preventive Services Task Force *JAMA* 2021;325(10):962-970

Lung CA Prevention?

- Well, there's
  - Smoking Cessation/Avoidance
  - Asbestos Avoidance
  - Radon Avoidance
  - Silica Dust
- Anything else?

Lung CA Prevention: NOT
The ATBC (α–tocopherol β–carotene) Study

- STUDY: Lung CA Prevention Trial 1985-93
- SUBJECTS: male smokers (n = 29,133)
- Rx: Vitamin E 50 mg/d vs β–Carotene 20mg/d vs Both vs placebo X mean 6.1 years
- RESULTS:
  - β-carotene 20 mg/d → 18% Lung CA↑
    → 8% Mortality ↑

ATBC Study Group N Engl J Med 1994;330:1029-1035

Lung CA Prevention: NOT NOT
CARET (carotene + retinol) Trial

- STUDY: High risk Lung CA Subjects (n =18,314)
  - Men & Women
  - Current & Former Smokers
  - Asbestos Workers (n= 4,060)
- Rx : 30 mg b-carotene + 25,000 IU Vit A daily
- OUTCOME: 4 Yrs Rx → 28%↑ lung CA, 17% ↑ deaths → study terminated 21months early

Omenn GS, et al β-Carotene & Retinol Efficacy Trial (CARET) IARC Sci Pub 1996;136:67-85

What to do about Vitamin Supplementation?

"Smokers should avoid beta carotene supplementation."

The ATBC Study Group "Incidence of Cancer and Mortality Following α-Tocopherol and β-Carotene Supplementation" JAMA 2004;290(4):476-485

Improving the Odds in Lung CA: Say "I do"

"One study of an American population showed…that patients who were married had better survival rates than patients who were single, divorced or widowed when examining all major primary site cancers."

Bailey J "Effect of Marital Status on Cancer Incidence and Survival Rates" Am Fam Phys 2009;80(120):1052-1058

2014 AAFP Clinical Recommendations
Lung CA Screening: Grade I (Insufficient Evidence)

" A shared-decision making discussion between the clinician and patient should occur regarding the benefits and potential harms of screening for lung cancer."

AAFP Clinical Recommendations aafp.org accessed 1/28/2014

Pretest Question

- The USPSTF recommends screening adults aged 50-80 years old with a 20 p/y smoking hx (or who have quit within the past 15 years) with

a) A Chest X-ray
b) One Low-dose Chest CT
c) Annual Low-dose Chest CT X 3
d) Annual Low-dose Chest CT through age 80

Pretest Question

- The SECOND most common cause of lung cancer in the US is

a) Asbestos
b) Air Pollution
c) Radon
d) e-cigarettes

Pretest Question

- The percent of FALSE POSITIVE low-dose CT lung scans in the National Lung Screening Trial (n=53,000) was

a) <10%
b) 10-30%
c) 40-60%
d) >90%

Pretest Question

- The absolute risk reduction in lung CA mortality found in the National Lung Screening Trial with Low-Dose CT was

a) <1%
b) 20%
c) 40%
d) >60%

SELF EVALUATION

Low Dose CT Screening of Lung Cancer

1. The mortality toll of lung cancer in the United States ranks how?

a. #1
b. #3
c. #10
d. #10

2. The 2021 USPSTF recommendation suggests as criteria for considering low-dose CT lung cancer screening:

a. Reducing the pack-year burden to 20 pack years (from the previous requirement of 30 pack years)
b. Increasing the age for inclusion to 60 years (from the previous requirement of 55 years)
c. Adding marijuana smoking into total smoking pack-years

3. The 2nd most common cause of lung cancer in the USA is

a. Asbestos exposure
b. Air pollution
c. Marijuana
d. Radon

4. The National Lung Screening Trial (n>53.000) is the largest Low Dose CT Trial ever performed. Which of the findings below was determined in the trial?

a. Low Dose CT screening reduces all-cause mortality, but not to a statistically significant degree
b. Low Dose CT screening reduces all-cause mortality to a statistically significant degree
c. Low Dose CT screening reduces lung-CA mortality to a statistically significant degree
d. Low Dose CT screening reduces Lung-CA mortality, but not to a statistically significant degree
e. B and C

5. Low Dose Chest CT is 80% less radiation than a full dose Chest CT. Using the radiation exposure from a typical chest x-ray as a comparison metric, ONE Low Dose CT is equivalent to

a. 5 chest xrays
b. 10 chest xrays
c. 50 chest xrays
d. >100 chest xrays

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

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Menopause and Sexual Health

Disclosure Information

- *I have no financial interests or relationships with commercial manufacturers to disclose*

Objectives

- Describe the clinical symptoms of menopause
- Define the indications and contraindications for HRT
- Describe the treatments for painful sexual intercourse
- Describe the recommendations for calcium and Vitamin D for prevention of osteoporosis
- Describe the management of postmenopausal bleeding
  – When to do an endometrial biopsy
  – When to order an ultrasound

Menopause

- At birth, the female has 1-2 million oocytes
- • By puberty, only 440,000 oocytes remain
- • By age 30-35 the number has dropped to 100,000
- • Follicular maturation is induced by the pituitary release of Follicle Stimulating Hormone (FSH)

Menopause

- With advancing age, the remaining oocytes become increasingly resistant to FSH
- FSH gradually rises until menopause when it is usually greater than 30 mIU/ml

Menopause

- Menopause is defined as the absence of menstrual periods for one year in a woman over 40
- In the USA, the average age of a woman at menopause is 51
- 1% of women will undergo menopause before age 40
- Women who smoke cigarettes and who are malnourished will have earlier menopause

Menopause Symptoms

- First symptoms are often menstrual irregularities
  – Menstrual cycles shorten or lengthen
- Hot flushes and vasomotor instability
  – sudden sensation of warmth, skin of face and chest will become flushed
  – then patient will experience a chill
  – this is the result of lower estrogen levels
  – more bothersome at night

Menopause Symptoms

- Sleep disturbance
– Total length of time asleep is shorter
- Vaginal dryness/genital tract atrophy
– vaginal mucosa and endometrium become thin and dry
– irritation, difficulty with sexual intercourse may develop

Menopause Symptoms

- Mood changes
– Depression, crying spells may develop
- Skin and nails
– skin and nails become thinner
- Osteoporosis
– Bone density is lost at a rate of 1-2% per year after menopause
– Risk of hip and vertebral fracture increases as soon as 5 years after menopause

Menopause Symptoms

- Cardiovascular Lipid changes
– Total cholesterol increases, high density lipoprotein (HDL) cholesterol decreases, and low density lipoprotein increases
– Risk of heart attack and stroke increases in women after menopause

Menopause Diagnosis

- Use symptoms and signs
- Do not depend upon FSH
- FSH will often not rise until late in the perimenopausal period and may fluctuate
- Normal FSH does not exclude the perimenopause
- Consider thyroid disease if FSH is normal
- No need for biopsy prior to staring HRT

Menopause Therapy

- For asymptomatic women, no therapy or treatment is necessary
- Calcium intake should be at least 1200 milligrams a day
- Weight bearing exercise will help in preventing osteoporosis
- For prevention of osteoporosis therapy is useful

Hormone Replacement Therapy

- Indications
– Relief of menopausal symptoms
- Hot flashes, mood irritability, vaginal dryness, loss of libido
- Osteoporosis prevention
- Contraindications
– Undiagnosed abnormal genital bleeding
– Estrogen dependent neoplasia (Breast, Uterus)
– History of thromboembolism, stroke
– Liver dysfunction/disease

Hormone Replacement Therapy

- Unopposed estrogen is associated with endometrial hyperplasia and carcinoma
- Progesterone withdrawal required at a minimum of every three months
- Five years or less rule

Bleeding on HRT

- What test should be performed on the patent with persistent irregular bleeding on HRT?
- What you are trying to rule in or out?

Postmenopausal Bleeding

- Etiologies:
  - Atrophic Endometritis: 30%
  - Endometrial Polyps: 10%
  - Submucosal Fibroids: 10%
  - Endometrial Hyperplasia: 10%
  - Uterine Malignancy: 10%
  - Miscellaneous: 30%

Postmenopausal Bleeding

- Workup
  - Endometrial biopsy
  - If Endometrial biopsy negative, observation
  - If persistent, then Dilation & Curettage

Evaluation

- Etiology
  - Hormonal-breakthrough bleeding, adjust dose
  - Structural-Polyps, myomas
  - Neoplasia-hyperplasia, carcinoma
- Endometrial biopsy is the standard test for any abnormal bleeding
  - very sensitive for neoplasia
  - not sensitive for polyps, fibroids

Evaluation

- Ultrasound
  - Transvaginal ultrasound allows for high resolution imaging of the endometrium
  - Normal is less than 4 millimeters by most studies
  - Stripe of greater than 4 millimeters requires further evaluation

Osteoporosis

- Bone is living tissue that has to be constantly repaired and renewed because of microscopic damage that occurs with daily physical activity
- This process of renewal is called bone turnover and is carried out by two sets of cells; one set (osteoclasts) dig up bone whilst the other set (osteoblasts) lay down new bone.
- The two processes are linked (coupled) together so that they balance each other.

Osteoporosis

- If there is a relative increase in bone resorption (removal), as happens following menopause, then bone tissue is lost and bones become thinner.
- The maximum amount of bone in the skeleton (peak bone mass) is achieved soon after linear growth ceases. There is gradual loss of bone with aging in adults, but major bone loss in women occurs with loss of estrogen at the menopause.

Prevention of Osteoporosis

- As the estrogen level decreases in a perimenopausal woman the calcium content of bones decreases
- HRT is indicated for the prevention of osteoporosis, not treatment

The Painful Vagina

- The vagina becomes very thinned and susceptible to injury from exercise and sexual intercourse as a woman enters menopause
- Vaginal pain, pain with sexual intercourse is from vaginal atrophy
- Use of water based lubricants, estrogen based creams/tablets, and vaginal dilators helpful
- Will be discussed further in a separate lecture

SELF EVALUATION

Menopause and Sexual Health

True/False

1.___ FSH levels decrease with advancing age.

2.___ In the United States the average age of menopause is age 51.

3.___ Women who smoke cigarettes on a regular basis have a later menopause than a woman who does not.

4.___ Calcium intake during menopause should be 1000mg

5.___ Weight bearing exercises such as swimming help prevent osteoporosis.

6.___ Bleeding is considered normal while taking hormone replacement therapy during the postmenopausal period.

7.___ The most common cause of postmenopausal bleeding is atrophic vaginitis.

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

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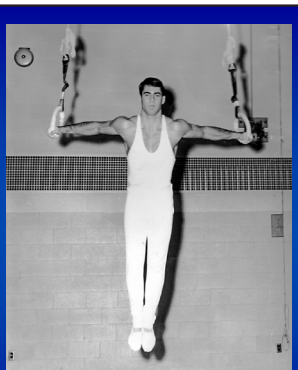
The 9 Strategies of Highly Successful and Effective Leaders

Life Aspirations ?



Kent State University, October 12, 1967
My Goals at the time ?

A Simple Question?

More than four decades ago, I became fascinated with a simple question: "Why do some people thrive while others seem to tread water and merely survive ?" After years of formal education, I realized that virtually no college course had prepared me for the "real life" career challenges I'd begun to experience. To find out, I began reading everything I could on leadership and success strategies, and carefully studied the "stars" in their respective fields. Were there common behaviors they exhibited on a daily basis ? You bet there were ! The "take home message" ? Leadership and professional opportunities don't just happen. YOU CREATE THEM, by demonstrating certain ACTIONS and behaviors on a regular basis.

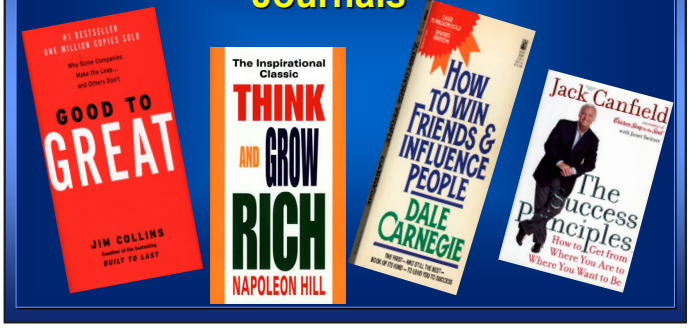
"YOU ARE YOUR OWN FORTUNE COOKIE"---Car Bumper Sticker

Top of the Hierarchical Order of Human Needs ?

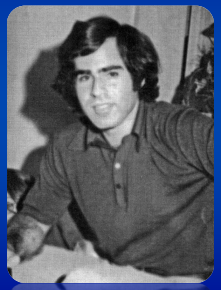
"The meaning of life is to find your gift. The purpose of life is to give it away."

Pablo Picasso

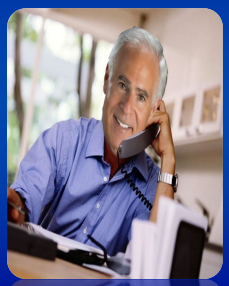
For Starters, Expand Your Library…Beyond Medical/Clinical Journals



Share Some Personal Experiences/Inspirational Stories I Learned Along the Way About Leadership & the 'Setback-Lined' Road to Success…*



4+ decades of work/association experience

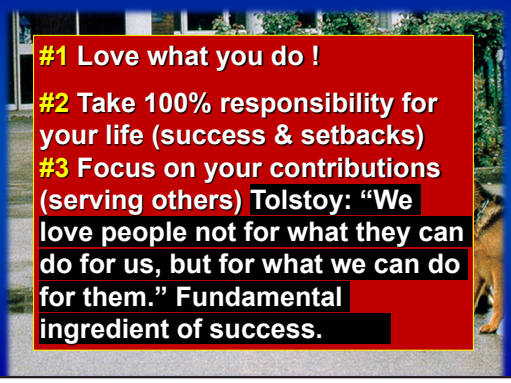


"If you want the rainbow, you've got to put up with the rain." ----Dolly Parton

Outline

- Foundational factors
- Nine strategies for success
- Intangibles: heighten your visibility, commit to never-ending improvement, exceed people's expectations, strive for greater rewards, organizational membership
- Some final thoughts….

Setting Yourself Apart from the Crowd : Foundational Factors for Success---The Big "3"



#1 Love what you do !

#2 Take 100% responsibility for your life (success & setbacks)
#3 Focus on your contributions (serving others) Tolstoy: "We love people not for what they can do for us, but for what we can do for them." Fundamental ingredient of success.

"The only way to do great work is to love what you do. If you haven't found it yet, keep looking." *Steve Jobs (1955- 2011)*

Take 100% Responsibility for Your Life:

The "10" Most Powerful Two Letter Words

If It Is To Be, It Is Up To Me.

My Thailand Trip & the Universal 'Secret" to Success

Making a Difference: Serving Others*

"You can get anything you want in life, if you help enough other people get what they want."

Zig Ziglar


Steve Jobs


Ray Kroc

Henry Ford


Walt Disney

Our Rewards Equal Our Contributions

Outline

- Foundational factors
- Nine strategies for success
- Intangibles: heighten your visibility, commit to never-ending improvement , exceed people's expectations, strive for greater rewards, organizational membership
- Some final thoughts….

Be an Optimist — Look for the "Good" in People and Situations

#1

Happiness + Optimism → Future Success

Look for the 'Good' in Everything that Life Throws at You…

An American shoe company sent two salesmen to the Australian outback. They wanted to find out whether there was any market for shoes among the Aborigines. They received telegrams from both salesmen. The first said, " No business here. The natives don't wear shoes." But the second telegram proclaimed, "Great opportunity here. The natives don't wear shoes."

The Common Question I Ask during my Interviews: How do You Read This ?

OPPORTUNITY

IS NOWHERE

The Unique Mindset of a True Super-Achiever in Life

W. Clement Stone, a self-made millionaire who mentored countless others in the fundamental principles of success, believed that every person he met or circumstance he encountered was meant to better or enrich him. He emphasized that every negative event in life contains in it the seed (e.g., opportunity) of an equal or greater benefit. Accordingly, he viewed life as a series of "Ups" and "Camouflaged Opportunities."

W. Clement Stone

When the latter occurs, you simply have to find the seed or opportunity the event provides and transition it to an "Up."

Be a Goal Setter — Program Your GPS

#2

Classic Study*

- 1,528 gifted children (IQ-genius)
- Relationship between IQ and achievement

- **Major Findings**
  - IQ was NOT the major ingredient for success
  - Three predictors of success
    - Self-confidence
    - Perseverance
    - Tendency to set goals in writing (#1)

** Dr. Lewis Terman, Stanford University, 1921*

The Single Idea For Which A Man Was Paid $25,000

"Write down the 6 most important things you had to do tomorrow. Prioritize them. Cross each one off once you've completed it. Complete unfinished items first the next day, and start the next 6." *Ivy Lee**

** Summoned by Charles M. Schwab, president Bethlehem Steel, 1918*

First Things First*

Make this one change in how you spend your day -- work on what is most important to you before you take care of everything else. Figure out the most important thing for you to be doing right now. **Do it!**

** Steven Covey*

Be a Goal Setter: Program Your GPS

A classic Volvo advertisement stated, "On the road of life there are passengers and there are drivers." The most successful people in the world are drivers – they know exactly where they are going. Moreover, they write (or digitalize) their goals and look at them often.

"Writing your goals is a gateway for transforming the world of conceiving (ideas) and believing to a world of achieving. Until it's on paper, it's vapor."
--Sir John Hargrave

Big Rocks: Scheduling Your Activities*

Big Rocks

Plus Gravel

Plus Sand

Plus Water

*Your "Hour of Power"

Be Proactive — Just Do It!

"Your life is a direct result of what you DO—not necessarily what you say you're going to do." –Art Williams

#3

THE STORY ABOUT FIVE PENGUINS: PICTURE THIS .....

Contemplators Personified

Take Action: The # 1 Success Strategy

"Inertia is the single greatest barrier to success. It's also the easiest to overcome. All you have to do is act. Any action you take, no matter how trivial, will do the trick. The easier you make it on yourself to act, the easier it is to overcome inertia. Focus on a single step, the smallest step you can think of. The moment you take action -- any action -- you will conquer inertia."

Keith Ellis

The Only Productivity Tip You'll Ever Need ?

A body at rest tends to remain at rest and a body in motion tends to remain in motion.

We have more than enough time. Achievement is driven by insight and selective action. Insight requires time – and time, despite conventional wisdom, is there in abundance.

OVERCOME INERTIA BY STARTING THE JOB !!!!!

The Law of GOYA

"Get Off Your Ass"

Tommy Hopkins

This simple law is very effective. You have to do something every day that moves you toward your goals and dreams.

The Universe Rewards Action!

Be Persistent — Overcoming Setbacks that Line the Road to Success

#4

Persistence/Tenacity Pays*…

- Thomas Edison had thousands of learning experiments before he invented the light bulb.
- Abraham Lincoln lost eight elections before becoming president.
- Colonel Sanders suffered more than 1,000 rejections before he sold his first chicken recipe.
- Theodor Geisel's first book was turned down by 28 publishers.

My Story, Student Interaction…I'm the King……

"The way to succeed is to double your failure rate."

Thomas J. Watson
(Founder of IBM)

"You miss 100 percent of the shots you don't take."

Wayne Gretzky
(Hockey Legend)

Michael Jordan: "I have missed more than 9,000 shots in my career. I have lost almost 300 games. On 26 occasions, I have been entrusted to take the game-winning shot, and I missed. I have failed over and over again in my life. And that's precisely why I succeed."

Benefits of Failure

"I think it fair to say that by any conventional measure, a mere 7 years after my graduation day, I had failed on an epic scale. An exceptionally short-lived marriage had imploded, and I was jobless, a lone parent, and as poor as it is possible to be in modern Britain, without being homeless."

"So why do I talk about the benefits of failure? Simply because failure meant a stripping away of the inessential. I stopped pretending to myself that I was anything other than what I was and began to direct all my energy into finishing the only work that mattered to me. I had an old typewriter and a big idea……."

Excerpted from J.K. Rowling's Commencement Speech at Harvard University, 2008

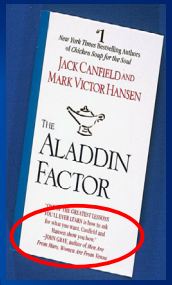
Be Someone Who Asks for What You Want — Reject Rejection

#5

The Aladdin Factor

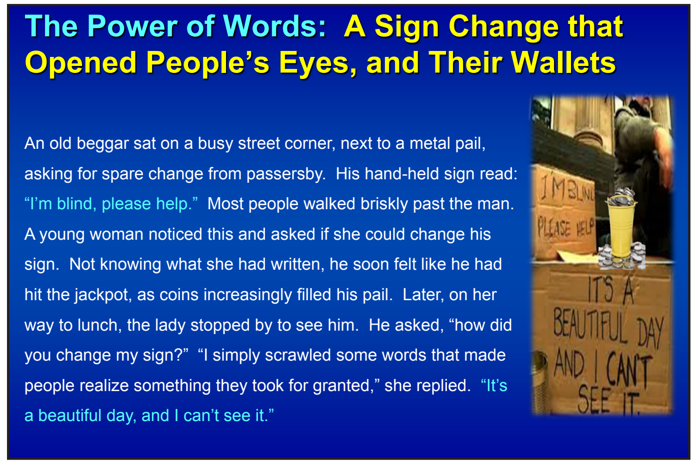
"Ask, and it shall be given you."

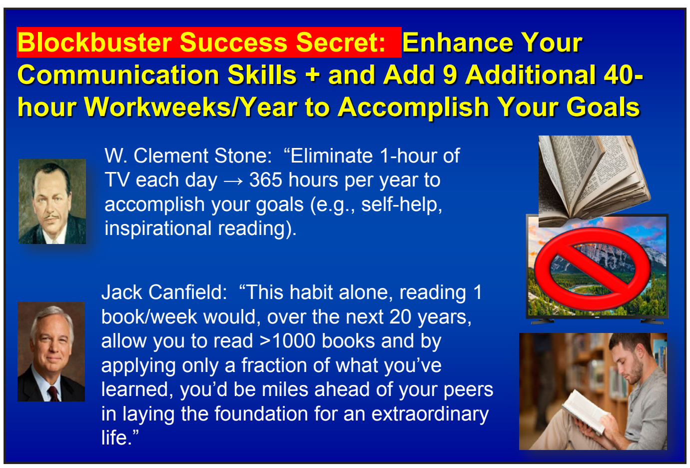
Sermon on the Mount



"You've got to ask! Asking is, in my humble opinion, the world's most powerful-and neglected-secret to success and happiness."
Philanthropist, multi-millionaire Percy Ross

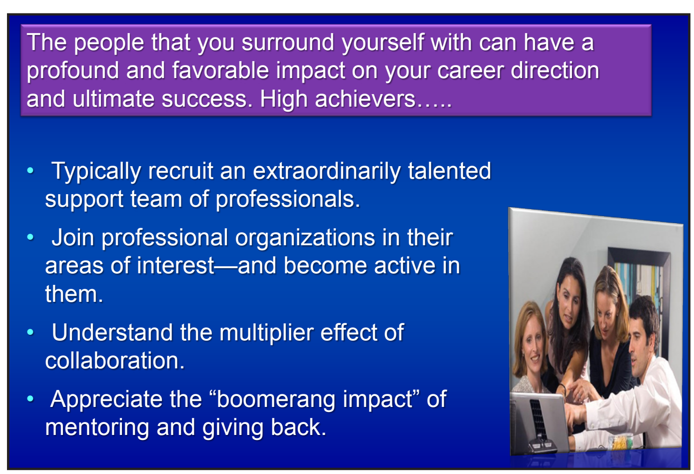

Be a Communicator —
Improve Your Speaking and
Writing Skills
#6
" To an astounding degree, your ability to use our language and the depth and breadth of your vocabulary will determine your income and future career goals." --- Jack Canfield


The Power of Words: A Sign Change that Opened People's Eyes, and Their Wallets
An old beggar sat on a busy street corner, next to a metal pail, asking for spare change from passersby. His hand-held sign read: "I'm blind, please help." Most people walked briskly past the man. A young woman noticed this and asked if she could change his sign. Not knowing what she had written, he soon felt like he had hit the jackpot, as coins increasingly filled his pail. Later, on her way to lunch, the lady stopped by to see him. He asked, "how did you change my sign?" "I simply scrawled some words that made people realize something they took for granted," she replied. "It's a beautiful day, and I can't see it."
IT'S A
BEAUTIFUL DAY
AND I CAN'T
SEE IT.


Blockbuster Success Secret: Enhance Your Communication Skills + and Add 9 Additional 40-hour Workweeks/Year to Accomplish Your Goals
W. Clement Stone: "Eliminate 1-hour of TV each day → 365 hours per year to accomplish your goals (e.g., self-help, inspirational reading).
Jack Canfield: "This habit alone, reading 1 book/week would, over the next 20 years, allow you to read >1000 books and by applying only a fraction of what you've learned, you'd be miles ahead of your peers in laying the foundation for an extraordinary life."


Become a Master Communicator*
▪ Improve your writing/speaking skills
▪ Seek graduate training/education
▪ Become "active" in professional organizations (# 1)
▪ Attend conferences (better yet, PRESENT at them) ; Practice speaking regularly….
▪ Leaders are readers; Talks are auditions!
"The ability to speak is a shortcut to leadership and distinction. The person who can speak acceptably is usually given credit for an ability all out of proportion to what he/she really possesses. "
* Lowell Thomas


Be a Connector — The Power of Positive Associations, Collaborations, and Relationships
#7


The people that you surround yourself with can have a profound and favorable impact on your career direction and ultimate success. High achievers…..
• Typically recruit an extraordinarily talented support team of professionals.
• Join professional organizations in their areas of interest—and become active in them.
• Understand the multiplier effect of collaboration.
• Appreciate the "boomerang impact" of mentoring and giving back.

Surround Yourself with 'Stars': The Power of Positive Association

Advertising agency empire-builder David Ogilvy established a tradition of welcoming new executives with a gift of 6 wooden dolls, each smaller than the other, one inside the other. When the recipient finally gets to the 6th little doll, the smallest doll, and opens it, he/she finds this message:

If each of us hires people who are smaller than we are, we shall become a diminishing company. But if each of us hires people who are bigger (better/smarter) than we are, we shall become a thriving company of giants.

USE COLLABORATION TO EXPONENTIALLY INCREASE YOUR PRODUCTIVITY

People working together to accomplish even more: The Clydesdale Analogy

- One Clydesdale horse can pull 8,000 pounds.
- Two Clydesdale horses can pull 24,000 pounds.
- Two Clydesdale horses that are matched correctly and trained can pull 32,000 pounds!

Be a People Person

#8

People Skills → Success

Most chief executives of major companies, when asked what one single characteristic is most needed by those in leadership positions, replied, "The ability to work with people." What are they looking for ? "The BIG 6".

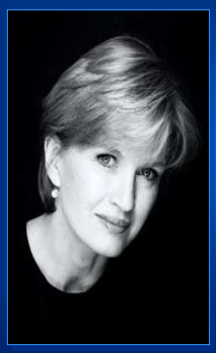
1.INTEGRITY: THE #1 QUALITY FOR SUCCESS
2.GIVE PEOPLE MORE THAN THEY EXPECT
3.OFFER COLLEAGUES/EMPLOYEES PRAISE/APPRECIATION
4.MAKE PEOPLE FEEL IMPORTANT (Danny Meyer, Founder Shake Shack)
5.INDIVIDUALS WHO ARE SIMPLY NICE PEOPLE
6.DON'T TELL PEOPLE, SHOW THEM

The Likeability Factor

"It's nice to be important, but it's more important to be nice."

Shay Kennedy

TAKE THE HIGH ROAD . . .



TAKE THE HIGH ROAD . . .

Class Act

Wisest Counsel I Ever Received?

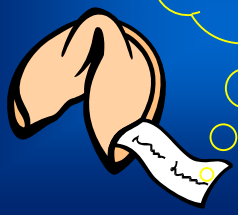
- It was from a Berkshire Hathaway board member, and it boiled down to exercising restraint and humility. He told me:
- "You can tell a guy to go to hell tomorrow – you don't give up the right. But keep your mouth shut today and see if you feel the same way tomorrow."
- Why ? "Because the person you did not tell off today, may be in a position to 'open up a door' for you tomorrow, or in the near future." Buffett learned.

Warren Buffett

Be Willing to Pay the Price
—
The Law of Sow and Reap

#9

None of the secrets of success will work unless you do.



What is the Law of Sow and Reap ? Positive Actions Today Produce a Rich Harvest in the Future

Casino Analogy

To reap is to gather a crop and to sow is to plant seeds. Accordingly, future outcomes are inevitably shaped by present actions or, what you do today, can influence all your tomorrows. The significance of this law?

We reap what we sow, but always more than we sow, and at a later date. In other words, to a large extent, you get back from life what you put into it – and more.

Preparing for Success

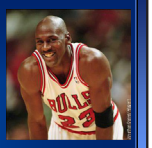
The great Italian violinist Niccolò Paganini was once partway through a solo performance when one of his strings suddenly broke – then a second string snapped, and then a third, leaving him with only a single violin string. He not only continued, but flawlessly carried off a virtuoso - performance, even limited to a single string, as the audience watched in awe! His secret? He had put in long hours practicing the instrument without all its strings, and even composed music to be played on a violin with just one string.

Requisition for Success? Preparation for Varied Circumstances

"Achievement takes preparation. Once you understand what an individual actually did to prepare for these kinds of events, then it becomes more understandable. Beyond talent, hard work differentiates the chumps from the champions."

Professor Anders Ericsson
Florida State University

Prepare, Prepare, Prepare! Be Willing to Pay the Price



"When I played with Michael Jordan on the Olympic team, there was a huge gap between his ability and the ability of the other great players on the team. But what impressed me was that Michael was always the first one on the floor and the last one to leave."

Steve Alford, Olympic gold medalist, NBA player

The 10,000 Hour Rule: A Common Trait of Highly Successful People*

One thing that seemed to be clear was that in order to be successful in anything, you need to put in 10,000 hours of work. Gladwell goes on to discuss professional athletes*, businessmen like Bill Gates, and musicians like the Beatles. They all prepared for their success.

Prepare, prepare, prepare, + prepare (one more time).

** Malcolm Gladwell, Outliers*

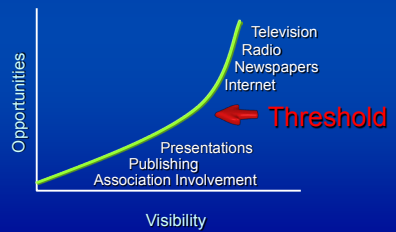
Law of Sow & Reap: The 'Famous' Gary Player Airport Story

Outline

- Foundational factors
- Nine strategies for success
- **Intangibles: heighten your visibility, commit to never-ending improvement , exceed people's expectations, strive for greater rewards, organizational membership**
- Some final thoughts….

VISIBILITY LEADS TO OPPORTUNITIES

THERE'S A WORLD OUT THERE, WAY BEYOND YOUR WORKPLACE



A Cardinal Tenet of Success ? It Pays to be Just a Little Bit Better.....

PGA Tour 2002 Scoring Average

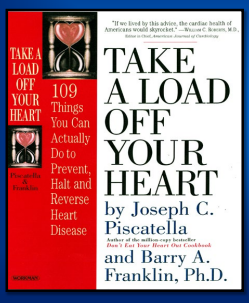
Rank	Player	Average
1	Tiger Woods*	68.56
2	Vijay Singh	69.47
3	Ernie Els	69.50
4	Phil Mickelson	69.58
5	Nick Price	69.59
6	Retief Goosen	69.69
7	David Toms	69.73
8	Justin Leonard	69.86
9	Fred Funk	69.99
10	Sergio Garcia**	70.00

* $6.9 million; ** $2.4 million

Give People More Than They Expect .....

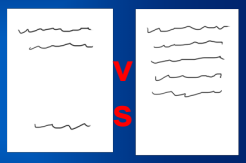
It's been reported that one New York cab driver makes **$40,000+** more a year in **tips** alone than other cabbies. Why? Because he offers passengers a choice of music, several newspapers, cold drinks, or fresh fruit. In hectic brusque Manhattan, his small acts of decency make him stand out.

My Northwest Airlines Story: Exceed People's Expectations



Strive for Greater Rewards: Go for the Gold.....

Exam Options



"Congratulations, you have just received an 'A' in this class. Keep believing in yourself."

The 'Magic' of Organizational Membership ?

"Dedicate your life to a cause greater than yourself, and your life will become a glorious adventure."

Mack Douglas

?

Active Association Involvement

Leadership, collaboration, writing, research, invited presentations, working with "stars" around the world who share your passion.

MasterCard **Priceless!**

American College of Sports Medicine · Founded 1954 ·

CVPR American Association of Cardiovascular & Pulmonary Rehabilitation

American Heart Association. Learn and Live.

Outline

- Foundational factors
- Nine strategies for success
- Intangibles: heighten your visibility, commit to never-ending improvement , exceed people's expectations , strive for greater rewards, organizational membership

Look Familiar ?

- Some final thoughts....

THE MOST POWERFUL STRATEGIES TO IMPROVE YOUR PERFORMANCE ?

#1 Early in your career surround yourself with people that personify the personal and professional qualities that you seek---and you'll thrive.

#2 Start making "to do" lists and follow up on a daily basis, moving unfinished items to the next day. Start the job !!! #3 Collaborate with others who have skills, abilities and resources that you desire.

"Until it's on paper, it's vapor."
— Str John Hargrave

THE PARETO PRINCIPLE ?

Vilfredo Pareto, an Italian economist, reported that 80% of Italy's land belonged to 20% of the (wealthiest) population. Subsequent studies in many different fields found that related comparisons were also distributed unevenly (~ 80/20)—the 80/20 rule.

TAKE HOME MESSAGE: Start focusing even more time on the 20% of activities that yield 80% of your most satisfying achievements/contributions.

Time Management: My Most Memorable Experience ?

" It's been my observation that most people get ahead during the time that others waste." ----Henry Ford

Great Leaders* Bring out the Very Best in those Around Them….

"If your actions inspire others to dream more, learn more, do more and become more, you are a leader."----John Quincy Adams

Leadership # 101

Don't tell people, show them.

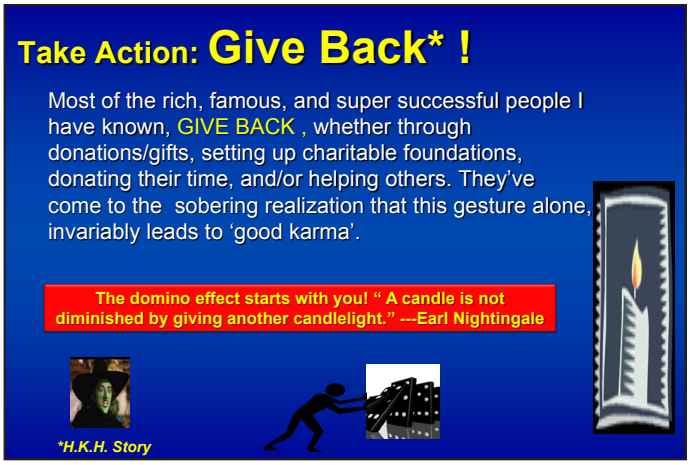
Gene Michalski Story

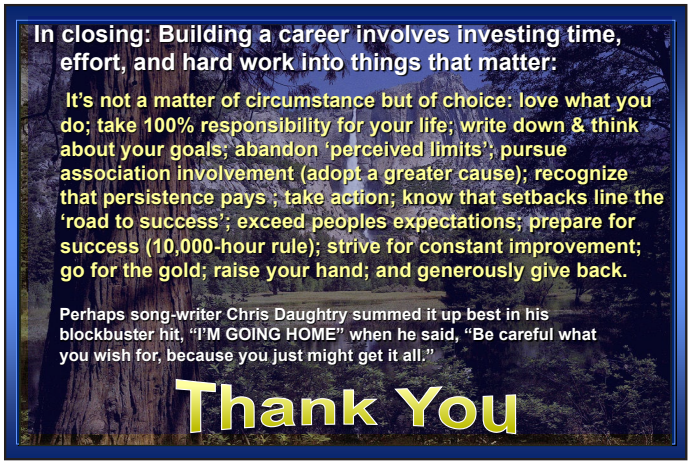
"You teach what you know, but you reproduce who you are." *John Maxwell*

"You can preach a better sermon with your actions than with your lips." *Oliver Goldsmith*

Volunteer Needed? Raising Your Hand High (And Often) Will Markedly Increase Your Likelihood of Professional Success*

"If you routinely do more than you are paid to do, ultimately you'll be paid much more for what you do."—Zig Ziglar





SELF EVALUATION

The 9 Strategies of Highly Successful and Effective Leaders

1. Who said, "The meaning of life is to find your gift. The purpose of life is to give it away."
- a. Nelson Mandela
- b. Bill Gates
- c. Oprah Winfrey
- d. Pablo Picasso

2. Identify the "foundational factors" for career success?
- a. Love what you do!
- b. Take 100% responsibility for your achievements/setbacks
- c. Focus on your contributions (serving others)
- d. All of the above

3. Dr. Lewis Terman at Stanford University conducted a classic study to determine the key characteristics of people who were highly successful in life. The #1 characteristic was:
- a. Voracious reader
- b. Tendency to set goals
- c. Perseverance
- d. Self-confidence

4. Use collaboration to exponentially increase your productivity. Two Clydesdale horses that are matched correctly and trained can pull _____ pounds!
- a. 8,000
- b. 24,000
- c. 32,000
- d. 40,000

5. Who coined the 10,000-hour (of practice) rule – a common trait of highly successful people?
- a. Jack Canfield
- b. Earl Nightingale
- c. Malcolm Gladwell
- d. Professor Anders Ericsson

6. Based on the experience of the Professional Golfer's Association (PGA) the average difference in annual score for an 18-hole round between the #1 and #10 golfers each year is:
- a. less than 1 stroke
- b. 1.4 – 2.0 strokes
- c. 3.0 – 4.0 strokes
- d. none of the above

7. According to the Pareto Principle, approximately 20% of your daily activities yield _____% of your most satisfying achievements/contributions.
- a. 40
- b. 50
- c. 80
- d. none of the above

8. T/F - The professional people that you surround yourself with early on typically have little or no impact on your career direction and ultimate success.

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

Dilip K. Moonka, MD, FAST, FAASLD

Dilip K. Moonka, MD, FAST, FAASLD, of Detroit, Michigan, is the Medical Director of Liver Transplantation at Henry Ford Hospital. He received his medical degree from Stanford University, trained in gastroenterology and hepatology at the University of Pennsylvania, and is board certified in internal medicine, gastroenterology and transplant hepatology. Dr. Moonka has won numerous teaching awards from both the Department of Medicine and the Division of Gastroenterology and he conducts both clinical and bench research in liver transplantation, viral hepatitis and liver cancer with numerous publications in these areas. He is a Fellow of the American Association for the Study of Liver Disease (FAASLD) as well as the American Society of Transplantation (FAST), and speaks or consults for Gilead, Intercept and AbbVie.

You may contact Dr. Moonka at dmoonka1@HFHS.org.

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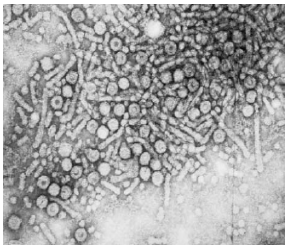
Division of Gastroenterology and Hepatology

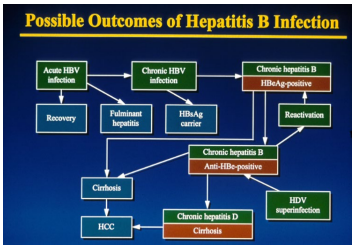
Dilip Moonka, MD, FAST, FAASLD
Medical Director of Liver Transplantation

Diagnosing and Treating Hepatitis B & C

HEPATITIS B

- THE OTHER VIRUS



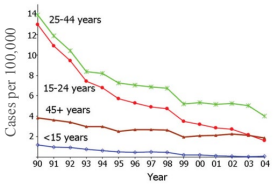


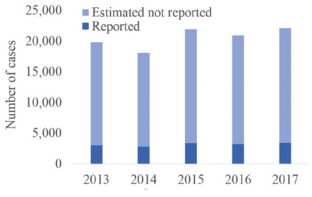
HEPATITIS B (HBV): BY THE NUMBERS

- Discovered in 1965
- Double-stranded DNA Virus
- 240-290 Million Worldwide
  - 75% in Asia
  - 50 million new cases per year
  - 786,000 deaths per year: 43% from liver cancer
- 800,000-2.2 million in the US
  - 50,000–100,000 new cases per year
  - 4,000–5,000 deaths per year
- Premature mortality from cirrhosis or hepatocellular carcinoma (HCC): 15–40%

Lok Hepatology 2001 Kim Hepatology 2009

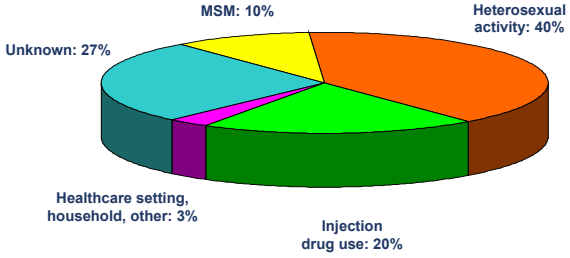
HBV: ACTUAL AND ESTIMATED CASES OF ACUTE HEPATITIS B IN US



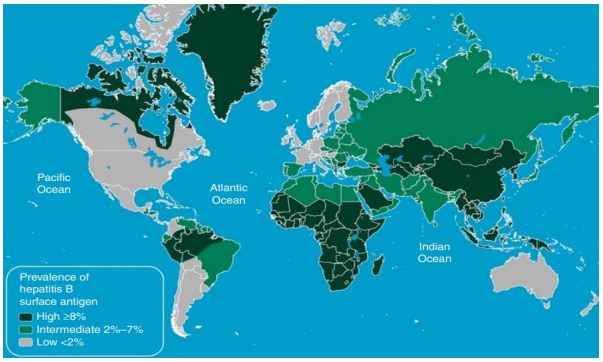


Source: CDC, National Notifiable Diseases Surveillance System

HBV: TRANSMISSION IN THE US

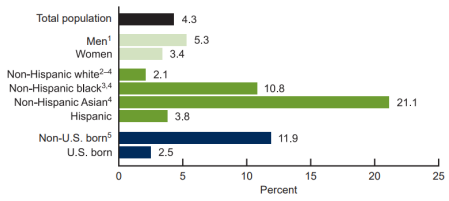


HBV: GLOBAL PREVALENCE



Centers for Disease Control 2012: MacLachlan Cold Spring Harbor Perspect Med 201

ADULT PREVALENCE OF HBV (PAST OR PRESENT) IN THE UNITED STATES



- Overall US Prevalence 0.3%
- Foreign born Asian-Americans 10-13%
- Foreign born Chinese-Americans 12-21.4% in New York
- HIV infected 8.4%

NCHS Data Brief, Number 361, March 2020

HEPATITIS B: SCREENING
CDC AND AASLD

	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+ • 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 requiring immunosuppressive therapy • Persons with elevated ALT or AST of unknown etiology • Persons being treated for hepatitis C

Abara et al. Ann Internal Med 2017

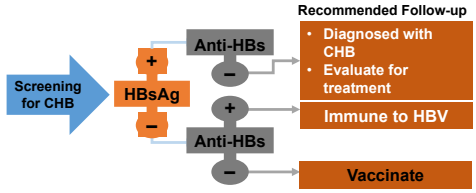
HBV: CANDIDATES FOR VACCINATION

- Persons with multiple sexual partner, or history of STDs
- Men who have sex with men
- Household and sexual contacts of HBsAg-positive persons
- Persons who have ever injected drugs
- Persons traveling to endemic areas
- Persons at risk for occupational exposure
- Developmentally disabled individuals in long-term care facilities
- Inmates of correctional facilities
- HIV positive persons
- Persons undergoing dialysis
- Persons with chronic liver disease

Weinbaum CM, et al. *MMWR Recomm Rep.* 2006;55(RR-16):1-26.

HBV SCREENING:
IDENTIFYING PERSONS WITH CHRONIC HBV

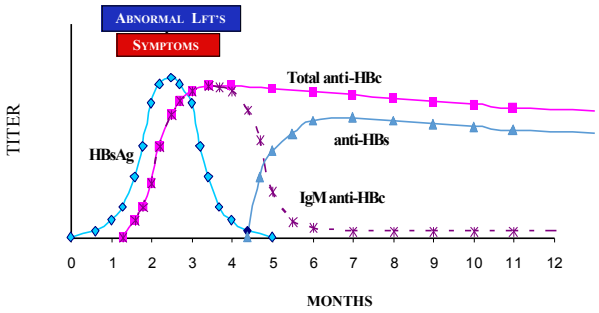
- HBV Screening: Identifying Persons With CHB



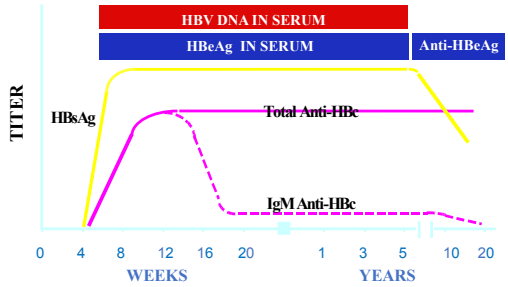
If HBsAg remains positive for 6 months
CHB=chronic hepatitis B

CDC. Morb Mortal Wkly Rep. 2008;57(No. RR-8):1-16. 2.
Keeffe EB, et al. Clin Gastroenterol Hepatol. 2008;6:1315-1341.

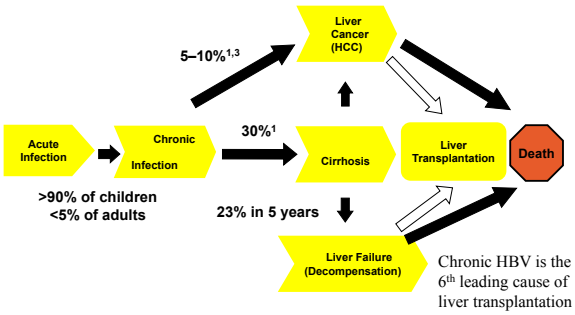
ACUTE HEPATITIS B: SEROLOGY



CHRONIC HEPATITIS B: SEROLOGY



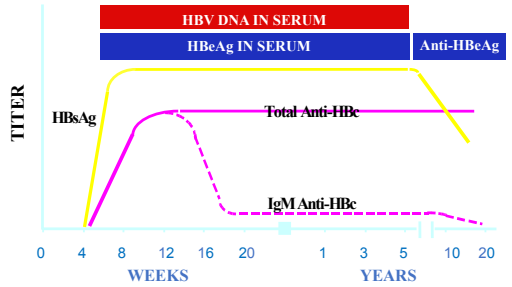
HBV DISEASE PROGRESSION



Chronic HBV is the 6th leading cause of liver transplantation in the US

Torresi J. Gastroenterology 2000: Fattovich G. Hepatology 1995.
Moyer LA. Am J Prev Med 1994: Perrillo R. Hepatology 2001.

CHRONIC HEPATITIS B: SEROLOGY



APPROACH TO THE PATIENT WITH HBsAg-POSITIVE HEPATITIS B

- HBeAg
- HBV DNA
- ALT levels over time
- FibroScan: Liver biopsy

APPROACH TO THE PATIENT WITH HBsAg-POSITIVE HEPATITIS B

Diagnostic Criteria and Definitions for CHB

AASLD HBV 2018 Guidance

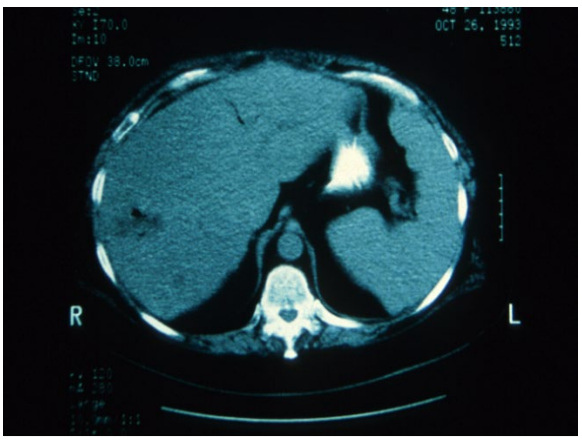
	ALT	HBV DNA	HBeAg	Liver Histology
Immune-tolerant CHB	Normal or minimally elevated ALT and/or AST	Elevated, typically > 1 million IU/mL	Positive	No fibrosis and minimal inflammation
Immune-Active CHB	Intermittently or persistently elevated ALT and/or AST	Elevated ≥ 20,000 IU/mL	Positive	Moderate-to-severe necroinflammation and with or without fibrosis
		Elevated ≥ 2,000 IU/mL	Negative	
Inactive CHB phase	Persistently normal ALT and/or AST levels	<2,000 IU/mL	Negative	Absence of significant necroinflammation and variable levels of fibrosis

Terrault NB et al. AASLD Guidelines Hepatology 2018

HBV: RECOMMENDATIONS
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.



HBV: AASLD GUIDELINES:
SURVEILLANCE FOR HEPATOCELLULAR CARCINOMA (HCC)

- 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

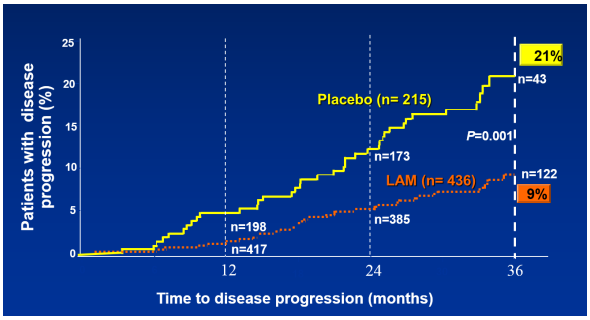
Bruix J, et al. Hepatology 2010.

CHRONIC HBV THERAPY
GOALS OF TREATMENT

- Complete viral suppression: HBV DNA < 10 IU
  - Normalization of AST and ALT
  - Loss of HBeAg
  - Improvement in liver histology
- Decrease HBV related mortality
  - Decrease in end-stage liver disease
  - Decrease in mortality and liver transplant
  - Decrease in liver cancer (?)

Terrault NA, et al. Hepatology. 2016.

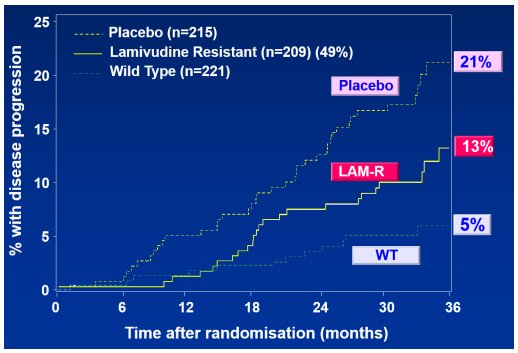
LONG TERM LAMIVUDINE IN PATIENTS WITH COMPENSATED CIRRHOSIS



Liver Cancer: Placebo 7.4: LAM 3.9% (*P*=0.047)

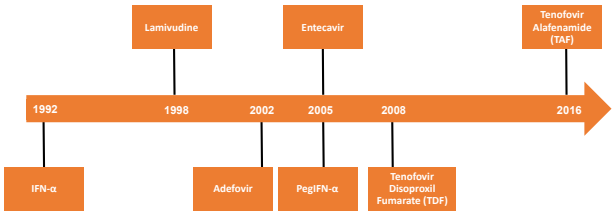
Liaw, et al. NEJM 2004.

LONG TERM LAMIVUDINE IN PATIENTS WITH COMPENSATED CIRRHOSIS



Liaw, et al. NEJM 2004.

THE EVOLUTION OF HBV THERAPY



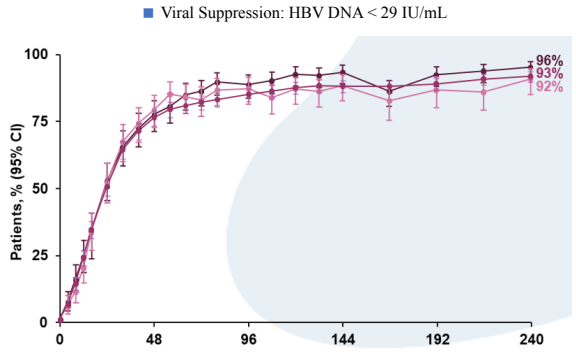
Courtesy of K. Brown

CHRONIC HBV THERAPY
ENTECAVIR AND TENOFOVIR

- Both are given as pills once a day
- Suppress virus in almost all cases
- Very high barriers to resistance
  - Entecavir resistance can be seen especially in patients already resistant to lamivudine
  - Tenofovir has no know resistance described anywhere in the world
- Both are well tolerated
  - Tenofovir dipivoxil (TDF) has described low incidence of renal insufficiency and loss of bone mineral density
  - Tenofovir alafenamide (TAF) has minimal effect on both parameters

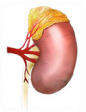
Terrault NA, et al. Hepatology. 2016.

CHRONIC HBV THERAPY
TENOFOVIR

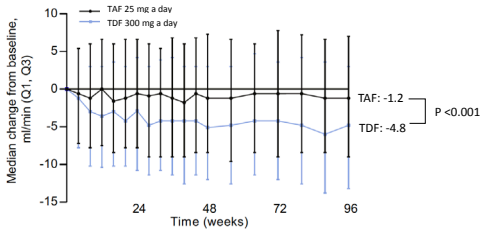


Terrault NA, et al. Hepatology. 2016.

HBV: TAF vs. TDF - CHANGE IN eGFR

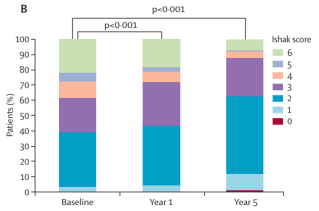


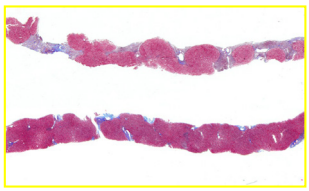
- Median change from in eGFR from baseline over 96 weeks
  TAF 25 mg (n=866) vs. TDF 300 mg (n=432)



Agarwal K, et al. J Hepatol 2018

HBV THERAPY: REGRESSION OF FIBROSIS WITH TENOFOVIR (TDF)





- 348 patients with paired baseline and 1 year liver biopsies
- 71 of 96 patients with cirrhosis at baseline did not have cirrhosis at year five

Marcellin, et al. Lancet 2013

HBV SPECIAL POPULATION: Case 1

- 36 y/o Asian woman who is 12 weeks pregnant comes to see you
- Her three y/o son received HBIG and the hepatitis B vaccine but still became infected with HBV. She does not want the same thing to happen again.
  - HBeAg positive
  - HBV DNA 2,830,000 IU/ml
  - Liver biopsy in past showed no fibrosis and no activity
- She wants to know is she can breast feed the infant.
  - Can she?

HBV SPECIAL POPULATION: Case 2

- A 36 y/o Hispanic man presents and states he has had hepatitis B for 10 years .
  - HBeAg negative
  - HBV DNA 2,200 IU/ml
  - Bilirubin is 2.7, INR is 1.6, Albumin is 2.7
  - AST is 225, ALT is 184,
  - Plt count is 67
  - AFP is 102
- What would you recommend?

HBV SPECIAL POPULATION Case 3

- A 62 y/o man presents to you because he was recently diagnosed with lymphoma. In preparation for chemotherapy, he had a HBsAg done and his oncologist wants to know if he needs anything done
  - HbsAg positive
  - Liver panel is normal
  - HBeAg negative
  - HBV DNA undetectable
- Does he need anything done.

HBV: CONCLUSIONS

- HBV is a major source of morbidity and mortality
- HBV vaccination is critical for viral eradication
- HBV is typically not cured
- HBV can be suppressed in almost all cases
- HBV therapy can lead to regression of fibrosis and improvement in patient outcomes

HEPATITIS C

- THE VIRUS YOU CURE

HEPATITIS C (HCV)

- Goal of therapy for hepatitis C is to cure the virus.
- Current "sustained response rates" (SVR) or cure rates 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

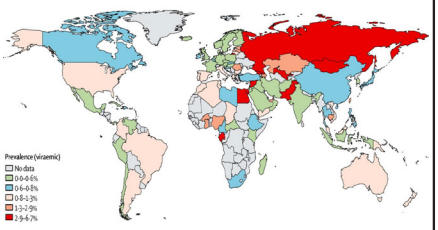
HEPATITIS C: BY THE NUMBERS

- 20% of exposed individuals will clear virus
- 75% to 85% will develop chronic infection
- Up to 25% will develop cirrhosis if untreated
- Typically takes 10-20 years to develop cirrhosis
- 5-20% of patients with cirrhosis will develop liver cancer
- Heavy alcohol use will accelerate hepatic damage
- Declining indication for liver transplant

http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#section2

HEPATITIS C: BY THE NUMBERS

- Estimated Global Prevalence of Viremic HCV is 1.0%
- Estimated number with HCV worldwide is 71.1 million
- 6 countries account for 51% of all HCV infections
  - China (9.8 million)
  - Pakistan (7.1 million)
  - India (6.2 million)
  - Egypt (5.6 million)
  - Russia (4.7 million)
  - US (2.9 million)



The Polaris Observatory HCV Collaborators. Lancet Gastroenterol Hepatol. 2017
Hill AM, et al. J Virus Erad. 2017;3

HEPATITIS C: BY THE NUMBERS

- 2.3 million Americans are infected with HCV
- There is a recent surge in new infections associated with the opioid epidemic
- 40% are undiagnosed
- Patients are typically asymptomatic
- 15,713 deaths from HCV in 2018

Rosenberg ES et al. JAMA Netw Open 2018: Ryerson MMWR 2020: CDC.gov

HEPATITIS C
WHO: CALL FOR VIRAL ERADICATION

- WHO vision: "Eliminate viral hepatitis as a major global public health threat by 2030"

2030 TARGETS

90% Diagnosed
80% Treated
65% Reduced mortality

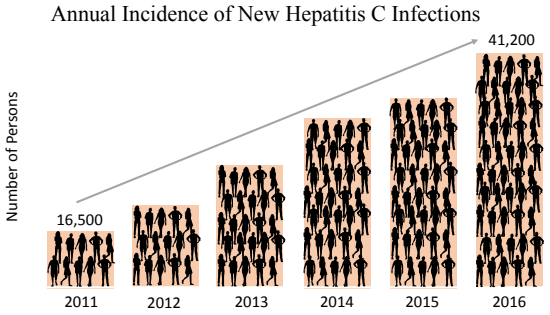
WHO Global Health Sector Strategy on Viral Hepatitis, 2016-2021.

HEPATITIS C: RISK FACTORS

- Transfusions or blood products before 1992
- Injection drug use
- Sexually transmitted disease
- Vertical transmission from mother to infant
- Tattooing in unregulated circumstances
- Non-injection cocaine use

CDC.gov

HEPATITIS C
NEW INFECTIONS ASSOCIATED WITH OPIOID CRISIS

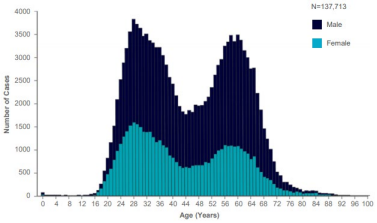


clinicaloptions.com

CDC Newsroom. https://www.cdc.gov/nchhstp/newsroom/images/2018/vh/HCV-infections-increase-highres.jpg

HEPATITIS C

- New patients are under 40
- Rural whites
- People who inject drugs (PWID)

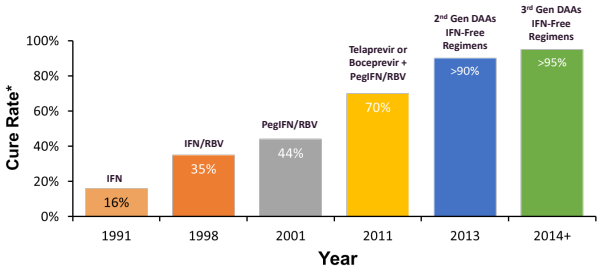


- All Adults over age 18 years and older should be screened once for hepatitis C:

American Association for Study of Liver Diseases (AASLD); US Preventative Services Task Force (USPSTF); Centers for Disease Control (CDC)

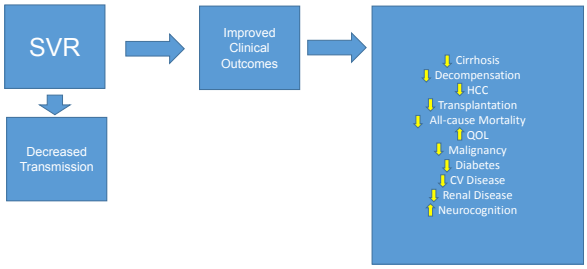
Schille MMWR Recomm Rep 2020: hcvguidelines.org

HCV CURE RATES NOW EXCEED 95%



*Cure rates based on data from clinical trials

HCV CURE IS ASSOCIATED WITH IMPROVED OUTCOMES

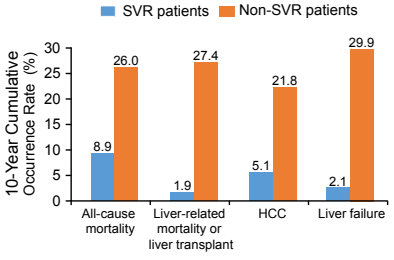


Smith-Palmer J, et al. BMC Infect Dis 2015: Negro F, et al. Gastroenterology 2015
George SL, et al. Hepatology 2009: Nahon et al. Gastroenterology 2017

HCV CURE IS ASSOCIATED WITH IMPROVED OUTCOMES

- Baseline factors significantly associated with all-cause mortality
  - Older age
  - GT 3 (2-fold increase in mortality and HCC)
  - Higher Ishak fibrosis score
  - Diabetes
  - Severe alcohol use

530 patients followed for a median of 8.4 years



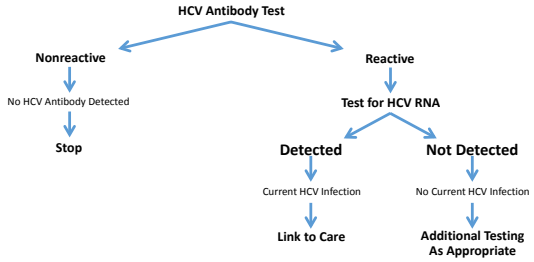
Van der Meer A, et al. *JAMA*. 2012

CHRONIC HCV THERAPY
SCREENING AND TREATMENT: AASLD/IDSA GUIDELINES

- All Adults 18 years and older should be screened
- Individuals less than 18 with risk factors should be screened
- PWIDs should be offered yearly opt-out testing even if previously treated
- Only contraindication to therapy is short life expectancy
- Active injection drug use or a concern for reinfection is not a contraindication to therapy
- Acute hepatitis C should be treated
- Patients co-infected with HIV and hepatitis C have similar cure rates compared to patients infected with HCV alone

American Association for Study of Liver Diseases (AASLD): Infectious Disease Society of America (IDSA)
US Preventative Services Task Force (USPSTF): Centers for Disease Control (CDC)

CDC RECOMMENDED TESTING SEQUENCE FOR IDENTIFYING CURRENT HCV INFECTION



AASLD-IDSA. http://www.hcvguidelines.org/full-report-view. Version May 24, 2018.

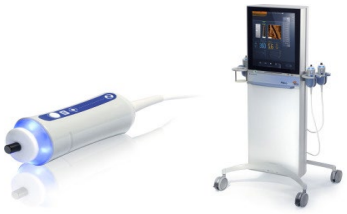
HCV EVALUATION

- Basic labs HCV
  - Genotype
  - Viral load (within 3-6 months depending on insurance)
- Assessment of liver function
  - INR, bilirubin, albumin, platelet
- Assessment of liver fibrosis
  - Fibrosure, FIB-4, APRI, Elastography (FibroScan)
- Assessment of renal function
  - Creatinine, GFR
- Additional Tests
  - Hepatitis B (HBsAg, HBcAb, HBsAb), HIV
- Drug/alcohol screen if required by payors

HCV EVALUATION
FIBROSIS ASSESSMENT

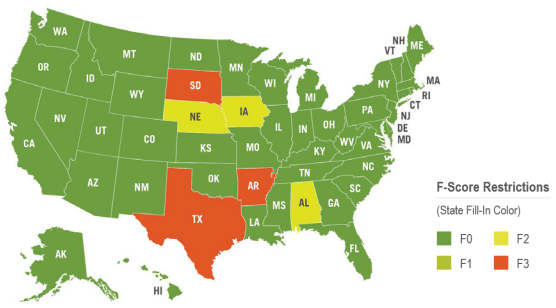
- Patients with bridging fibrosis or cirrhosis need screening
  - Varices
  - Hepatocellular carcinoma: AFP and ultrasound every six months
- Used by some payors as a way to restrict access
- Determines post-treatment follow-up

HCV EVALUATION
TRANSIENT ELASTOGRAPHY: FibroScan



- Non-invasive
- High sensitivity and specificity for advanced fibrosis

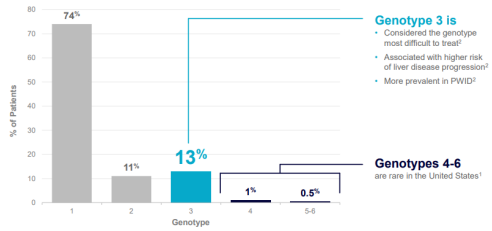
HCV: STATE MEDICAID F-SCORE RESTRICTIONS ARE EVOLVING ARE



Hepatitis C State of Medicaid accessed at: https//stateofhepc.org.

HCV EVALUATION
GENOTYPE

- Genotypes 1, 2 and 3 account for 98% of infections in the US

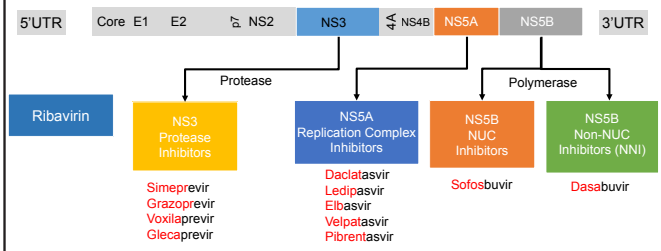


MappingHepC (www.mappinghepc.com) accessed 2020

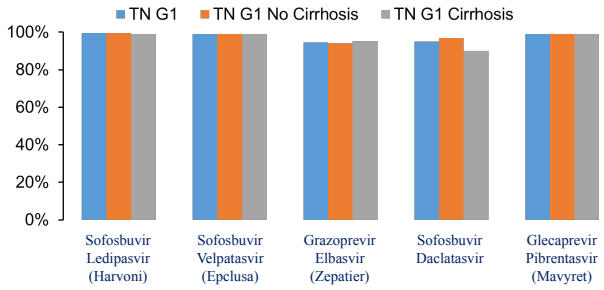
CHRONIC HCV THERAPY
RECOMMENDATIONS TO PATIENTS

- Abstinence from alcohol
- One time screening of spouse
- One time screening of children of infected women
- Vaccination against HAV, HBV and pneumococcal infection (in patients with cirrhosis)
- Education on avoidance of transmission
- Reinfection possible with high-risk activity

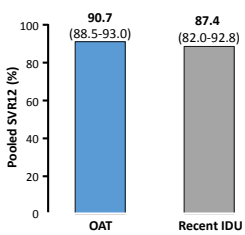
APPROVED DAAs FROM MULTIPLE CLASSES:
Combination All-oral Regimens for HCV

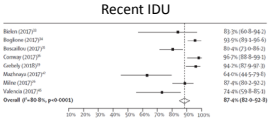


EFFICACY OF CURRENT REGIMENS
>95%-100% CURE RATES (SVR)



HCV THERAPY: DAA Therapy Is Effective Among PWID in "Real World" Data





- In meta-regression analysis, clinical trials significantly associated with higher SVR rates vs observational studies
  - aOR: 2.18 (95% CI: 1.27-3.75; *P* = .006)
- Difference due to loss to follow-up, not virologic failure

Hajarizadeh. Lancet Gastroenterol Hepatol. 2018

CHRONIC HCV THERAPY
EPCLUSA AND MAVYRET

- Both are given as pills once a day
- Both are Pangenotypic, panfibrotic, pan-renal function
- Both have cure rates over 99% per protocol in treatment naïve patients

- Epclusa
  - 12 weeks
  - Potential concerns with anti-acid drugs
  - Avoid amiodarone
- Mavyret
  - 8 weeks
  - Cannot be used in patients with decompensated cirrhosis

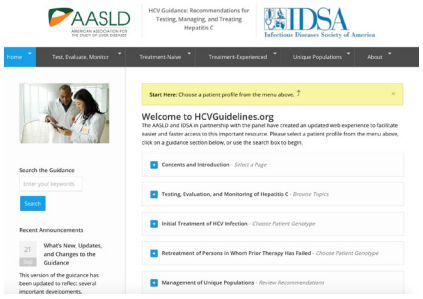
CHRONIC HCV THERAPY
CHECKLIST

- Treatment naïve or experienced
- Drug-Drug interactions
  - Few of concern
  - Proton pump inhibitors, phenytoin, St. John's Wort, statin drugs, HAART medications, amiodarone
  - University of Liverpool HEP Drug Interactions Checker
- Decompensated liver disease
- Bridging fibrosis or cirrhosis
- HBV status: HBsAg positive

CHRONIC HCV THERAPY

- Treatment is eight weeks with Mavyret and twelve weeks with Epclusa
- Bloodwork monthly
  - Liver panel, creatinine, HCV RNA
- HCV RNA will go undetectable on therapy
- If HCV RNA undetectable at end of therapy, patient is cure
- Hepatitis C antibody will remain positive with cure

AASLD/IDSA WEBSITE FOR SPECIAL POPULATIONS



- Document remains current: constantly updated

www.hcvguidelines.org

CHRONIC HCV THERAPY
EMERGING AREAS

- Treatment of patients with decompensated liver disease from HCV
  - Protease inhibitors should be avoided
  - Little data in patients with MELD scores over 20
  - Patients with MELD > 27 should be treated after transplant
- Routine use of hepatitis C infected organs in uninfected transplant recipients
- Treatment of infected pregnant women
  - Ongoing clinical trials
- Treatment of patients who have failed Epclusa and Mavyret
  - Vosevi: combination of sofosbuvir, ledipasvir and voxilaprevir

SELF EVALUATION

Diagnosing and Treating Hepatitis B & C

1. Which is true of hepatitis B transmission?
   a. Vertical transmission from mother to infant can occur but is rare.
   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. Prevalence of hepatitis B is the same in foreign born and native born Asian-Americans.

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?
   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 about 5-7 years.
   d. Liver cancer is prevalent in patients with hepatitis C with or without cirrhosis.
   e. Over 95% 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. Which statement is true about hepatitis C transmission?
   a. New guidelines recommend individuals born between 1945-1965 be tested for HCV if they acknowledge risk factors on careful questioning.
   b. Receiving infected blood products is the most common risk factor for HCV in the U.S.
   c. Sexual transmission of HCV is unusual in a long-term, monogamous relationship.
   d. Injection drug use is an effective form of transmission and up to 10% of such individuals can be infected with hepatitis C.
   e. The U.S. blood supply has been generally safe from hepatitis C starting in 2001.

6. 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.

7. Which of the following statements is true about therapy for hepatitis C?
   a. All oral regimens for patients with renal failure are in development and should be available in 2023.
   b. Newer anti-viral regimens have increased cure rates but, so far, are associated with significant side effects and discontinuation rates.
   c. All oral regimens have cure rates of over 95% in patients without cirrhosis and 75% in patients with cirrhosis.
   d. Cure rates in patients co-infected with hepatitis C and HIV are as high as in patients infected with HCV alone.
   e. Cure rates for patients with genotype 1 and 2 are over 90% and cure rates for genotype 3 are close to 80%.

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

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Health Center
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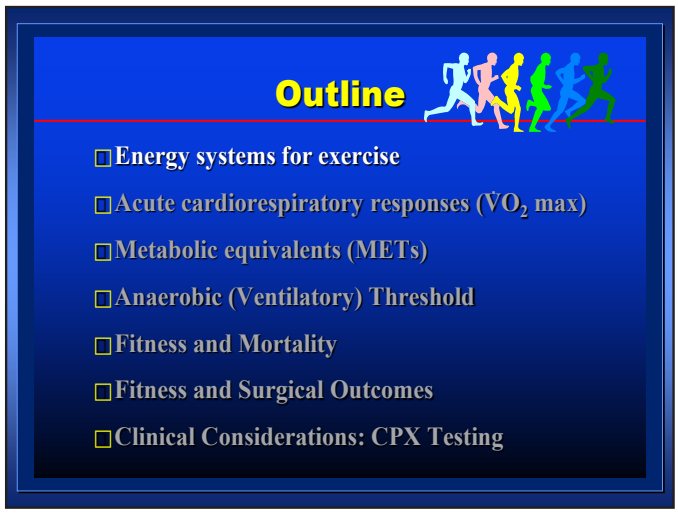
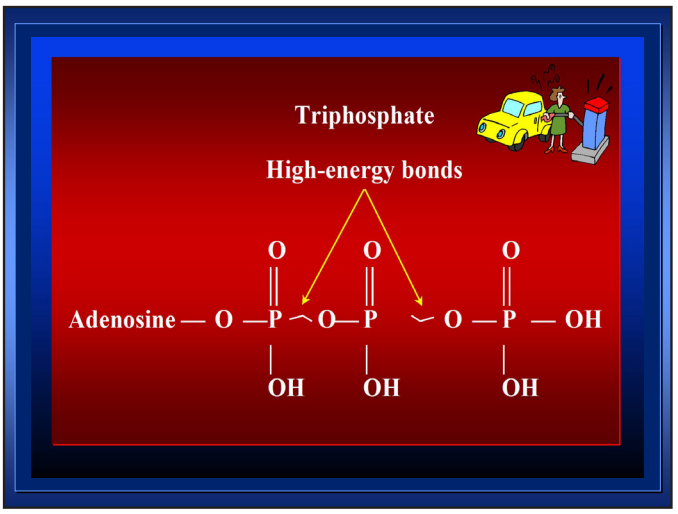
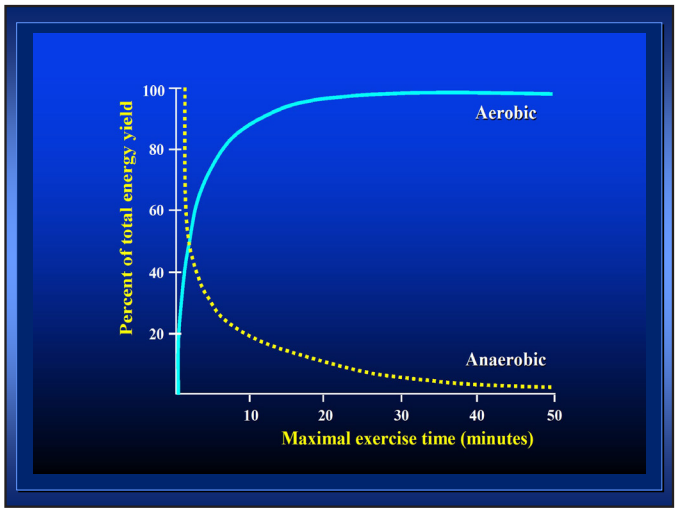
Royal Oak, MI 48073

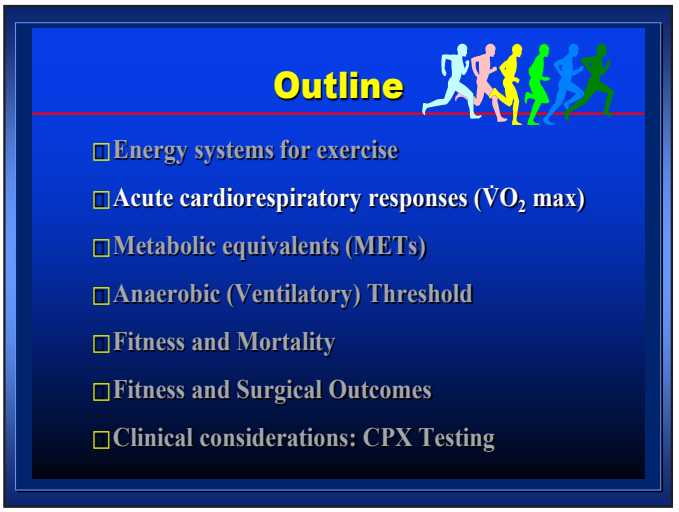
Barry A. Franklin, PhD
Director of Preventive Cardiology and Cardiac Rehabilitation

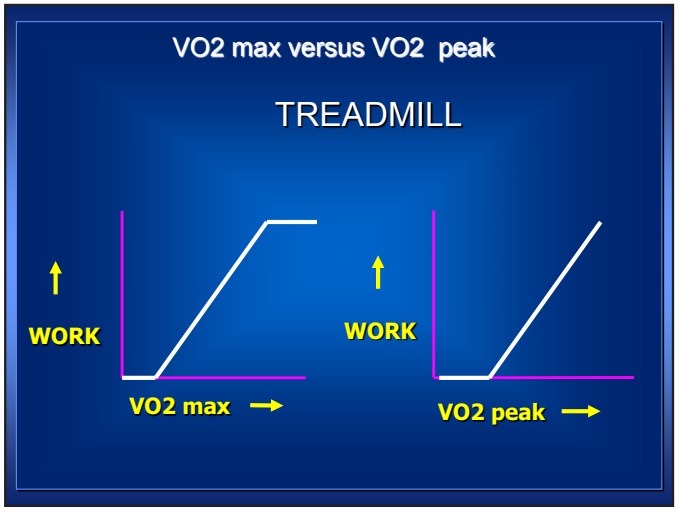
Clinical Implications of Exercise Physiology, Aerobic Capacity and Metabolic Equivalents

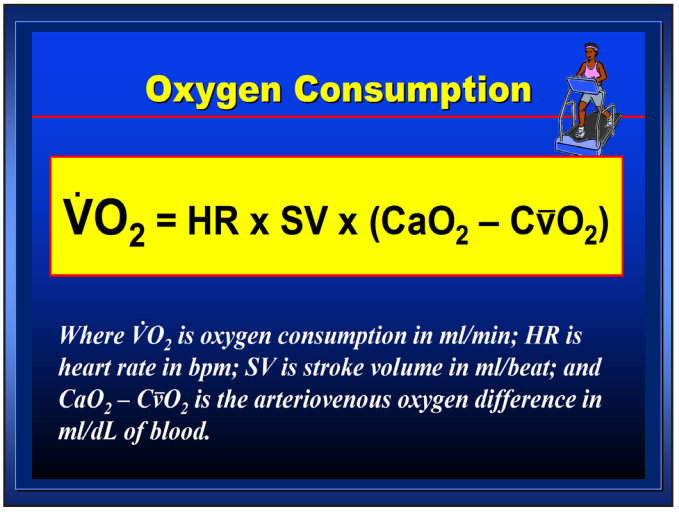












Key Players

Variable	Rest → Exercise	Relative Increase
Heart Rate		2.7 x ↑
Stroke Volume		1.4 x ↑
Cardiac Output		4 x ↑
a-v̄ O_2 Difference		3 x ↑
Blood Pressure	SBP / DBP	1.3 – 1.5 x ↑ ↔or ↓
Pulmonary Ventilation		15-25 x ↑

OXYGEN-CARRYING CAPACITY OF BLOOD: TRANSPORT MECHANISMS

- Dissolved in plasma (0.3 ml O_2 /100 ml plasma)
- Combined with hemoglobin (Hb)
  1 gm of Hb carries 1.34 ml O_2
  ~ 15 gm Hb/100 ml blood
  O_2 Capacity = 15 x 1.34 =
  20 ml O_2 /100 ml blood

Outline

- ☐ Energy systems for exercise
- ☐ Acute cardiorespiratory responses ($\dot{V}O_2$ max)
- ☐ Metabolic equivalents (METs)
- ☐ Anaerobic (Ventilatory) Threshold
- ☐ Fitness and Mortality
- ☐ Fitness and Surgical Outcomes
- ☐ Clinical considerations: CPX Testing

Resting Metabolic Rate*

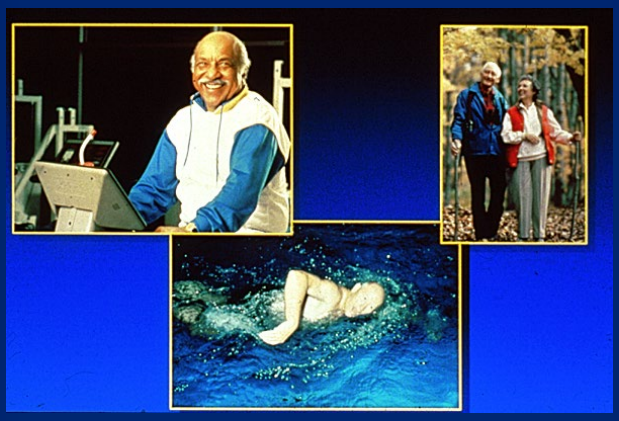
- 5,000 ml blood/min x 5 ml O_2/100 ml blood = 250 ml O_2/min = 1.25 Kcal/min
- 250 ml O_2/min ÷ 70 kg = 3.5 ml O_2/kg/min
- 3.5 ml O_2/kg/min = 1 MET

*70 kg man

Exercise Metabolic Rate

- 20,000 ml blood/min x 15 ml O_2/100 ml blood = 3,000 ml O_2/min = 15 Kcal/min
- 3,000 ml O_2/min ÷ 70 kg = 42.9 ml O_2/kg/min
- 42.9 ml O_2/kg/min ÷ 3.5 = 12 METs

The typical 12-fold increase in oxygen transport and utilization achieved at maximal exercise is brought about by respective increases in the hemodynamic correlates of $\dot{V}O_2$, e.g, a 4-fold increase in cardiac output and a 3-fold increase in arterio-venous oxygen difference (4 x 3 = 12 METs)

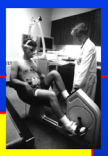


Maximal Oxygen Consumption for Varied Population Subsets

Group	METs
Normals	10-12
Cardiacs	6-8
Endurance Athletes	15-20+

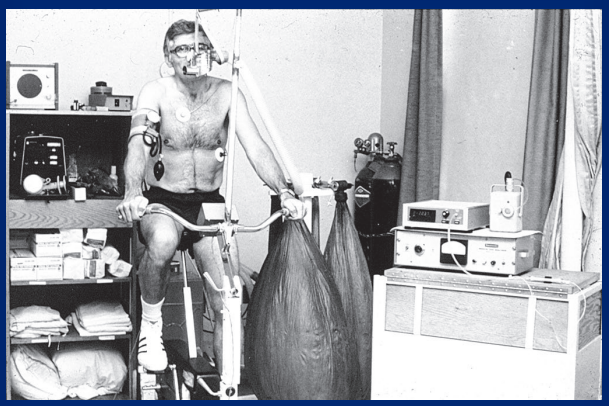
The reduced aerobic (MET) capacity in the cardiac patient appears primarily due to decreased maximal cardiac output, secondary to reduced stroke volume and/or heart rate, rather than impairment in the peripheral extraction of oxygen.

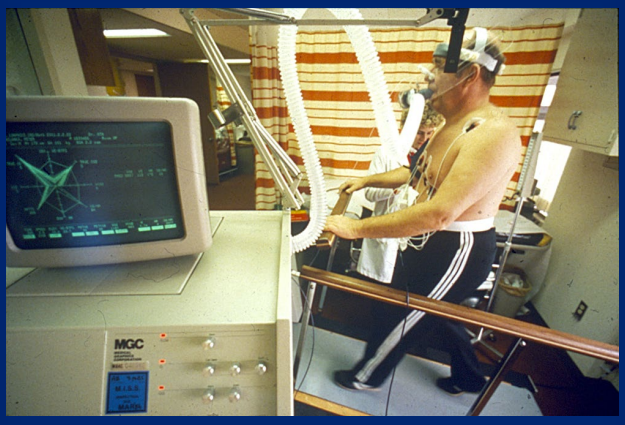
Measurement of $\dot{V}O_2$



$$\dot{V}O_2 = \dot{V}_E (F_I O_2 - F_E O_2)$$

Where $\dot{V}_E$ is the expired minute ventilation, $F_E O_2$ is the directly measured concentration of O_2 in the expired air, $F_I O_2$ is the concentration of oxygen in the inspired air, and normal room air is 0.2093.

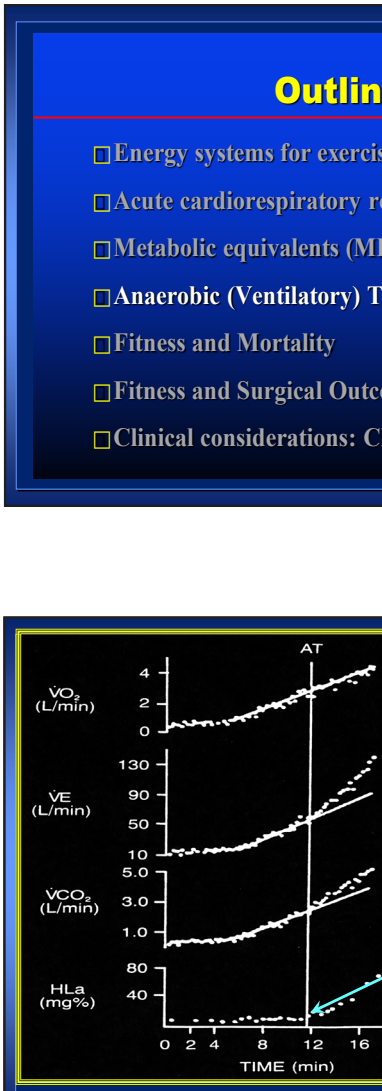




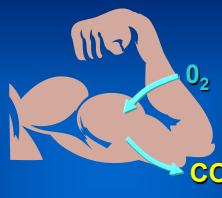
Outline

- Energy systems for exercise
- Acute cardiorespiratory responses ($\dot{V}O_2$ max)
- Metabolic equivalents (METs)
- Anaerobic (Ventilatory) Threshold
- Fitness and Mortality
- Fitness and Surgical Outcomes
- Clinical considerations: CPX Testing

Anaerobic or Ventilatory Threshold ~ (50-80 % VO2 peak)



Understanding the Ventilatory Threshold

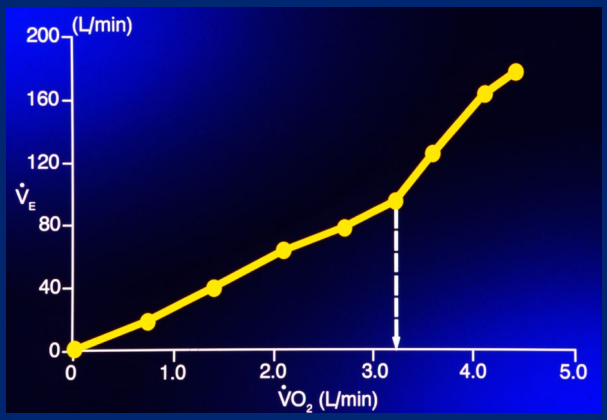


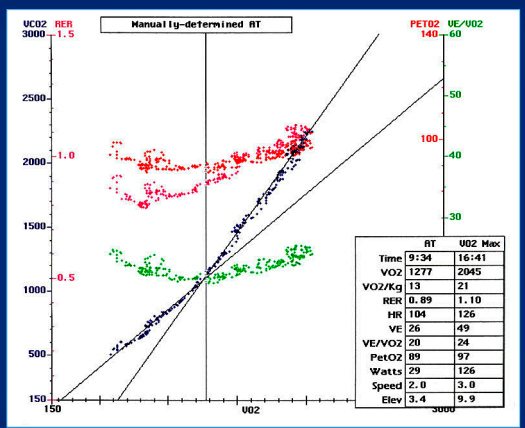
HLA + $NaHCO_3$ → NaLa

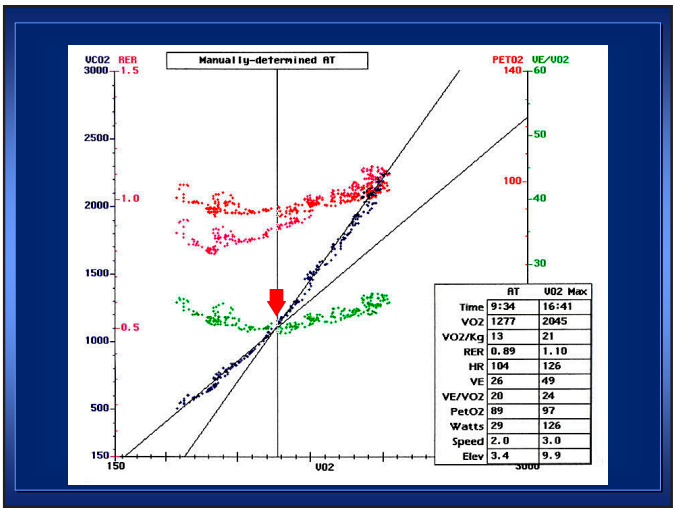
(lactic acid)(sodium bicarbonate) (sodium lactate)

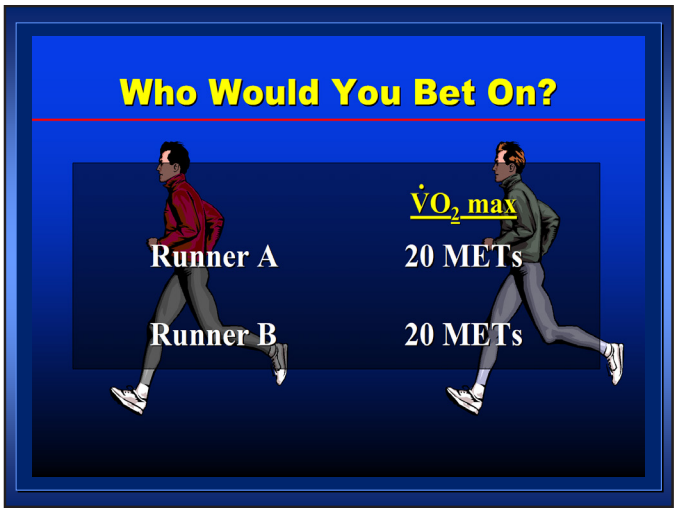
+ H_2CO_3 → H_2O + CO_2

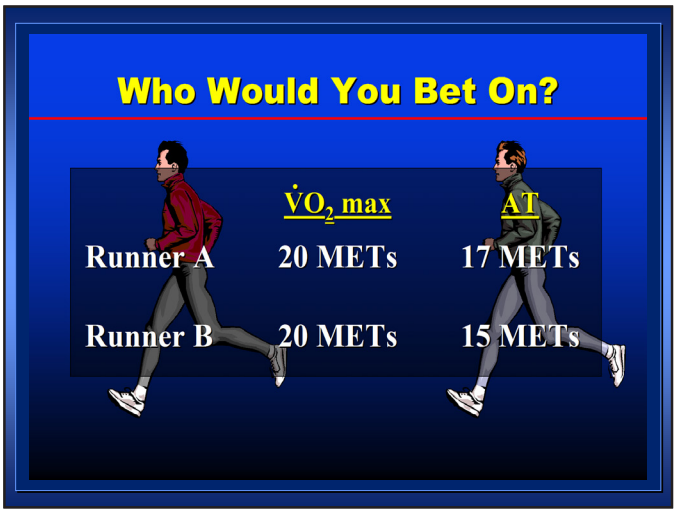
(carbonic acid)

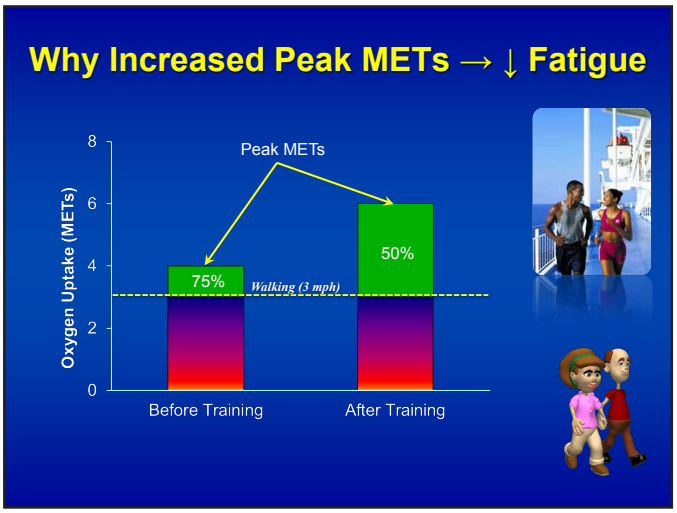


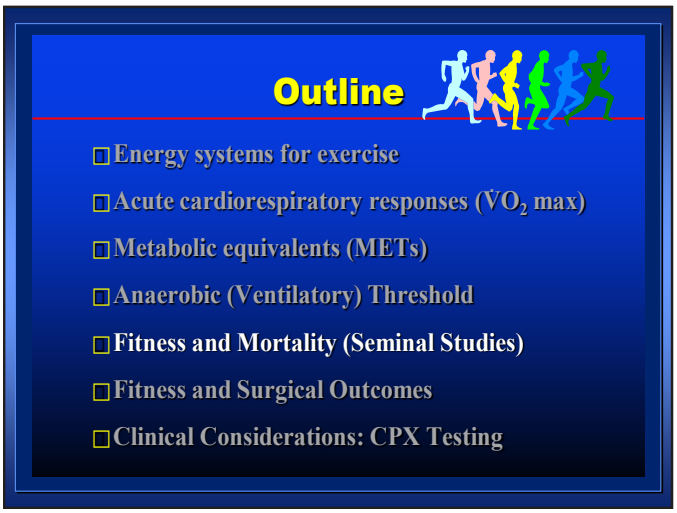


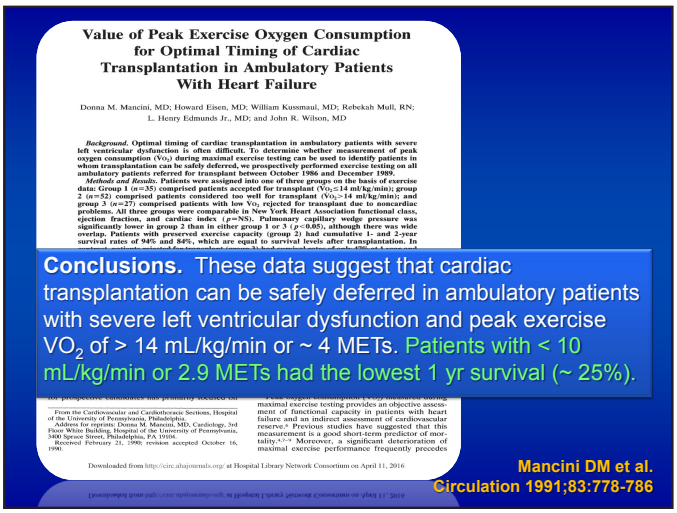

Manually-determined AT
VCO2 RER
PETO2 VE/VO2
3000
2500
2000
1500
1000
500
150
1.5
1.0
0.5
140
100
60
50
40
30
VO2
AT VO2 Max
Time 9:34 16:41
VO2 1277 2045
VO2/Kg 13 21
RER 0.89 1.10
HR 104 126
VE 26 49
VE/VO2 20 24
PetO2 89 97
Watts 29 126
Speed 2.0 3.0
Elev 3.4 9.9

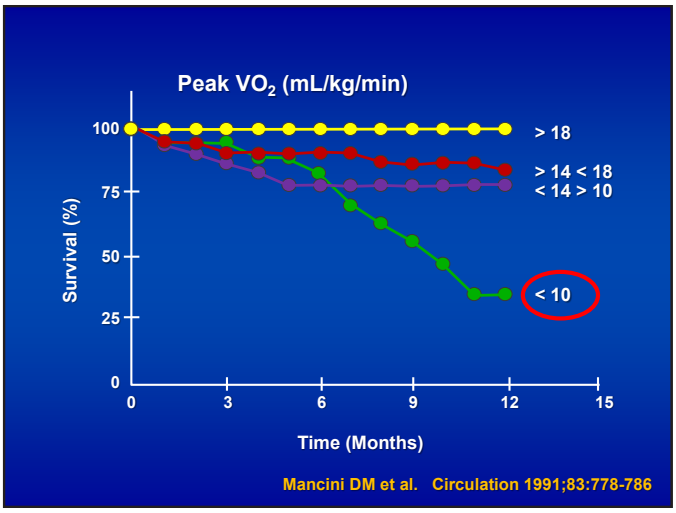

Who Would You Bet On?
V̇O2 max
Runner A
20 METs
Runner B
20 METs

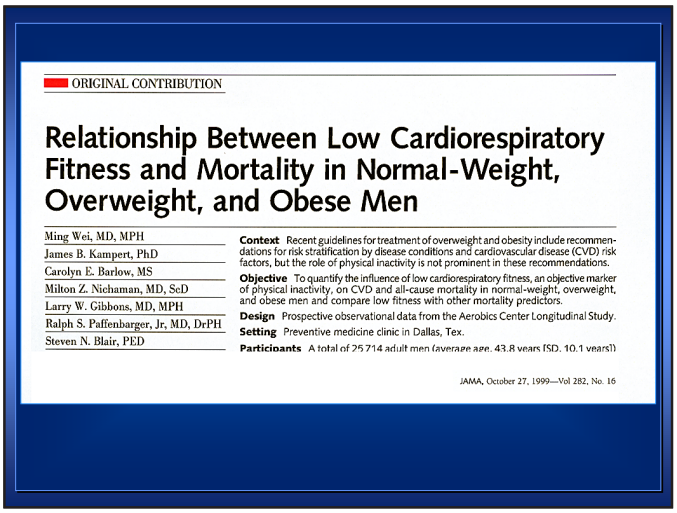

Who Would You Bet On?
V̇O2 max
AT
Runner A
20 METs
17 METs
Runner B
20 METs
15 METs


Why Increased Peak METs → ↓ Fatigue
Peak METs
Oxygen Uptake (METs)
8
6
4
2
0
75%
50%
Walking (3 mph)
Before Training
After Training


Outline
Energy systems for exercise
Acute cardiorespiratory responses (V̇O2 max)
Metabolic equivalents (METs)
Anaerobic (Ventilatory) Threshold
Fitness and Mortality (Seminal Studies)
Fitness and Surgical Outcomes
Clinical Considerations: CPX Testing


Value of Peak Exercise Oxygen Consumption for Optimal Timing of Cardiac Transplantation in Ambulatory Patients With Heart Failure
Donna M. Mancini, MD; Howard Eisen, MD; William Kussmaul, MD; Rebekah Mull, RN; L. Henry Edmunds Jr., MD; and John R. Wilson, MD
Conclusions. These data suggest that cardiac transplantation can be safely deferred in ambulatory patients with severe left ventricular dysfunction and peak exercise VO2 of > 14 mL/kg/min or ~ 4 METs. Patients with < 10 mL/kg/min or 2.9 METs had the lowest 1 yr survival (~ 25%).
Mancini DM et al.
Circulation 1991;83:778-786




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.

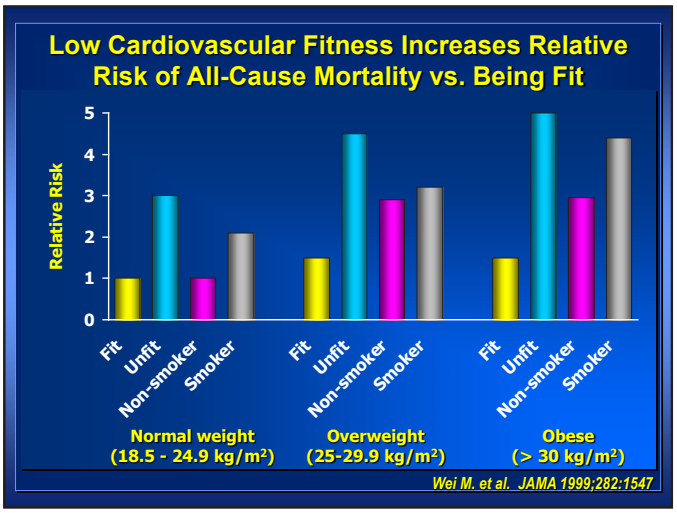
Objective To quantify the influence of low cardiorespiratory fitness, an objective marker of physical inactivity, on CVD and all-cause mortality in normal-weight, overweight, and obese men and compare low fitness with other mortality predictors.

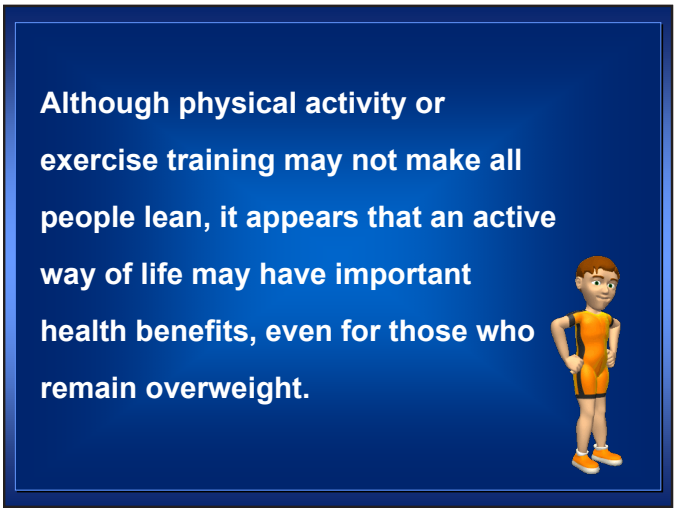
Design Prospective observational data from the Aerobics Center Longitudinal Study.

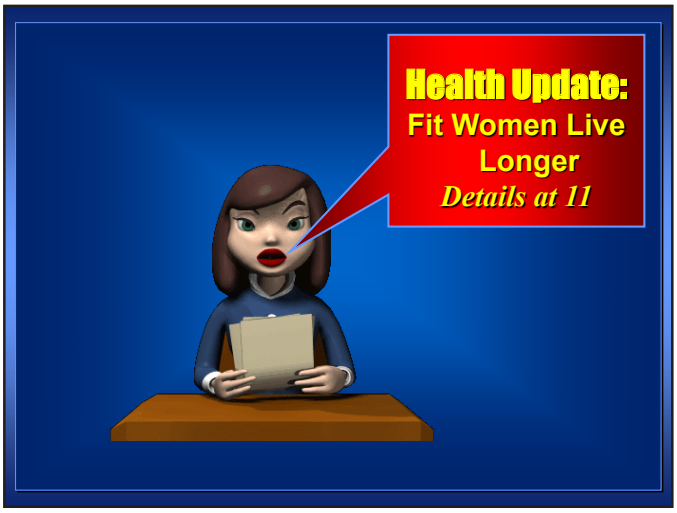
Setting Preventive medicine clinic in Dallas, Tex.

Participants A total of 25 714 adult men (average age, 43.8 years [SD, 10.1 years])

JAMA, October 27, 1999—Vol 282, No. 16







Clinical Investigation and Reports

Exercise Capacity and the Risk of Death in Women

The St James Women Take Heart Project

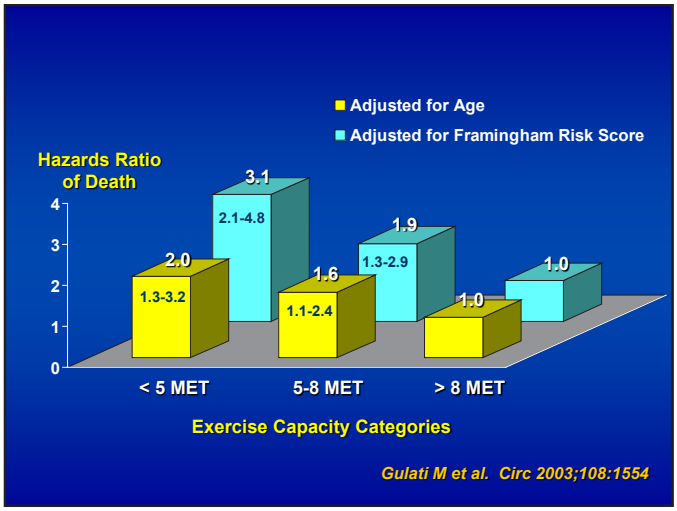
Martha Gulati, MD, MS; Dilip K. Pandey, PhD; Morton F. Arnsdorf, MD; Diane S. Lauderdale, PhD; Ronald A. Thisted, PhD; Roxanne H. Wicklund, RN; Arfan J. Al-Hani, MD†; Henry R. Black, MD

Background—Cardiovascular disease is the leading cause of death among women and accounts for more than half of their deaths. Women have been underrepresented in most studies of cardiovascular disease. Reduced physical fitness has been shown to increase the risk of death in men. Exercise capacity measured by exercise stress test is an objective measure of physical fitness. The hypothesis that reduced exercise capacity is associated with an increased risk of death was investigated in a cohort of 5721 asymptomatic women who underwent baseline examinations in 1992.

Methods and Results—Information collected at baseline included medical and family history, demographic characteristics, physical examination, and symptom-limited stress ECG, using the Bruce protocol. Exercise capacity was measured in metabolic equivalents (MET). Nonfasting blood was analyzed at baseline. A National Death Index search was performed to identify all-cause death and date of death up to the end of 2000. The mean age of participants at baseline was 52±11 years. Framingham Risk Score–adjusted hazards ratios (with 95% CI) of death associated with MET levels of <5, 5 to 8, and >8 were 3.1 (2.0 to 4.7), 1.9 (1.3 to 2.9), and 1.00, respectively. The Framingham Risk Score–adjusted mortality risk decreased by 17% for every 1-MET increase.

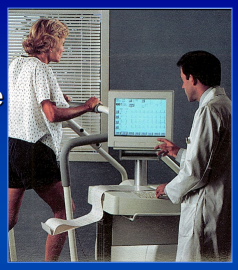
Conclusions—This is the largest cohort of asymptomatic women studied in this context over the longest period of follow-up. This study confirms that exercise capacity is an independent predictor of death in asymptomatic women, greater than what has been previously established among men. The implications for clinical practice and health care policy are far reaching. **(*Circulation*. 2003;108:1554-1559.)**

Key Words: exercise ■ epidemiology ■ mortality ■ women



Gulati M et al. Circ 2003;108:1554

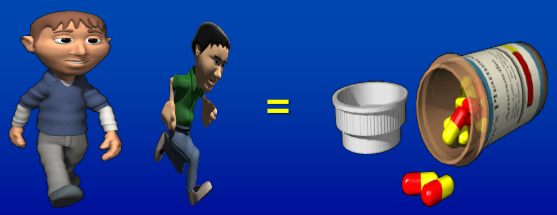
Exercise capacity is a strong independent predictor of all-cause death in asymptomatic women, after adjusting for traditional cardiac risk factors.



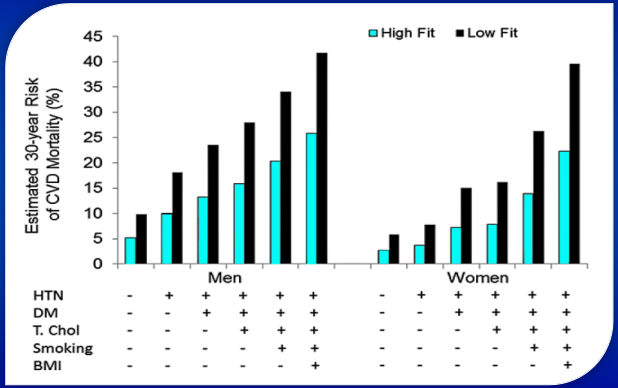
For each 1-MET increase in exercise capacity, there was a 17% reduction in mortality rate.

Gulati M et al. Circ 2003;108:1554

If there was a pill that you could take to cut your risk in HALF of dying from heart disease over the next 30 years, would you take it ? There is such a pill---and its called EXERCISE.

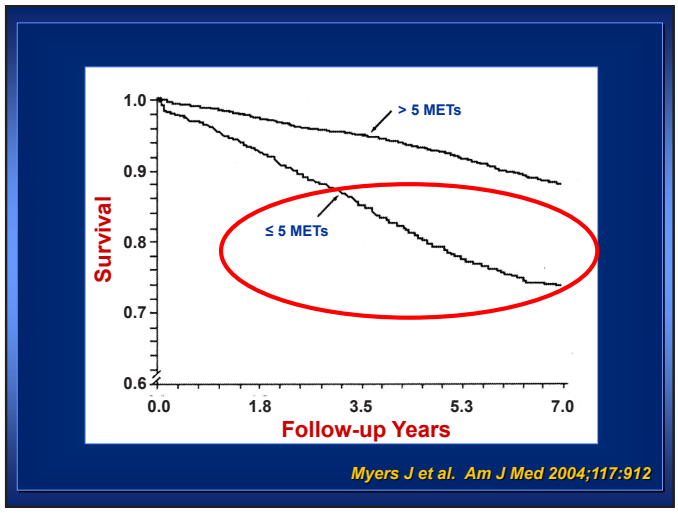


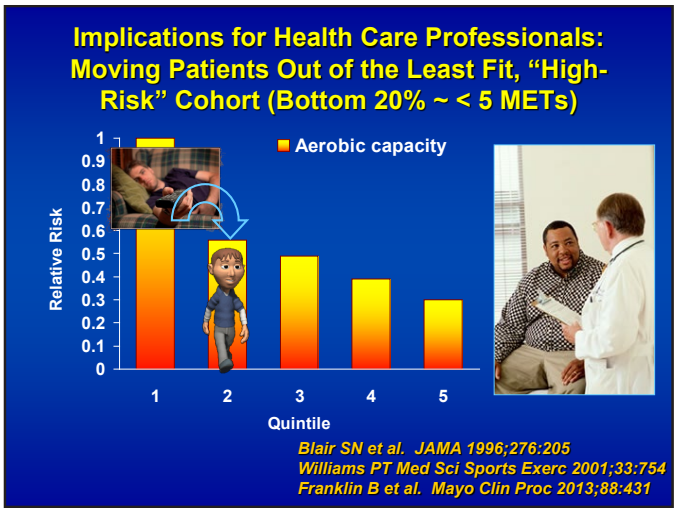
Regardless of the Risk Factor Profile, Low Fit Men and Women have ~ 2x the Mortality

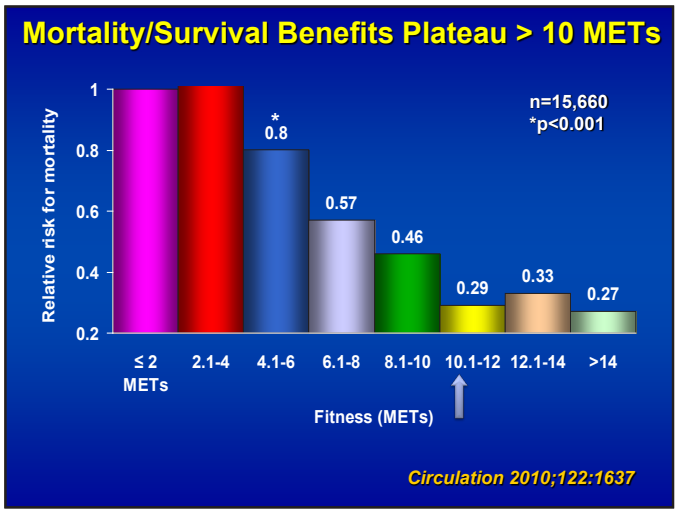


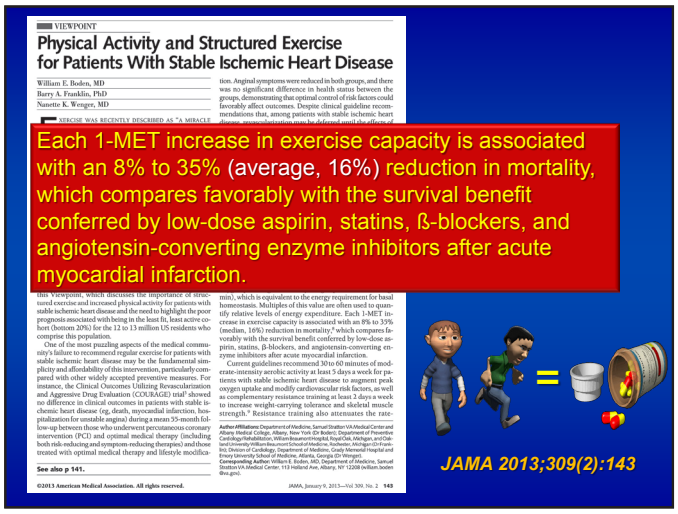
Wickramasinghe CD et al. Circ Cardiovasc Qual Outcomes 2014 (lifetimerisk.org)

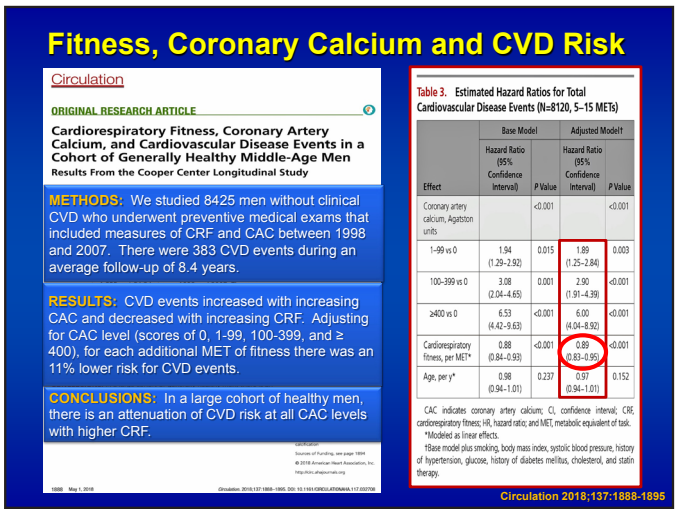
The 'Rule' of 5 and 10 METs*

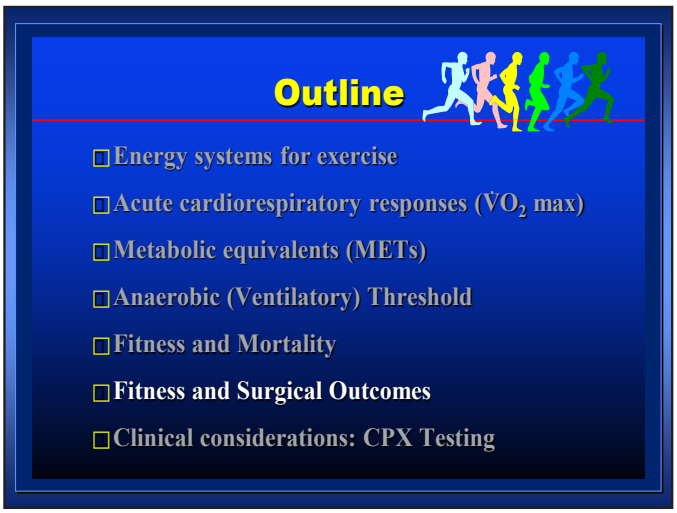

1.0
0.9
0.8
0.7
0.6
Survival
> 5 METs
≤ 5 METs
0.0
1.8
3.5
5.3
7.0
Follow-up Years
Myers J et al. Am J Med 2004;117:912


Implications for Health Care Professionals: Moving Patients Out of the Least Fit, "High-Risk" Cohort (Bottom 20% ~ < 5 METs)
Aerobic capacity
Relative Risk
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
1
2
3
4
5
Quintile
Blair SN et al. JAMA 1996;276:205
Williams PT Med Sci Sports Exerc 2001;33:754
Franklin B et al. Mayo Clin Proc 2013;88:431


Mortality/Survival Benefits Plateau > 10 METs
Relative risk for mortality
1
0.8
0.6
0.4
0.2
*
0.8
0.57
0.46
0.29
0.33
0.27
n=15,660
*p<0.001
≤ 2 METs
2.1-4
4.1-6
6.1-8
8.1-10
10.1-12
12.1-14
>14
Fitness (METs)
Circulation 2010;122:1637


VIEWPOINT
Physical Activity and Structured Exercise for Patients With Stable Ischemic Heart Disease
William E. Boden, MD
Barry A. Franklin, PhD
Nanette K. Wenger, MD
Each 1-MET increase in exercise capacity is associated with an 8% to 35% (average, 16%) reduction in mortality, which compares favorably with the survival benefit conferred by low-dose aspirin, statins, ß-blockers, and angiotensin-converting enzyme inhibitors after acute myocardial infarction.
JAMA 2013;309(2):143

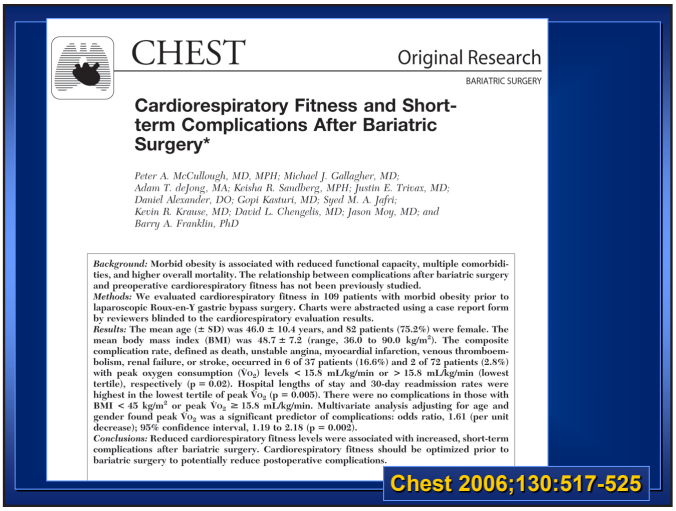

Fitness, Coronary Calcium and CVD Risk
Circulation
ORIGINAL RESEARCH ARTICLE
Cardiorespiratory Fitness, Coronary Artery Calcium, and Cardiovascular Disease Events in a Cohort of Generally Healthy Middle-Age Men
Results From the Cooper Center Longitudinal Study
METHODS: We studied 8425 men without clinical CVD who underwent preventive medical exams that included measures of CRF and CAC between 1998 and 2007. There were 383 CVD events during an average follow-up of 8.4 years.
RESULTS: CVD events increased with increasing CAC and decreased with increasing CRF. Adjusting for CAC level (scores of 0, 1-99, 100-399, and ≥ 400), for each additional MET of fitness there was an 11% lower risk for CVD events.
CONCLUSIONS: In a large cohort of healthy men, there is an attenuation of CVD risk at all CAC levels with higher CRF.
Table 3. Estimated Hazard Ratios for Total Cardiovascular Disease Events (N=8120, 5–15 METs)
Base Model
Adjusted Model†
Effect
Hazard Ratio (95% Confidence Interval)
P Value
Hazard Ratio (95% Confidence Interval)
P Value
Coronary artery calcium, Agatston units
<0.001
<0.001
1–99 vs 0
1.94 (1.29–2.92)
0.015
1.89 (1.25–2.84)
0.003
100–399 vs 0
3.08 (2.04–4.65)
0.001
2.90 (1.91–4.39)
<0.001
≥400 vs 0
6.53 (4.42–9.63)
<0.001
6.00 (4.04–8.92)
<0.001
Cardiorespiratory fitness, per MET*
0.88 (0.84–0.93)
<0.001
0.89 (0.83–0.95)
<0.001
Age, per y*
0.98 (0.94–1.01)
0.237
0.97 (0.94–1.01)
0.152
CAC indicates coronary artery calcium; CI, confidence interval; CRF, cardiorespiratory fitness; HR, hazard ratio; and MET, metabolic equivalent of task.
*Modeled as linear effects.
†Base model plus smoking, body mass index, systolic blood pressure, history of hypertension, glucose, history of diabetes mellitus, cholesterol, and statin therapy.
Circulation 2018;137:1888-1895


Outline
Energy systems for exercise
Acute cardiorespiratory responses ($\dot{V}O_2$ max)
Metabolic equivalents (METs)
Anaerobic (Ventilatory) Threshold
Fitness and Mortality
Fitness and Surgical Outcomes
Clinical considerations: CPX Testing

Metabolic Equivalents as Pre-Operative Risk Assessment

- One of the strongest indicators of all-cause and cardiovascular mortality is aerobic capacity.
- Reduced cardiorespiratory fitness levels are associated with increased morbidity/mortality after:
  - Bariatric 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



CHEST Original Research
BARIATRIC SURGERY

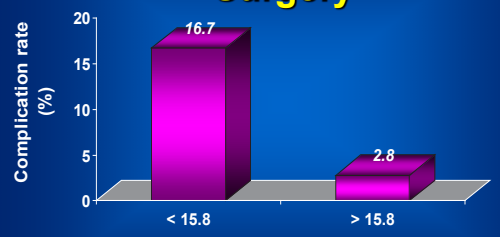
Cardiorespiratory Fitness and Short-term Complications After Bariatric Surgery*

Peter A. McCullough, MD, MPH; Michael J. Gallagher, MD; Adam T. deJong, MA; Keisha R. Sandberg, MPH; Justin E. Tricas, MD; Daniel Alexander, DO; Gopi Kasturi, MD; Syed M. A. Jafri; Kevin R. Krause, MD; David L. Chengelis, MD; Jason Moy, MD; and Barry A. Franklin, PhD

Background: Morbid obesity is associated with reduced functional capacity, multiple comorbidities, and higher overall mortality. The relationship between complications after bariatric surgery and preoperative cardiorespiratory fitness has not been previously studied.
Methods: We evaluated cardiorespiratory fitness in 109 patients with morbid obesity prior to laparoscopic Roux-en-Y gastric bypass surgery. Charts were abstracted using a case report form by reviewers blinded to the cardiorespiratory evaluation results.
Results: The mean age (± SD) was 46.0 ± 10.4 years, and 82 patients (75.2%) were female. The mean body mass index (BMI) was 48.7 ± 7.2 (range, 36.0 to 90.0 kg/m^2). The composite complication rate, defined as death, unstable angina, myocardial infarction, venous thromboembolism, renal failure, or stroke, occurred in 6 of 37 patients (16.6%) and 2 of 72 patients (2.8%) with peak oxygen consumption (Vo_2) levels < 15.8 mL/kg/min or > 15.8 mL/kg/min (lowest tertile), respectively (p = 0.02). Hospital lengths of stay and 30-day readmission rates were highest in the lowest tertile of peak Vo_2 (p = 0.005). There were no complications in those with BMI < 45 kg/m^2 or peak Vo_2 ≥ 15.8 mL/kg/min. Multivariate analysis adjusting for age and gender found peak Vo_2 was a significant predictor of complications: odds ratio, 1.61 (per unit decrease); 95% confidence interval, 1.19 to 2.18 (p = 0.002).
Conclusions: Reduced cardiorespiratory fitness levels were associated with increased, short-term complications after bariatric surgery. Cardiorespiratory fitness should be optimized prior to bariatric surgery to potentially reduce postoperative complications.

Chest 2006;130:517-525

Cardiorespiratory Fitness and Outcomes after Bariatric Surgery



Death, unstable angina, myocardial infarction, venous thromboembolism, renal failure, or stroke Moy J, Gallagher M de Jong A, Sandberg K, Trivax J, Alexander D, Kasturi G, Jafri S, Krause K, Chengelis D, Franklin B, McCullough P. Obesity Research 2005;13, A14 (54-OR).

Patient population

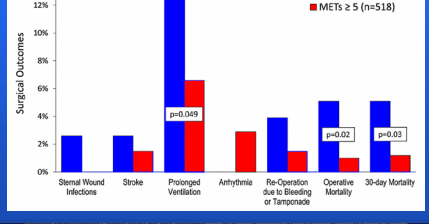
- 596 patients underwent pre-operative exercise stress testing < 90 days prior to their bypass at William Beaumont Hospitals in Royal Oak and Troy, MI campuses, from 2002-2010.

ARTICLE IN PRESS

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).

from January 2002 to December 2010 at Beaumont Health Systems. Electronic medical



with increased morbidity after abdominal aortic aneurysm Medicine, Beaumont Hospitals in Royal Oak and Troy, Michigan. Patients who underwent simultaneous intercoll-

Smith JL et al. AJC 2013; 112:1104

Merits of exercise therapy before and after major surgery

Thomas J. Hoogeboom[a], Jaap J. Dronkers[b], Erik H.J. Hulzebos[c], and Nico L.U. van Meeteren[a,c]

Purpose of review
Advances in medical care have led to an increasing elderly population. Elderly individuals should be able to participate in society as long as possible. However, with an increasing age their adaptive capacity gradually decreases, specially before and after major life events (like hospitalization and surgery) making them vulnerable to reduced functioning and societal participation. Therapeutic exercise before and after surgery might augment the postoperative outcomes by improving functional status and reducing the complication and mortality rate.

Recent findings
There is high quality evidence that preoperative exercise in patients scheduled for cardiovascular surgery is well tolerated and effective. Moreover, there is circumstantial evidence suggesting preoperative exercise for thoracic, abdominal and major joint replacement surgery is effective, provided that this is offered to the high-risk patients. Postoperative exercise should be initiated as soon as possible after surgery according to fast-track or enhanced recovery after surgery principles.

Summary
The perioperative exercise training protocol known under the name 'Better in, Better out' could be implemented in clinical care for the vulnerable group of patients scheduled for major elective surgery who are at risk for prolonged hospitalization, complications and/or death. Future research should aim to include this at-risk group, evaluate perioperative high-intensity exercise interventions and conduct adequately powered trials.

Keywords
exercise therapy, functional status, postoperative, preoperative, surgery

INTRODUCTION
The successes of society in terms of education, urbanization, industrialization and innovation, not in the least in healthcare, have led to an increasing elderly population [1]. This still expanding generation of the elderly should be able to participate in society for as long as possible. However, with an increasing age their adaptive capacity gradually decreases [2], which makes the elderly vulnerable to reduced functioning and societal participation [3] due to gradually diminishing physical activity [4,5], stereotypical 'to be old is to be ill' and 'let it be' beliefs [6,7]. Major life events like hospitalization and surgery can further compromise their functional status and activities of daily living [8]. This decrease in adaptive capacity of (vulnerable) elderly can be reduced by recent medical innovations and can be reduced more or possibly even prevented by therapeutic physical exercise training and maintaining physical activity in the course of an event; enabling the elderly to remain independent and live independently for a longer period of time after the event [4,9,10].
In case of elective surgery, exercise therapy could be initiated preoperatively in patients at risk

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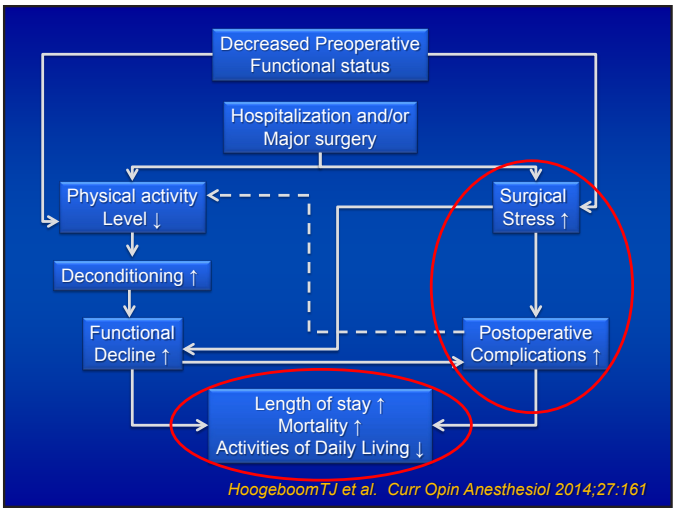
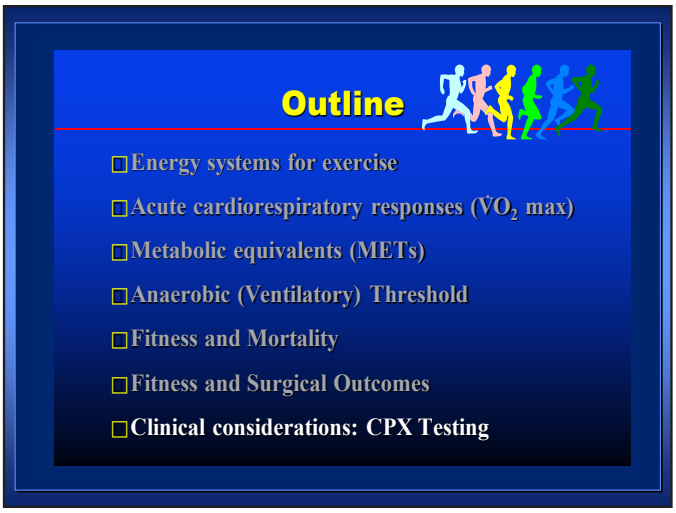
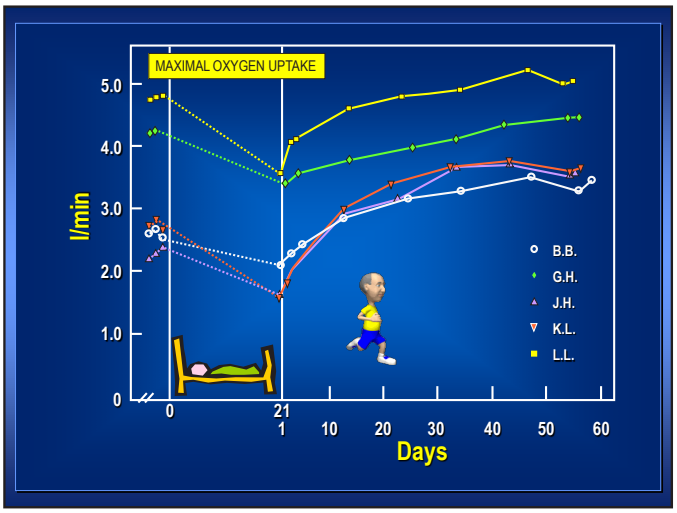
Correspondence to Thomas J. Hoogeboom, Universiteitssingel 40, 6229 ER, Maastricht, The Netherlands. Tel: +31 622021209; e-mail: thomashoogeboom@gmail.com

Curr Opin Anesthesiol 2014, 27:161–166
DOI:10.1097/ACO.0000000000000062

Hoogeboom TJ et al. Curr Opin Anesthesiol 2014;27:161-166







Three weeks of bed rest resulted in a reduction in the maximal oxygen uptake ($\dot{V}O_2$ max) of **25 %,** equivalent to the decrease in aerobic capacity that normally occurs over **30** years!

Saltin B et al. Circ 1968;38[suppl 7]:1

Mean Changes in Aerobic Capacity ($\dot{V}O_2$ max) Before and After Bed Rest*

Remedial Treatment Mode	*Bed Rest (days)*	$\dot{V}O_2$ max (liters/min) *Before*	*After*	*% Δ*
None	14	3.9	3.3	-15
Venous pooling	14	3.3	3.1	- 6

% Δ = percent change

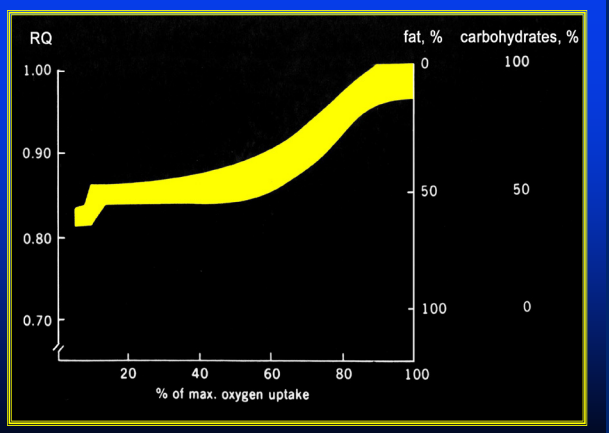
** Convertino VA et al. J Appl Physiol 1982;52:1343-1348*

6

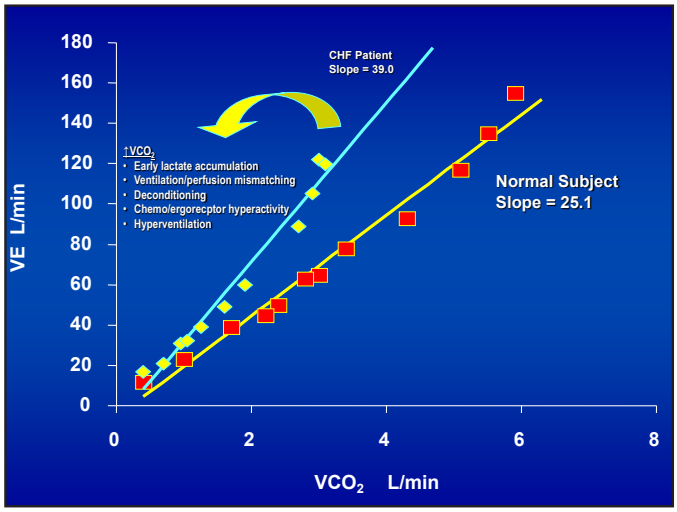
It appears that deterioration of exercise performance resulting from bed rest may be largely obviated by regular exposure to orthostatic stress, such as intermittent sitting or standing during the hospital confinement period.*

*Convertino VA et al. J. Cardiac Rehabil. 1983;3:660

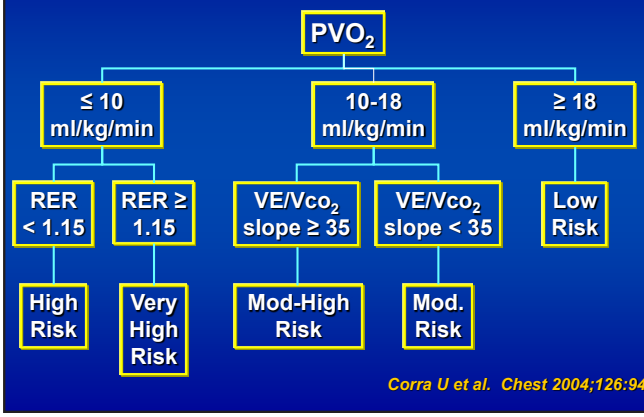
Cardiopulmonary Exercise Testing (CPX)



Respiratory Quotient (RQ) or RER: The 'Lie' Detector (Values > 1.15-1.20 = Max Effort)



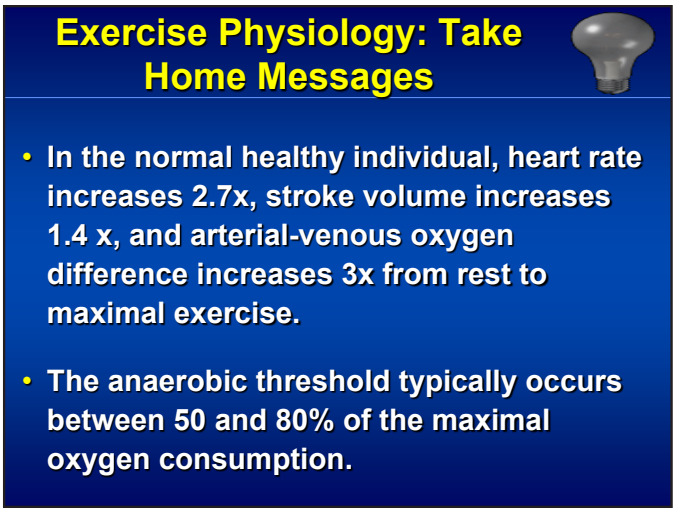
Risk Stratification Algorithm

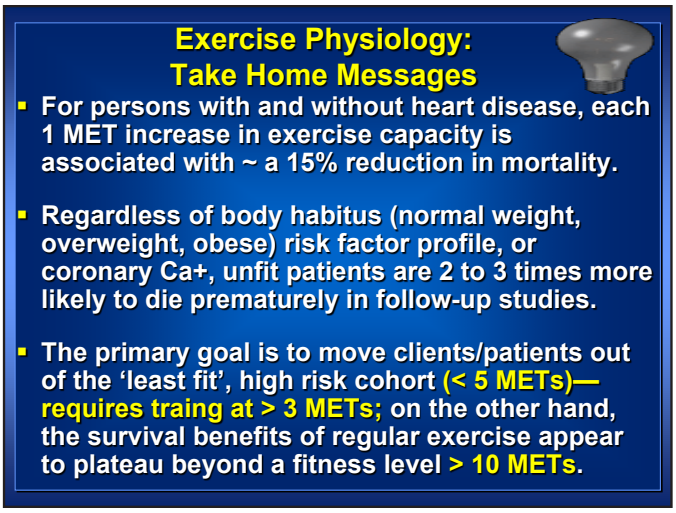


Corra U et al. Chest 2004;126:942

Conclusions

Last 3 slides...





SELF EVALUATION

Clinical Implications of Exercise Physiology, Aerobic Capacity and Metabolic Equivalents

1. At about _____ minutes of moderate-to-vigorous intensity exercise, there is approximately equal contribution (aerobic vs. anaerobic) of energy (ATP).
   a. 2
   b. 4
   c. 6.5
   d. none of the above

2. A heart failure patient undergoing a cardiopulmonary exercise stress test demonstrates a V̇O2 peak of 14 mL O2/kg/min. How many METs does this correspond to?
   a. 3
   b. 4
   c. 5
   d. 7

3. The anaerobic or ventilatory threshold for a relatively fit 40-year old male with a 10 MET exercise capacity would most likely occur at _____ METs?
   a. 3
   b. 4
   c. 6.5
   d. 9

4. Regardless of the specific risk factor profile, low fit men and women have approximately _____ times the mortality in follow-up studies.
   a. 2
   b. 4.5
   c. 7
   d. none of the above

5. T/F - A preoperative level of cardiorespiratory fitness less than 4.5 – 5.0 METs immediately prior to undergoing bariatric or coronary artery bypass surgery is associated with poorer short-term outcomes.

6. According to a classic study, 3 weeks of bed rest in young, healthy individuals, resulted in a reduction in the maximal oxygen consumption of _____ %, equivalent to the decrease in aerobic capacity that normally occurs over 30 years!
   a. 10
   b. 15
   c. 25
   d. 45

7. T/F - A respiratory quotient, also known as the respiratory exchange ratio, above 1.0 during a cardiopulmonary exercise test, indicates that a "true" V̇O2 max had been obtained.

8. During cardiopulmonary exercise testing, which variable, in addition to the V̇O2 peak, has the greatest prognostic significance relative to life expectancy or long-term survival?
   a. Ventilatory threshold (%)
   b. Peak respiratory exchange ratio
   c. V̇E/V̇CO2 slope
   d. Oxygen pulse (peak value)

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

David J. Norris, MD, MBA, CPE

David J. Norris, MD, MBA, CPE, of Wichita, Kansas, is a practicing cardiac anesthesiologist and maintains deep expertise in the communication, financial and organizational skills, as well as business processes, needed for effective, economical, and efficient delivery of high-quality patient care. He is currently medical director for the HCA Woodlawn Campus and is president of Wichita Anesthesiology. Dr. Norris is a frequent speaker on medical practice business, leadership and financial issues and is author of *The Financially Intelligent Physician*, with a short, weekly podcast of the same name, and *Great Care, Every Patient***.**

You may learn more about Dr. Norris at www.davidnorrismdmba.com, and contact him with your questions and comments at david@davidnorrismdmba.com, or by phone at 316-200-2785.

THE FINANCIALLY INTELLIGENT PHYSICIAN
WHAT THEY DIDN'T TEACH YOU IN MEDICAL SCHOOL

David J. Norris, MD, MBA, CPE
316-200-2785 david@davidnorrismdmba.com

Emotional Intelligence - Improving Relationships with Staff and Patients

Better Relationships

Staff

Better Relationships

Staff

Co-workers

Better Relationships

Staff Patients

Co-workers

Better Relationships

Staff Patients

Co-workers

Family

Self awareness

Self awareness

Self control

Self awareness

Social awareness

Self control

Self awareness

Social awareness

Emotional Intelligence

Self control

Understand Yourself

Of all knowledge, the wise and good seek most to know themselves

- William Shakespeare

From there you can understand people

Understand Others

The biggest mistake you can make in trying to talk convincingly is to put your highest priority on expressing your ideas and feelings. What most people really want is to be listened to, respected, and understood. The moment people see that they are being understood, they become more motivated to understand your point of view.

- Dr. David Burns, UPenn

Understanding Yourself

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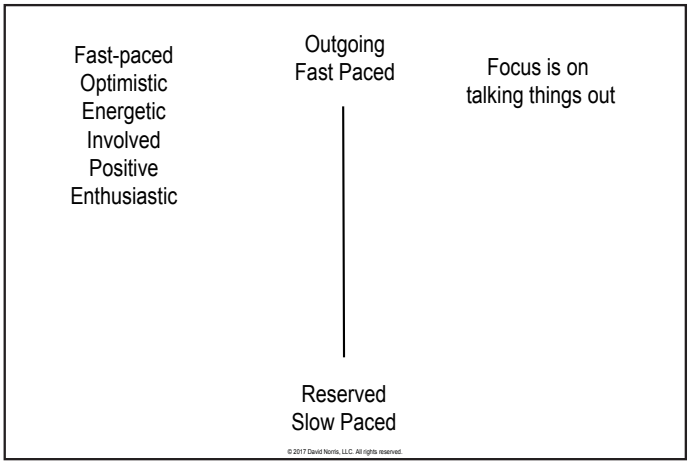
What's your pace?


Fast-paced
Optimistic
Energetic
Involved
Positive
Enthusiastic
Outgoing
Fast Paced
Focus is on
talking things out
Reserved
Slow Paced
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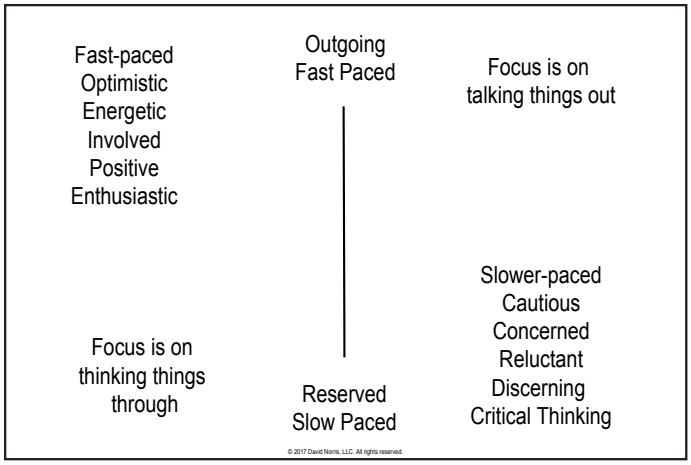
Fast-paced
Optimistic
Energetic
Involved
Positive
Enthusiastic
Outgoing
Fast Paced
Focus is on
talking things out
Slower-paced
Cautious
Concerned
Reluctant
Discerning
Critical Thinking
Focus is on
thinking things
through
Reserved
Slow Paced
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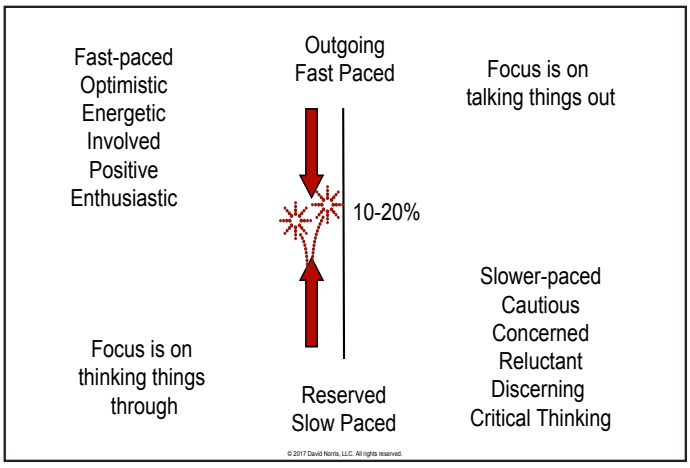
Fast-paced
Optimistic
Energetic
Involved
Positive
Enthusiastic
Outgoing
Fast Paced
Focus is on
talking things out
10-20%
Slower-paced
Cautious
Concerned
Reluctant
Discerning
Critical Thinking
Focus is on
thinking things
through
Reserved
Slow Paced
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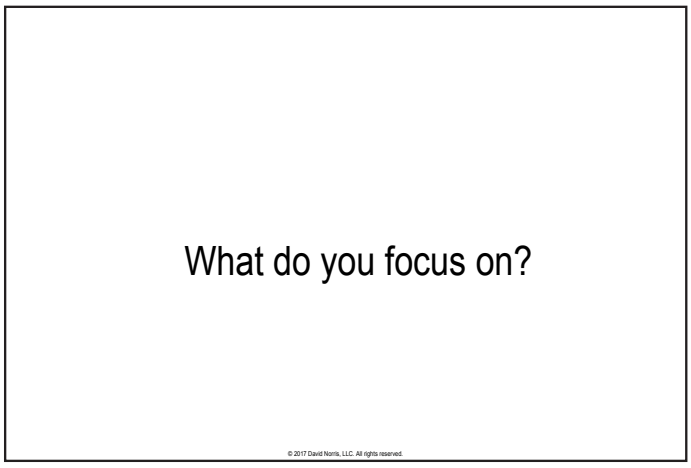
What do you focus on?
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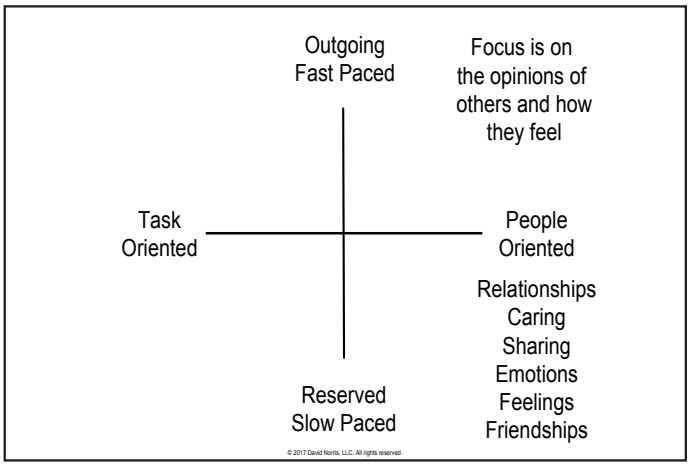
Outgoing
Fast Paced
Focus is on
the opinions of
others and how
they feel
Task
Oriented
People
Oriented
Relationships
Caring
Sharing
Emotions
Feelings
Friendships
Reserved
Slow Paced
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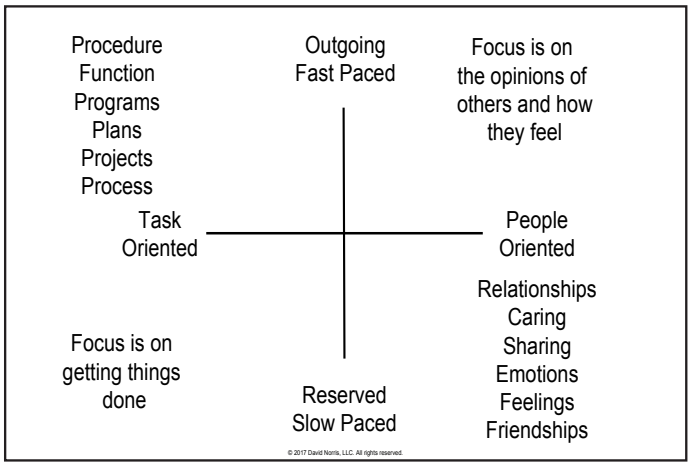
Procedure
Function
Programs
Plans
Projects
Process
Outgoing
Fast Paced
Focus is on
the opinions of
others and how
they feel
Task
Oriented
People
Oriented
Relationships
Caring
Sharing
Emotions
Feelings
Friendships
Focus is on
getting things
done
Reserved
Slow Paced
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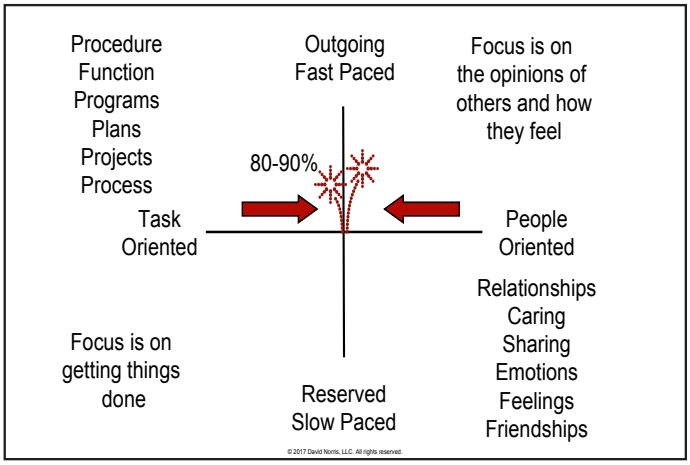
Procedure
Function
Programs
Plans
Projects
Process
Outgoing
Fast Paced
Focus is on
the opinions of
others and how
they feel
80-90%
Task
Oriented
People
Oriented
Relationships
Caring
Sharing
Emotions
Feelings
Friendships
Focus is on
getting things
done
Reserved
Slow Paced
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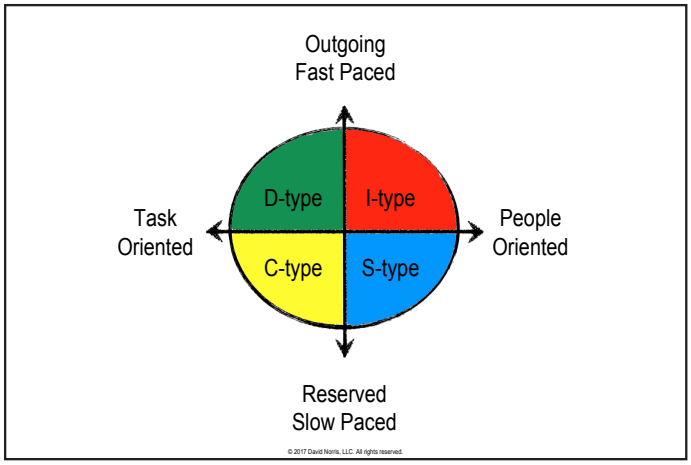
Outgoing
Fast Paced
Task
Oriented
D-type
I-type
C-type
S-type
People
Oriented
Reserved
Slow Paced
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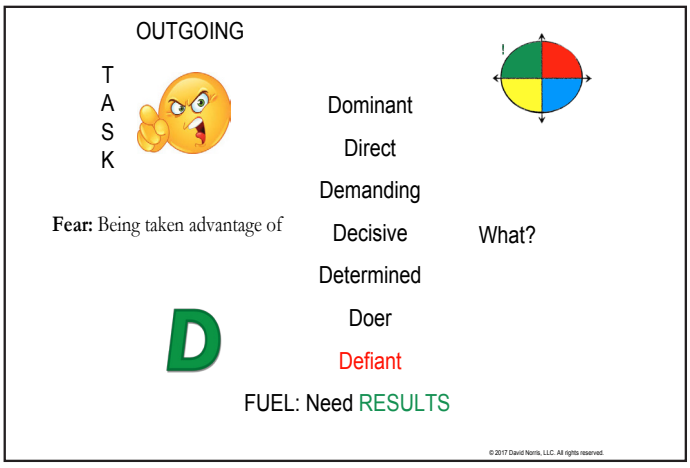
OUTGOING
T
A
S
K
Fear: Being taken advantage of
D
Dominant
Direct
Demanding
Decisive
Determined
Doer
Defiant
What?
FUEL: Need RESULTS
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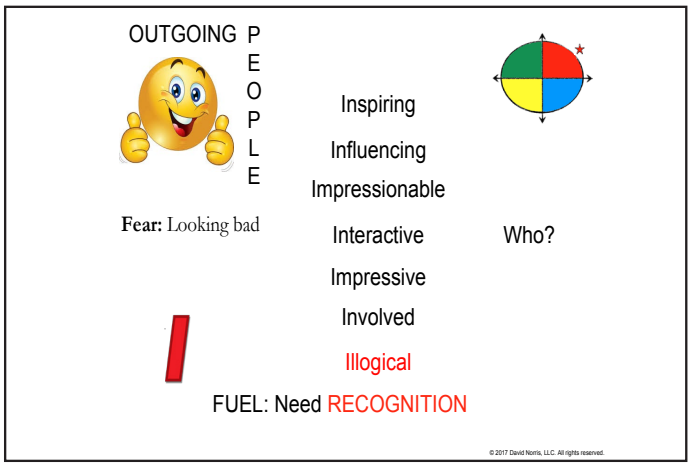
OUTGOING
P
E
O
P
L
E
Fear: Looking bad
I
Inspiring
Influencing
Impressionable
Interactive
Impressive
Involved
Illogical
Who?
FUEL: Need RECOGNITION
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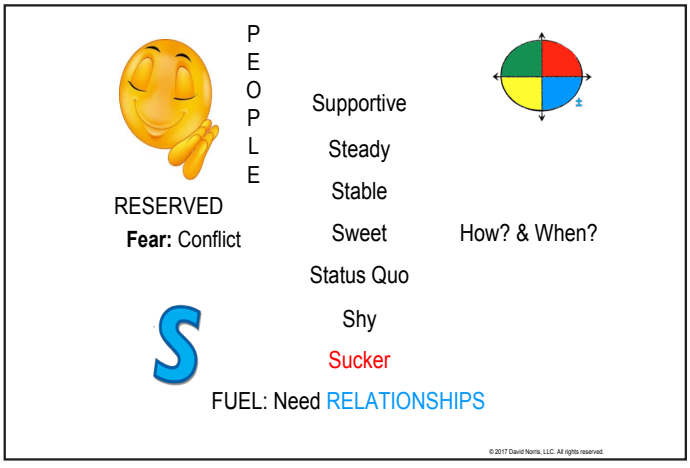
P
E
O
P
L
E
RESERVED
Fear: Conflict
S
Supportive
Steady
Stable
Sweet
Status Quo
Shy
Sucker
How? & When?
FUEL: Need RELATIONSHIPS
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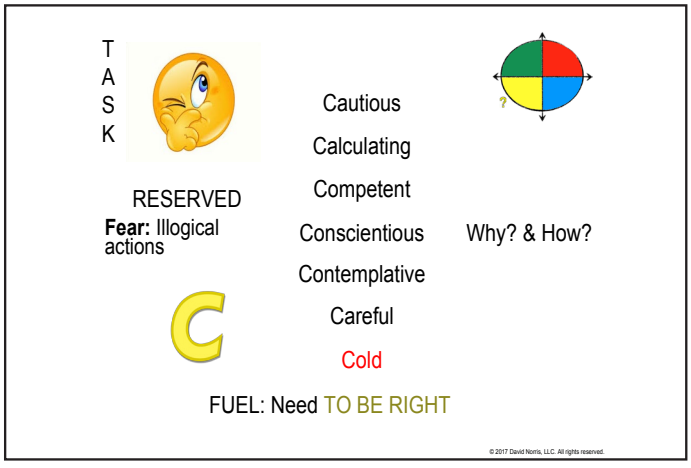
T
A
S
K
RESERVED
Fear: Illogical
actions
C
Cautious
Calculating
Competent
Conscientious
Contemplative
Careful
Cold
Why? & How?
FUEL: Need TO BE RIGHT
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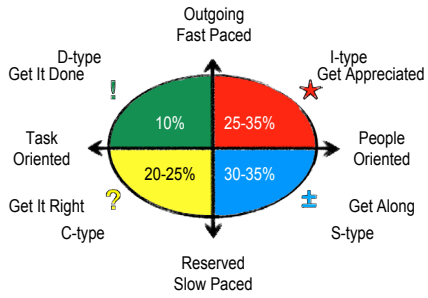

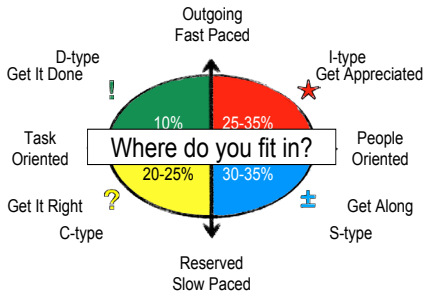

Keys to Self - Management

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WHAT THEY DIDN'T TEACH YOU IN MEDICAL SCHOOL

D-Type Self-Management Keys

People are important

Relaxation is not a crime

Some controls are necessary

Everyone has a boss

Verbalizing conclusions helps others understand them better

I-Type Self-Management Keys

Time must be managed

Too much optimism can be harmful

Listening is important

Tasks must be completed

Accountability is imperative

S-Type Self-Management Keys

Change provides opportunity

Friendship isn't everything

Discipline is good

It is OK to say "No!"

Being a "servant" doesn't mean being a "sucker"

C-Type Self-Management Keys

Total agreement is not always necessary

Thorough explanations are not always possible

Deadlines must be met

Taking a calculated risk can be profitable

There are varying degrees of excellence

Relationships

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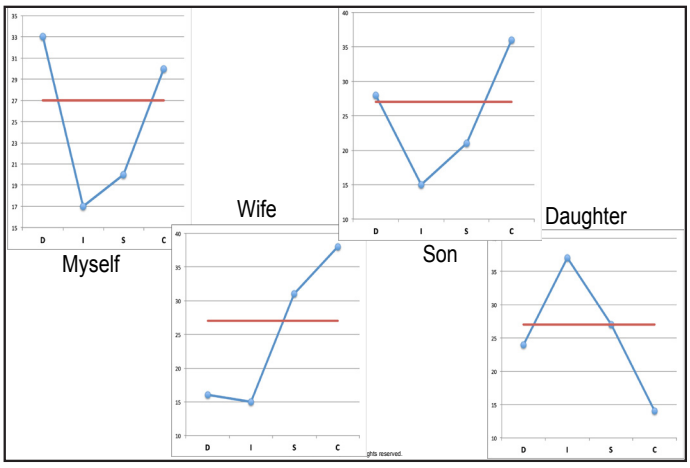
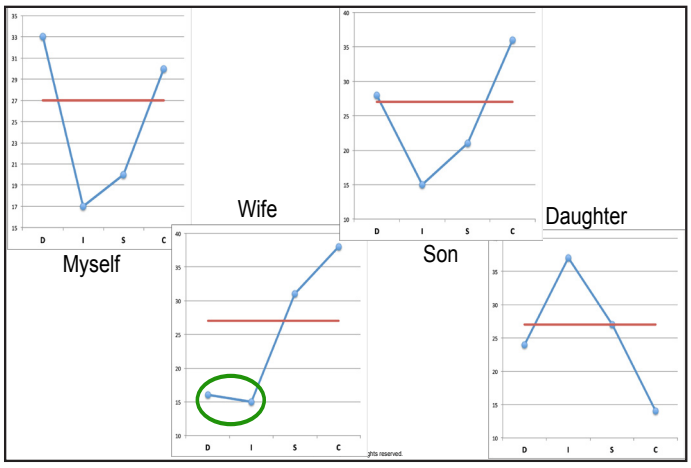
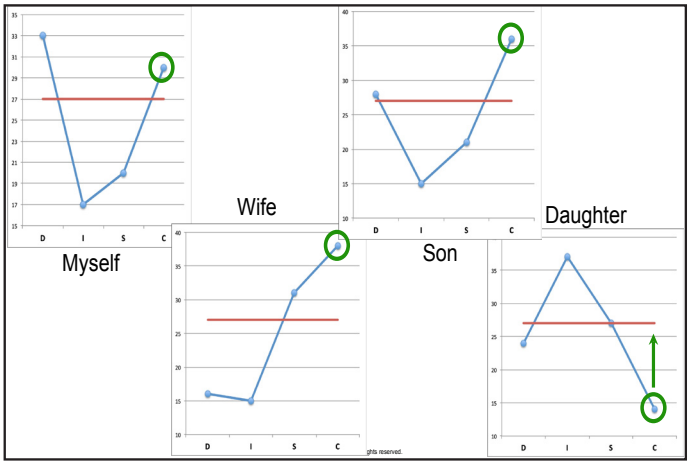
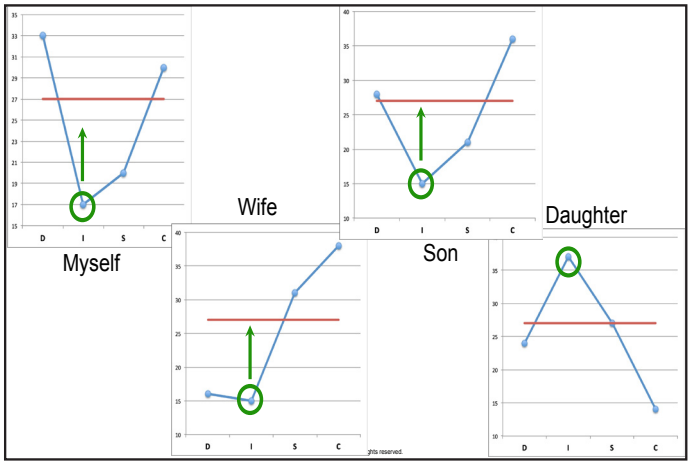
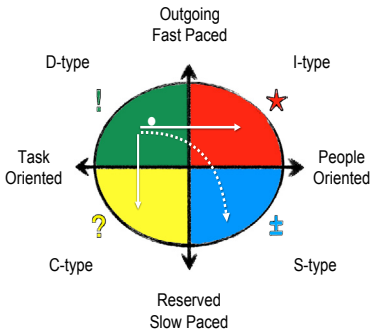
WHAT THEY DIDN'T TEACH YOU IN MEDICAL SCHOOL











Building Rapport

THE FINANCIALLY INTELLIGENT PHYSICIAN
WHAT THEY DIDN'T TEACH YOU IN MEDICAL SCHOOL

Why?

Connection

↓

Communication

↓

Compliance

Everyone Is Different

- What is natural for you, may take EFFORT for others
- What energizes you, may DE-MOTIVATE others
- Some multi-task easily, while other excel at mono-tasking
- Some work best ALONE and prefer to ISOLATE or RETREAT
- Others need discussion and dialogue to stimulate them. They want to ENGAGE and INTERACT
- Some are FAST-PACED and other are SLOW-PACED

Task-oriented people

Building Rapport

To do business or be in a relationship with you
They must first TRUST you

Rapport

For most Task people "I will trust you when you prove I can"

- Highest state of relatability
- Relationships - Based on task
  - I see value in you
  - I believe in your accomplishments
  - I believe you get things done
- Trust - Based on performance
  - Earned
  - Proven
  - Results

People-oriented people

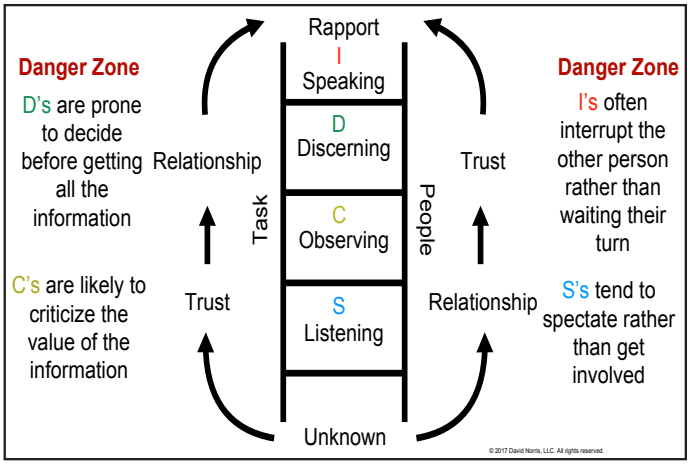
Building Rapport

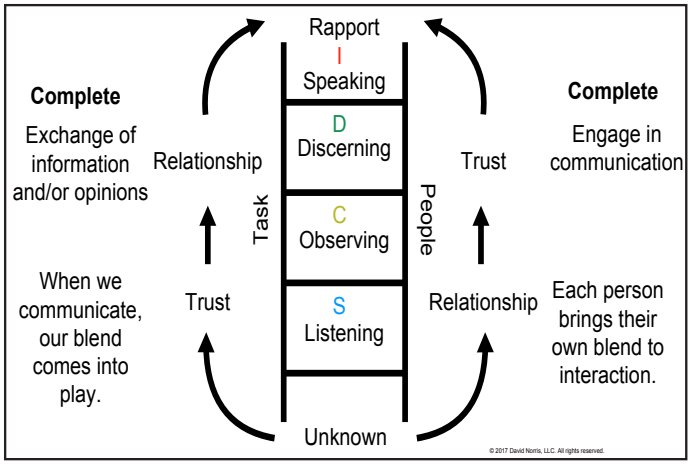
To do business or be in a relationship with you
They must first LIKE you

Rapport

For most People people "I will trust you until you prove I can't"

- Highest state of relatability
- Relationships - Based on emotions
  - Kind
  - Pleasant
  - Caring
- Trust - Based on feelings
  - I like you
  - Do you care about me?
  - I feel safe with you





A Recent Personal Example

56 y/o female

Admitted with abdominal pain

Liked to tell stories

- I asked about allergies

- Well, it all started when I was seven. I was visiting my cousins in … and that's how I discovered I was allergic.

- Let's see, it was three years ago when I began to experience some chest pain and I went to the ER… but it turned out to be GERD.

What Happened Next

I let her talk. I quickly recognized she might be a high I and allowed her to talk while gently redirecting her to stay on topic

The endoscopist is a high C - doesn't "have time to listen to the stupid stories"

He barges in "What questions? That's not a question. What's your question"

Who got good marks and who got bad marks?

D Type Patients

Direct

Want to get in and out

Concerned about one, maybe two issues

Expect you to be on time

Expect you to have answers and a plan

D-Type Patients

Outline tasks for them and they will follow

Tie your instructions/tasks to other tasks or the ability to do other tasks

If you appear confident, they'll trust you

The minute you demonstrate a lack of confidence, you're in trouble

Will push back if they don't agree with plan

I Type Patients

Talkative

Their answers might take a few minutes

They might not know the medicine they're on or why they are taking it

They might get distracted or go off on a tangents easily

Wanders from point to point

Expects you to be friendly, talkative

I-Type Patients

Expects you to listen

Don't interrupt them immediately, let them talk a bit

Judges you based upon your friendliness

Provide written instructions and repeat all instructions

They might not focus on the task, particularly if it isn't fun

To motivate them, tie the task to the people in their life and how un-fun things can get

S Type Patients

Very quiet

Patient

Will typically say "Ok Doc, whatever you say."

Won't push back if they think the diagnosis or treatment is wrong

Won't question you

S Type Patients

Forgiving if you're late

If you seem rushed or uninterested, they will shut down and not ask questions they need/want to

Judges you on compassion

Tie the tasks to the people. It'll motivate them comply and follow through

They may be your best referral source

C Type Patients

Will have their own copy of their medical record

Lists, lists, lists (meds, surgeries, every doctor's appointment they've ever had)

Will have questions written down

Will push you for answers

Won't tolerate / accept "I don't know"

C Type Patients

Will challenge you if they think you're wrong

Wants you to be right, confident

Answer all their questions

Have reasons for each task you want them to complete

If things make sense, they'll follow orders

Communication

THE FINANCIALLY INTELLIGENT PHYSICIAN
WHAT THEY DIDN'T TEACH YOU IN MEDICAL SCHOOL

Attitudes that Hinder Listening

D	I
You've already decided, made up your mind	You are day dreaming
You're "acting out" before completely understanding or listening to all the necessary information	You have distractions or are focusing on other activities
You jump to conclusions too quickly	You assume you know know what is going on when you really don't
You're hearing specific things that were said in a general manner	You've developed "selective hearing"
You're trying remember too much detail	You shut down when you're processing or don't understand information
You tend to find one word or concept that might be incorrect rather than seeing the big picture	You try to change the subject or procrastinate because don't like the topic
C	S

Obstacles that Keep Others From Listening to You

D	I
Thinking of their own agenda Quit listening once they've determined the information is useless	Thinking how they can get attention and recognition They tune out "boring" conversations and are easily distracted by the environment
What you need to do: GET TO THE POINT	What you need to do: BE MORE EXCITING
They will stop listening to judge the speaker They try to run ahead and form their own conclusion but if the information doesn't mesh with their conclusion, they'll shut down	They can lose the speaker's train of thought They might shut down in response to a tone of voice information they find fearful, or you're speaking too fast
C: What you need to do: I KNOW I'M RIGHT	S: What you need to do: SLOW DOWN A LITTLE

To be an effective communicator with

D	I
• Be prepared with support material in a well-organized "package." • Be clear, specific, brief and to the point. • Stick to business.	• Provide a warm and friendly environment. • Ask "feeling" questions to draw their opinions or comments. • Don't deal with a lot of details but when you do, put them in writing.
• Be accurate and realistic. • Prepare your "case" in advance. • Stick to business.	• Present your case softly, non-threateningly. • Ask "How?" questions to draw their opinions. • Begin with a personal comment in order to break the ice.
C	S

Leadership

There's more to it than meets the eye…

It's really a blend of all the styles - it's emotional intelligence

- Self-awareness - knowing yourself
- Self-control - having disciplined actions
- Social awareness - knowing other
- Social skill - connecting with others

Building Trust

Trust is a cornerstone for relating and communicating more effectively with others.

Without trust:

- Barriers and guards go up
- Lower performance
- Limited communication takes place
- Ideas and creativity stops
- Lower morale
- Increase in conflicts and misunderstanding
- People become indifferent
- Time and energy is wasted in conflicts

Building Trust

Trust is a cornerstone for relating and communicating more effectively with others.

Attitudes that Create or Reflect a Poor Environment

Criticism
Disengaged Involvement
Indifference / Apathy
Resentment
"Not My Responsibility" Mindset
Blame
No Accountability
Low Morale
Uncommitted
Negative Assumptions
Unproductive
Defiant Mindset
Tension
Fear
Hurt Feelings
Anger

Building Trust

Trust is a cornerstone for relating and communicating more effectively with others.

With trust:

- Open and honest dialogue for effectiveness and improvement
- Increased performance
- Ideas and creativity flow freely
- Higher levels of mutual respect
- Higher morale
- People become engaged
- Productive with time
- People take personal responsibility

Building Trust

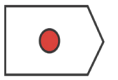
Trust is a cornerstone for relating and communicating more effectively with others.

Attitudes that Create or Reflect a Great Environment

Excitement
Energy
Can-Do Attitude
Peak Performance
Team Effort
"I'm Responsible" Mindset
Ownership
Personal Accountability
Influence
Commitment
Confidence
Positive Energy
High Morale
Co-operative mindset
Productivity
Peaceful Environment

High **D**'s lead DIRECTIVELY

They lead from out in front. Their attitude is, "I'm going. Follow me!"

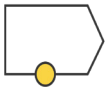


High **I**'s lead INSPIRATIONALLY

They lead from the middle of the "pack". They inspire others to join them in the effort.

High **S**'s lead SUPPORTIVELY

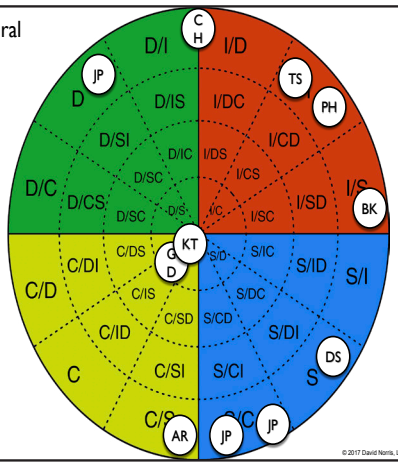
They lead from behind encouraging the team to move forward with their words of affirmation.



High **C**'s lead CAREFULLY

They lead from the side, making sure everyone is in step and following the right procedures.

Natural



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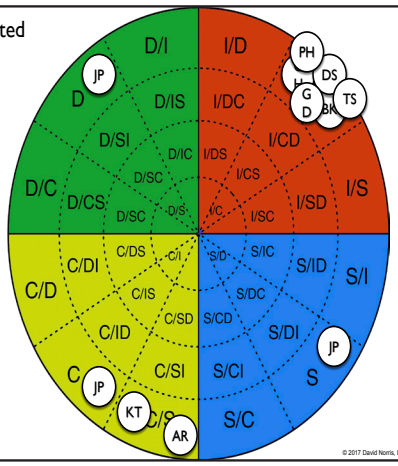

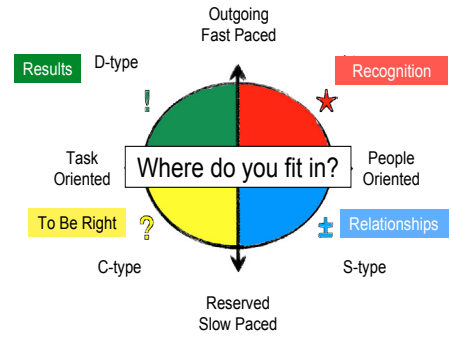

Reading Others

THE FINANCIALLY INTELLIGENT PHYSICIAN
WHAT THEY DIDN'T TEACH YOU IN MEDICAL SCHOOL

D — Reading D's - Outgoing & Task

Verbal Tones	Speech Patterns	Body Language	Workspace
States more than asks	Limited. Maybe not even say "hello"	Firm handshake	Full calendars
Talks more than listens	Avoids small talk or chit chat	Steady eye contact	Pressure-cooker schedule
Primarily verbal, not written	Attempts to direct the conversation	Gestures to emphasize points	Frequently looks at watch
Makes strong statements	Dislikes "touchy-feely" terms	Displays impatience	Makes phone calls while speaking to you
Blunt: to the point	Under stress may become aggressive / defensive	Fast-moving body language	Few family photos
Uses forceful tones	Directive tones	Dislikes being casually touched	Few "personal" distractions
Communicates readily	Abrupt	Big gestures	Large desk
Demonstrates high volume, fast speech	Interrupts often	Leans forward	Awards displayed
Challenging voice tones	Often engaged in another activity during conversation	Pushy	Useful accessories

I — Reading I's - Outgoing & People

Verbal Tones	Speech Patterns	Body Language	Workspace
Tells stories, anecdotes	Talks and listens in "feeling" terms	Animated facial expressions	Decor reflects open and lively atmosphere
Shares personal feelings	Uncomfortable with people use sophisticated words	A lot of hand and body movement	May appear cluttered & disorganized
Expresses opinions readily	Talkative	Contact - oriented body language	Notes posted on wall with little rhyme or reason
Uses an abundance of inflection	Varied tones	Spontaneous actions	Furniture reflects warmth
Flexible time perspective - looses track of time	Often distracted by things in their environment	People tend to gravitate towards their space	Furniture is arranged to encourage a conversation
Variety in vocal quality	Moves from serious to light-hearted quickly	Energetic	Flashy fun pictures
Dramatic	Tends to tell everything they know	Poised and charming	Like to do things the fun way
High volume	Speaks in "telling" mode	Personable	
Fast speech	Asks very few questions	Often look distracted	

S — Reading S's - Reserved & People

Verbal Tones	Speech Patterns	Body Language	Workspace
Asks more than states	Natural listeners	Wears subdued colors	Personal & relaxed environment
Listens more than talks	Prefers to listen	Favors conventional styles	Friendly and informal atmosphere
Reserves their opinions	Focuses on the conversation	Prefers conventional vehicles	Systematic and traditional organization
Less verbal communication	Warm tones	Intermittent eye contact	Items reflecting their relationships (group photos)
Steady, even-tempered	Very friendly	Gentle gestures	Family pictures
Less forceful tone of expression	Conversational	Exhibits patience	Personal mementos
Lower volume of speech	Talks a little softer and stops quickly if interrupted	Slower-moving body language	Items recognizing their volunteer work
Slower rate of speech	Usually last one to speak	Comes across as reassuring	Likes to support and help others
	Usually has important information to share		

C — Reading C's - Reserved & Task

Verbal Tones	Speech Patterns	Body Language	Workspace
Fact & task-oriented	Asks pertinent questions	Formal and conservative	Formal and neat workspace
Limited sharing	Speaks carefully with less expression	Faultless grooming	Highly organized and structured desk
Formal & proper	Reluctant to share personal feelings	Conservative clothes with matching accessories	Aesthetically pleasing
Little inflection	Uses "thinking" words	Non-emotional	Charts, graphs, credentials
Less variety in vocal tones	Prefers non-contact & distance	Few facial expressions	Pictures neatly on walls and shelves
Less verbal, more written communication	Likes precise speech from all participants	Few gestures	Favor a functional decor for efficient work
Prefers their given name - no nicknames	Will fact-check things/issues discussed	Slower moving	State of the art technology
Structured speech	Always clarifying with goal of obtaining more information	Comes across as assessing	Uses lists
Planned speech	Logical and emotionless	Will stand their ground in stressful situations with facts	

Final Thought

You cannot change other people. The only person you can change is yourself.

When in doubt, start with **PEOPLE**, then shift to **TASK**.

These are not **LABELS**.

These are not **EXCUSES**.

Learn More

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SELF EVALUATION

Emotional Intelligence - Improving Relationships with Staff and Patients

1. T/F - Your mindset about the adversary, the situation, and the negotiation event is the most important aspect you can control.

2. All of the following are behaviors that we should use during the a negotiation EXCEPT:

a. Blank slating
b. Take notes
c. Push to close
d. No talking

3. T/F - Neediness is the physical display of our fears as we negotiate.

4. T/F - Verb-led questions are the best tool to discover the pain and needs of the adversary.

5. Items that we should review before any negotiation task such as a meeting, phone call, or email include all of the following except:

a. The mission and purpose of the negotiation
b. The problems we are facing
c. Baggage we and the adversary might be carrying
d. What we want
e. What happens next
f. All of the above

6. T/F - Keeping a written log or account of what happened during the negotiation event isn't necessary.

7. T/F - You only need to know the decision making process of the adversary during a negotiation.

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

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Diagnosing and Treating Atopic Dermatitis

WHY BOTHER?

Atopic Dermatitis: Why Bother?
It's Common

"Atopic dermatitis…is one of the most common inflammatory disorders, affecting up to 20% of children and 10% of adults…"

Langan SM, Irvine AD, Weidinger S *Lancet* 2020;396:345-360

Atopic Dermatitis: Why Bother?
It's Associated with Important Comorbidities

"Individuals with atopic dermatitis are at ↑ risk of having asthma, allergic rhinitis, and food allergy…."

Langan SM, Irvine AD, Weidinger S *Lancet* 2020;396:345-360

Atopic Dermatitis: Why Bother?
Most *Could* Be Addressed in Primary Care

- Prevalence (age 0-17) = 12.5%
- "…the vast majority (~ 67%) are reported to have mild disease, and as such may be adequately managed by their pediatrician or other primary care provider"

Eichenfeld LF et al *PEDIATRICS* 2015;136(3):554

Atopic Dermatitis: Why Bother
At Least in Pediatrics, Most Are Referred

"However, the majority of pediatricians refer even their mild patients to dermatologists (~85%)…and provide only initial, limited care…."

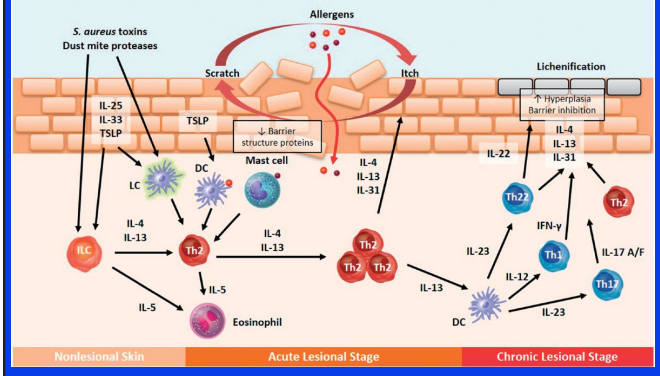
Eichenfeld LF et al PEDIATRICS 2015;136(3):554

Atopic Dermatitis: The Basic Story Line

"Atopic dermatitis is a chronic, pruritic eczematous disease that nearly always begins in childhood and follow a remitting/flaring course that may continue throughout life…. It may be exacerbated by infection, psychologic stress, seasonal/climate changes, irritants, and allergens…patients carry a life-long sensitivity to irritants, and this atopy predisposes them to occupational skin disease."

Habif T Clinical Dermatology 4th Ed Mosby (Edinburgh) 2004

Pathophysiology



Cork MJ, Danby SG, Ogg GS *J Dermatological Treat* 2020;11(8):801-809

The Pathology of Atopic Dermatitis is SIMPLE

- Skin barrier defects
- Altered cutaneous microbiome
- Dysregulation of cell-mediated immunity
- Pruritus-driven skin damage

Dinulos JGH *Habif's Clinical Dermatology* 7th Ed Elsevier (New York) 2021

So….The Rx of Atopic Dermatitis Seems Like It Should Also be SIMPLE

Pathology	Intervention
Skin barrier defect	Moisturization
Microbiome	Antibacterial Rx
Immune Dysregulation	IL-4 R MAB, PDE4i
Scratch-induced damage	Rx Pruritus

Dinulos JGH *Habif's Clinical Dermatology* 7th Ed Elsevier (New York) 2021

Atopic Dermatitis: Epidermal Barrier Dysfunction

- ↑ TEWL
- ↑ pH
- Altered lipid composition
- ↑ Cutaneous permeability
- Altered microbiome
- Involves affected & unaffected skin

Langan SM, Irvine AD, Weidinger S *Lancet* 2020;396:345-360

Extrinsic Atopic Dermatitis Pathophysiology: The Role of Filaggrin

FLG gene loss-of-function mutation (20-40% AD)

↓filaggrin

Disrupted epidermal barrier

TEWL (transepidermal water loss)

Inflammation

Langan SM, Irvine AD, Weidinger S *Lancet* 2020;396:345-360

Atopic Dermatitis: Microbiome Dysbiosis

- S aureus dominant colonization
  - Lesional skin: 70%
  - Non-lesional skin: 39%
  - Transitions during flare from uninvolved to involved
  - Resolves with successful Rx
- Malassezia yeast colonization

Langan SM, Irvine AD, Weidinger S *Lancet* 2020;396:345-360

Atopic Dermatitis: Microbiome Disruption

Dysregulated Th2 cells

↑Skin pH

90% S Aureus Colonization Rate

- S aureus ↑ during exacerbation
- Rx restores skin microbiome diversity

Varothal S et al *Asian Pac J Allergy Immunol* 2013;31:91-98

Atopic Dermatitis Pathophysiology: Pruritus

Th2 cytokines
IL-4, IL-13, IL-31

↓

Sensory Nerve Activation

↓

Pruritus

Langan SM, Irvine AD, Weidinger S *Lancet* 2020;396:345-360

Atopic Dermatitis: IgE

- Total IgE Elevated in 80%
- Levels do not correlate with disease activity
- Higher levels with comorbid asthma
- inhalant allergens testing positive >50% of the time, HOWEVER desensitization ⫩→ much atopic dermatitis improvement

Dinulos JGH *Habif's Clinical Dermatology* 7th Ed Elsevier (New York) 2021

Dx

Atopic Dermatitis: A *CLINICAL* Dx

"There are no specific cutaneous signs, no known distinctive histologic features, and no characteristic laboratory findings."

Habif TP Clinical Dermatology 6th Edition 2016 Elsevier

Atopic Dermatitis: Dx Features

Essential Both	Important Seen in most cases	Associated Supportive
Pruritus	Early age onset	Vascular dysregulation
Eczema	Atopy	Keratosis pilaris
	Xerosis	Pityriasis alba
		Ocular/periorbital Δs
		Perioral Δs
		Periauricular Δs
		Perifollicular accentuation
		Lichenification
		Ichthyosis

Habif TP *Clinical Dermatology* 6th Edition 2016 Elsevier

Atopic Dermatitis: Epidemiology

- Childhood prevalence 7.0-17.2%
- Increasing since the 1960s
- Children with generalized AD:
  - >50% get asthma/allergic rhinitis by age 13
- 70% have +FH asthma, allergic rhinitis, or eczematous dermatitis

Habif T Clinical Dermatology 4th Ed Mosby (Edinburgh) 2004

"Many irritants provoke pruritus…with AD"

- Heat/perspiration (96%)
- Wool (91%)
- Emotional stress (81%)
- Vasodilatory foods (49%)
- histamine-releasing foods (49%)
- Alcohol (44%)
- URI (41%)
- Dust mites (36%)

Tramp C, Kaplan DL Atopic Dermatitis: How to Recognize, How to Treat" Consultant 2000;November:2220s-2232s

Atopic Dermatitis: Phases

- Infant Phase (birth-2 years)
- Childhood Phase (2-12 years)
- Adult Phase (12 years and older)

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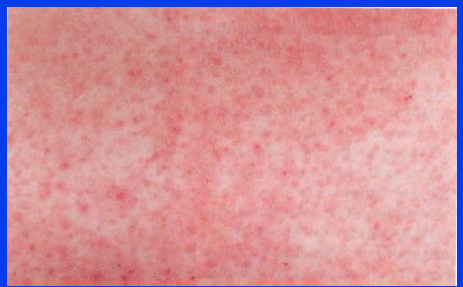
Papules



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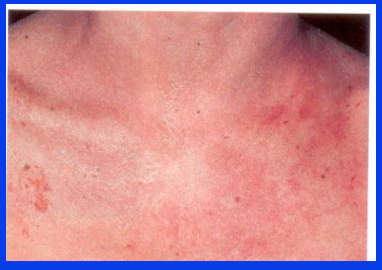
Eczematous Dermatitis with Redness and Scaling



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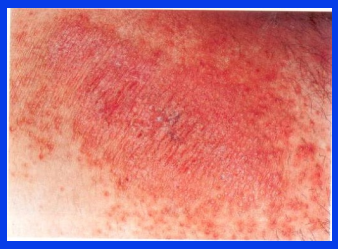
Lichenification



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Atopic Dermatitis: Infant Phase (Birth – 2 years)

- Uncommon at birth
- Onset usually by age 3 months
- Dry, red scaling areas on cheeks, sparing perioral and paranasal areas

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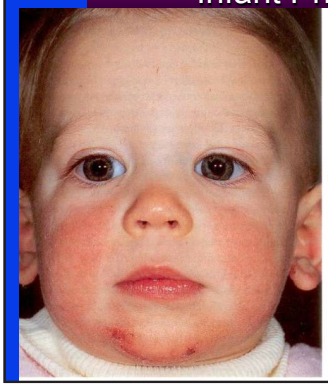
Atopic Dermatitis Infant Phase (Early)



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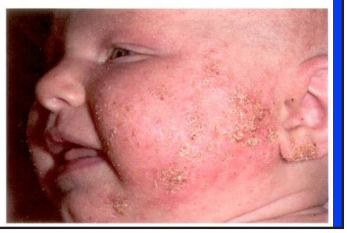
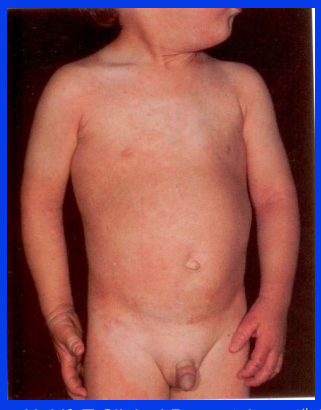
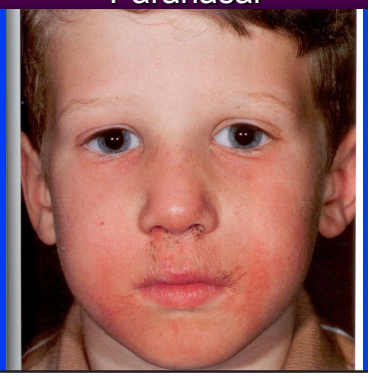




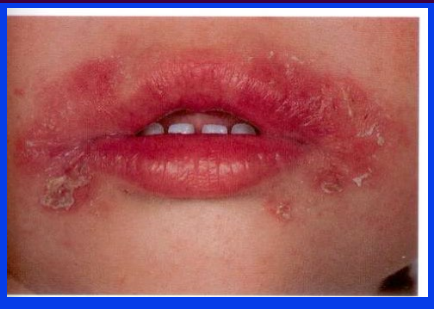
Accessibility: Diaper Sparing

Habif T Clinical Dermatology 4th Ed Mosby (Edinburgh) 2004

Progression to Perioral and Paranasal



Habitual Licking Advances PeriOral AD



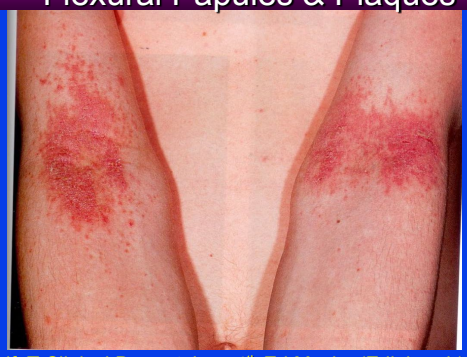
Habif T Clinical Dermatology 4th Ed Mosby (Edinburgh) 2004

Childhood Phase (2-12)

- Flexural areas
- Worsens with perspiration
- Worsens with tight clothing
- Papules initially, then plaques

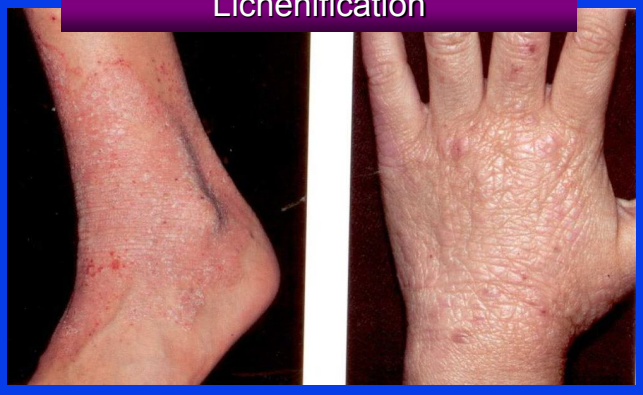
Habif T Clinical Dermatology 4th Ed Mosby (Edinburgh) 2004

Childhood Phase (2-12): Flexural Papules & Plaques



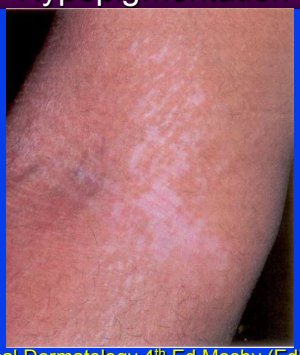
Habif T Clinical Dermatology 4th Ed Mosby (Edinburgh) 2004

Lichenification



Habif T Clinical Dermatology 4th Ed Mosby (Edinburgh) 2004

Damaged Melanocytes Hypopigmentation



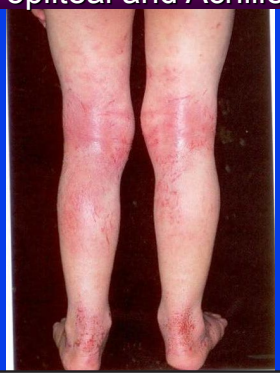
Habif T Clinical Dermatology 4th Ed Mosby (Edinburgh) 2004

Adult Phase (12 and older)

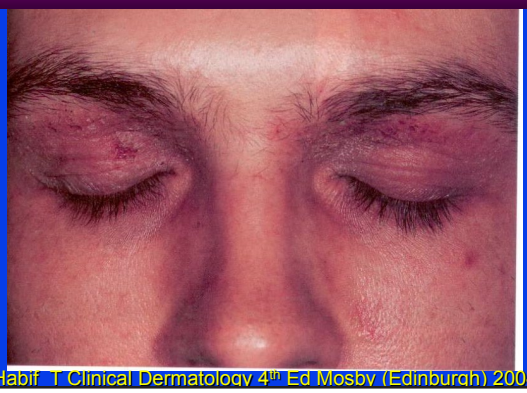
- Four Characteristic Patterns (alone or in combination)
  - Flexural
  - Hand Dermatitis
  - Peri-orbital
  - Anogenital

Habif T Clinical Dermatology 4th Ed Mosby (Edinburgh) 2004

Flexural Involvement: Popliteal and Achilles



Adult Atopic Dermatitis: Peri-orbital



Habif T Clinical Dermatology 4th Ed Mosby (Edinburgh) 2004

Rx

Atopic Dermatitis: Topical Pharmacologic Rx

Initial Rx

- High potency steroid (Group I or II) X 2 weeks
- Lowest effective potency steroid X 2-12 weeks
- Calcineurin inhibitor X 2-6 weeks
- Steroid + calcineurin inhibitor X 2-12 weeks

Upon Clearance

- Intermittent lowest effective potency steroid
- Calcineurin inhibitor + lowest effective potency steroid pulses

Habif TP Clinical Dermatology 6th Edition 2016 Elsevier

Moisturizers

Atopic Dermatitis: Moisture

- Avoid over-frequent hand washing
- Avoid over-frequent bathing
- Avoid lengthy bathing
- Use tepid water
- Avoid abrasive washcloths
- Soap: axilla, groin, feet only

Dinulos JGH *Habif's Clinical Dermatology* 7th Ed Elsevier (New York) 2021

Moisturizers: MOA

OCCLUSIVES	HUMECTANTS	EMOLLIENTS
Hydrophobic film on skin surface	LMW water attractants	Oil deposition between corneocytes

Varothai S et al *Asian Pac J Allergy Immunol* 2013;31:91-98

Moisturizers: Occlusives

- MOA: Hydrophobic skin film → ↓ TEWL
- 1st generation (oily)
  - Petrolatum
  - Lanolin
  - Mineral oil
- 2nd generation (oil-free, less greasy)
  - Dimethicone (silicone derivative)
  - Cyclomethicone (silicone derivative)

Varothal S et al *Asian Pac J Allergy Immunol* 2013;31:91-98

Occlusives: Best In Class

"The prototype of occlusives is
petrolatum
which is the most efficacious occlusive moisturizer."

Varothal S et al *Asian Pac J Allergy Immunol* 2013;31:91-98

Occlusives: Added Active Ingredients

- Ceramide
- Cholesterol
- Free fatty acids
- Intention: deep permeation to restore stratum corneum lipid barrier

Varothal S et al *Asian Pac J Allergy Immunol* 2013;31:91-98

Ceramides: What's The Deal?

"Ceramides are the main component of the multilayered lamellar bilayer between corneocytes…."

Varothal S et al *Asian Pac J Allergy Immunol* 2013;31:91-98

Ceramides: Clinical Trial Data

- AD: Global cutaneous lipid deficiency
- Selective deficiency in ceramide
- Ceramide Rx improves
  - Skin barrier function
  - Skin hydration
  - Severe AD: steroid sparing

Varothal S et al *Asian Pac J Allergy Immunol* 2013;31:91-98

Occlusives: Examples

- Beewax
- Carnuba
- Lanolin
- Mineral Oil
- Paraffin
- Petrolatum
- Proplylene glycol
- Silicones
- Squalene

Varothal S et al *Asian Pac J Allergy Immunol* 2013;31:91-98

Humectants: MOA

- LMW
- Hygroscopic: draw water from dermis and deeper epidermis
- Environmental (atmospheric) water: only if humidity >70%

Varothal S et al *Asian Pac J Allergy Immunol* 2013;31:91-98

Humectants: NOT a Good Monotherapy

"Moisturizers that contain only humectants actually ↑ TEWL when applied to skin with a defective barrier"

↓

Combine with Occlusive

- attract dermal water & prevent water evaporation (mimicks physiologic skin barrier function)

Varothal S et al *Asian Pac J Allergy Immunol* 2013;31:91-98

Humectants: Examples

- A-Hydroxy Acids
- Urea
- Hyaluronic Acid
- Propylene glycol
- Pyrrolidone carboxylic acid
- Sorbitol
- Sugars
- Glycerin (aka Glycerol)

Varothal S et al *Asian Pac J Allergy Immunol* 2013;31:91-98

Humectants: Best in Class

"Glycerol is the most effective humectant."

Varothal S et al *Asian Pac J Allergy Immunol* 2013;31:91-98

Emollients: MOA

- Instill small oil droplets between desquamating corneocytes →↑ skin softness, flexibility, and smoothness.
- ↓Humectant washout from water contact
- Primary function: cosmetic

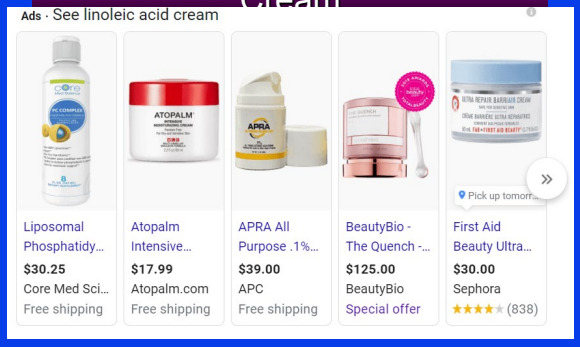
Varothal S et al *Asian Pac J Allergy Immunol* 2013;31:91-98

Emollients: Examples

- Lauric acid
- Linoleic acid
- Linolenic acid
- Oleic acid
- Stearic acid

Varothal S et al *Asian Pac J Allergy Immunol* 2013;31:91-98

Google Search: Linoleic Acid Cream



Pediatric Dermatology Vol. 26 No. 3 273–278, 2009

Quantitative Assessment of Combination Bathing and Moisturizing Regimens on Skin Hydration in Atopic Dermatitis

Charles Chiang, M.D.,* and Lawrence F. Eichenfield, M.D.†‡

Bathing: Shall We Consult the Guidelines?

"Atopic dermatitis guidelines have not provided consistent recommendations regarding optimal bathing and emollient application frequencies."

Chiang C, Eichenfield LF *Ped Dermatol* 2009;26(3):273-278

Atopic Dermatitis Rx: Bathing

Bathing: The 3-minute Rule

- Bathing can hydrate skin ONLY if moisturizer applied within 3-minutes of exiting tub
- Pat skin dry before moisturizer
- Cream (or petrolatum) more effective than lotion

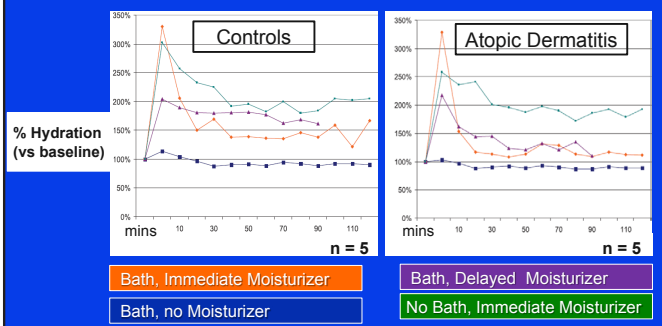
Dinulos JGH *Habif's Clinical Dermatology* 7th Ed Elsevier (New York) 2021

Comparing Moisturizer Regimens

- Study: Atopic dermatitis subjects (n=5) vs controls (5)
- Intervention (Cetaphil™ cream):
  - A) 10 min bath, no moisturizer
  - B) 10 min bath, immediate moisturizer
  - C) 10 min bath, delayed (30 min) moisturizer
  - D) no bath, immediate moisturizer
- Outcome (2 hrs post Rx): Skin hydration (Nova units)

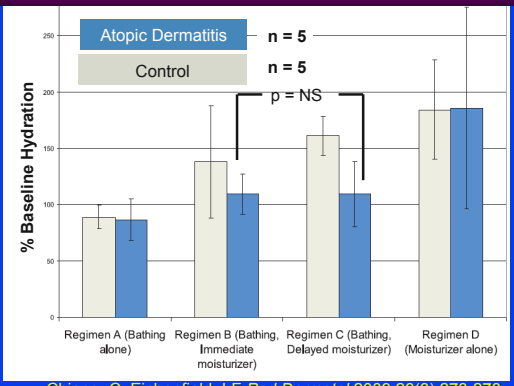
Chiang C, Eichenfield LF *Ped Dermatol* 2009;26(3):273-278

Hydration Status: Control



Chiang C, Eichenfield LF *Ped Dermatol* 2009;26(3):273-278

Hydration 90 mins Post Intervention



Chiang C, Eichenfield LF *Ped Dermatol* 2009;26(3):273-278

Post-Bath: Hydrate At Your Convenience?

"This study indicated no statistical difference in mean hydration status between immediate and delayed moisturizaton regimens despite guidelines recommending immediate moisturizer application postbathing."

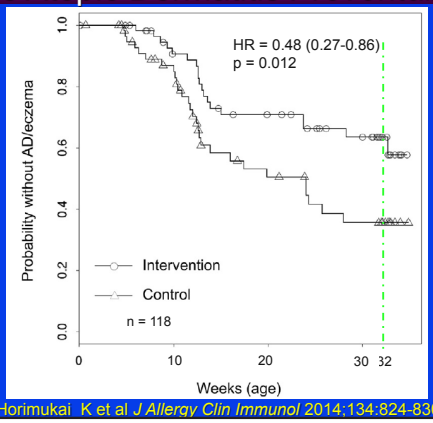
Chiang C, Eichenfield LF *Ped Dermatol* 2009;26(3):273-278

Is Atopic Dermatitis *Preventable*?

- Study: High-risk infants (n=118)
- Inclusion: parent or sib(s) AD+
- Rx:
  - 2e Douhet emulsion vs no Rx
  - Petrolatum rescue (both groups)
- Skin exam weeks 4, 12, 24, 32
- Outcome: incident Atopic dermatitis

Horimukai K et al *J Allergy Clin Immunol* 2014;134:824-830

Is Atopic Dermatitis *Preventable*?



Horimukai K et al *J Allergy Clin Immunol* 2014;134:824-830

Is Atopic Dermatitis *Preventable*?

"Findings from our RCT support our hypothesis that daily application of a moisturizer would prevent development of AD/eczema during the first 32 weeks of life."

Horimukai K et al *J Allergy Clin Immunol* 2014;134:824-830

What is 2e Douhet Emulsion, You Say?

INGREDIENTS: WATER (AQUA/EAU), ALCOHOL DENAT., GLYCERIN, BUTYLENE GLYCOL, DIPROPYLENE GLYCOL, DIPHENYLSILOXY PHENYL TRIMETHICONE, XYLITOL, DIETHYLHEXYL SUCCINATE, DIMETHICONE, ERYTHRITOL, PEG/PPG-14/7 DIMETHYL ETHER, SILICA, BEHENYL ALCOHOL, CARBOMER, BATYL ALCOHOL, METHYLPARABEN, AMINOMETHYL PROPANOL, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, TRISODIUM EDTA, DIPOTASSIUM GLYCYRRHIZATE, POLYQUATERNIUM-51, FRAGRANCE (PARFUM), THIOTAURINE, PHENOXYETHANOL, ALCOHOL, LINALOOL, BENZYL BENZOATE, LIMONENE, BETULA PLATYPHYLLA JAPONICA BARK EXTRAC

Atopic Dermatitis Rx: Topical Steroids in Children

- Children 3 months-6 years
  - Group V , e.g., fluticasone propionate cream 0.05% (Cutivate) safe for up to 4 weeks
- Low potency (group VI-VII) ineffective
- If recurrent, for maintenance: 2 days q week (may also resolve early new outbreak)

Habif T Clinical Dermatology 4th Ed Mosby (Edinburgh) 2004

Short-term High Potency Steroids in Children

- Study: Open label study 0.1% fluocinonide cream (Class I) qd-b.i.d X 2 weeks
- Subjects: mod-severe atopic dermatitis of ≥20% body surface
  - 3 months-2 years
  - 2-6 years
  - 6-12 years
  - 12-18 years

Schlessinger J, et al Arch Dermatol 2006;142:1568-1572

Feeling BRAVE?: Short-term High Potency Steroids in Children

Outcomes:

- Assessment of HPA axis suppression
- Adverse events
- Disease status change

Schlessinger J, et al Arch Dermatol 2006;142:1568-1572

Short-term High Potency Steroids in Children

Assessment of HPA axis suppression

Serum cortisol level 18 mcg/dL or less (≤497 nmol/L) 30 minutes after IV cosyntropin stimulation between 7:30-8:30 AM

Schlessinger J, et al Arch Dermatol 2006;142:1568-1572

Short-term High Potency Steroids in Children HPA Suppression at 2 weeks

Application	.25-2 yrs	2-6 yrs	6-12 yrs	12-18 yrs
QD	None	None	None	None
BID	None	None	2/16	1/15

Schlessinger J, et al Arch Dermatol 2006;142:1568-1572

Short-term High Potency Steroids in Children OTHER OUTCOMES

- At week 4, all subjects HPA WNL
- 2-weeks post Rx % clear-almost clear

	.25-2 yrs	2-6 yrs	6-12 yrs	12-18 yrs
QD	>90%	>80%	>70%	>80%
BID	>90%	>80%	>70%	>80%

Schlessinger J, et al Arch Dermatol 2006;142:1568-1572

Atopic Dermatitis Rx: Calcineurin Inhibitors

- Pimecrolimus cream (Elidel)
- Tacrolimus ointment (Protopic)

Habif T Clinical Dermatology 4th Ed Mosby (Edinburgh) 2004

Atopic Dermatitis Rx: Tacrolimus ointment 0.03%, 0.1% (Protopic)

- Indication: SECOND-LINE therapy for short-term and non-continuous chronic Rx of mod-severe AD in immunocompetent patients when other topical therapies are inadvisable or ineffective
- Age 2-15: use 0.03% b.i.d. Do Not Occlude
- Age 16: use either strength b.i.d.
- Metabolism: CYP3A4

Monthly prescribing Reference February 2008

Atopic Dermatitis Rx: Pimecrolimus 1% Cream (Elidel)

- Indication: SECOND-LINE therapy for short-term and non-continuous chronic Rx of mild-moderate AD in immunocompetent patients when other topical therapies are inadvisable or ineffective
- Age >2: apply b.i.d. Do Not Occlude
- Metabolism: CYP3A4

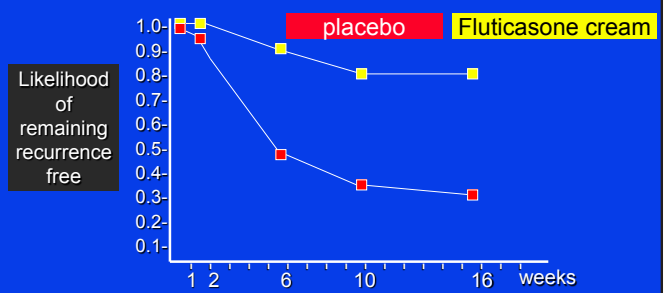
Monthly prescribing Reference February 2008

Can AD Recurrences be PREVENTED?

- Study: Moderate-severe atopic dermatitis patients (n=376) stabilized after disease flare with 4 weeks QD-b.i.d fluticasone
- Rx: emollient + fluticasone (0.05% cream or 0.005% ointment) or fluticasone vehicle QD-b.i.d. twice weekly X 16 weeks
- Outcome: time to relapse of AD

Berth-Jones J, Damstra RJ, Golsch, S, Livden JK, Van Hooteghem O, Allegra F, Parker CA BMJ 2003;326:1367-70

Can AD Recurrences be PREVENTED?



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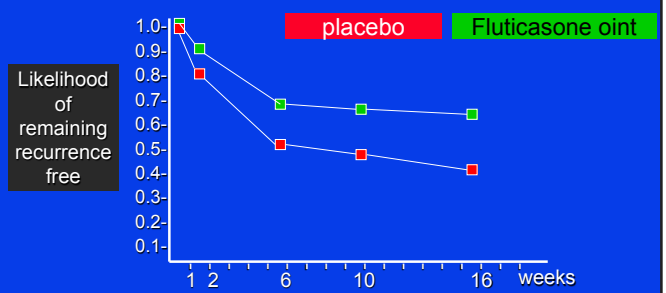
Can AD Recurrences be PREVENTED?



Berth-Jones J, Damstra RJ, Golsch, S, Livden JK, Van Hooteghem O, Allegra F, Parker CA BMJ 2003;326:1367-70

ORIGINAL ARTICLES

Efficacy and safety of crisaborole ointment, a novel, nonsteroidal phosphodiesterase 4 (PDE4) inhibitor for the topical treatment of atopic dermatitis (AD) in children and adults

Paller AS et al *J Am Acad Dermatol* 2016;75:494-503

Crisaborole (Eucrisa) 2% Ointment

- $PDE4_B$ inhibitor
- Blocks
  - TNF-alpha
  - Interleukin-12
  - Interleukin-23
  - Other inflammatory cytokines

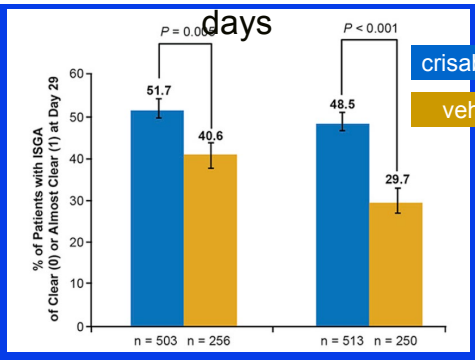
Wikipedia 018/Feb/24

Atopic Dermatitis: Crisaborole vs Placebo

- Study: Atopic dermatitis patients (n=1527)
  - Age ≥2
  - Mild-Moderate ISGA Score
  - ≥5% BSA involved
- Rx crisaborole 2% ointment b.i.d. vs vehicle
- 1^0 outcome (day 29): Clear/almost clear & ≥2 grade improvement

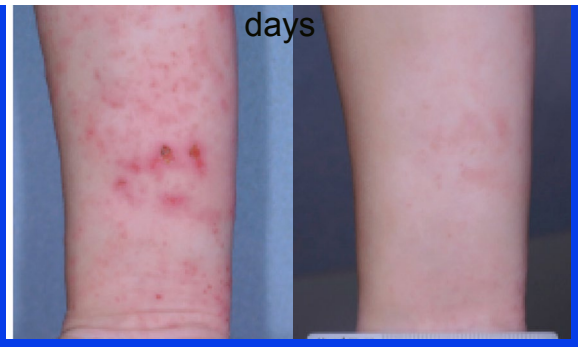
Paller AS et al *J Am Acad Dermatol* 2016;75:494-503

Crisaborole 2% Ointment vs Placebo at 29 days



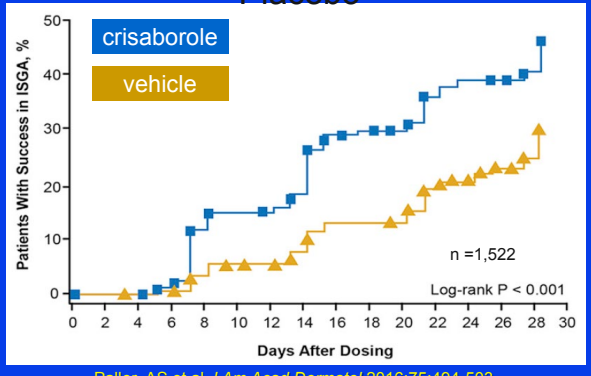
Paller AS et al *J Am Acad Dermatol* 2016;75:494-503

Crisaborole 2% Ointment vs Placebo at 29 days

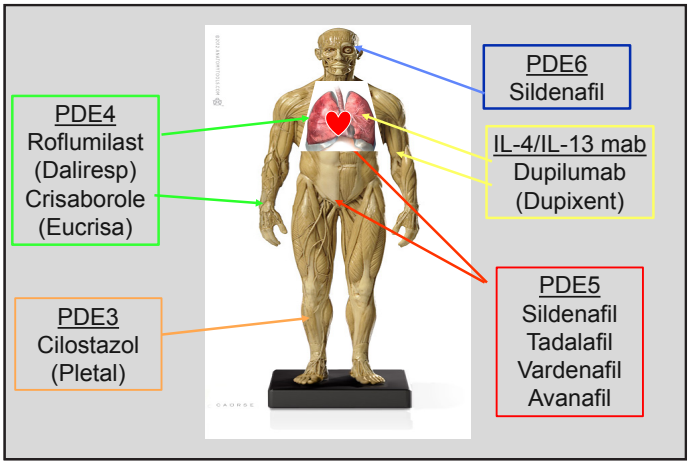


Paller AS et al *J Am Acad Dermatol* 2016;75:494-503

Crisaborole 2% Ointment vs Placebo



Paller AS et al *J Am Acad Dermatol* 2016;75:494-503

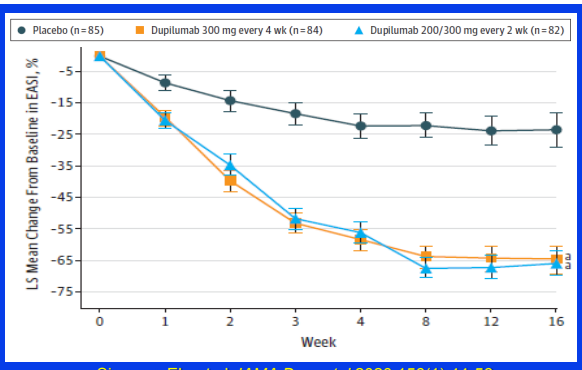


Dupilumab: % Δ Eczema Area & Severity

- Study: RDBPCT Atopic Dermatitis Mod-Severe (n = 251)
- Rx: dupilumab vs placebo x 16 weeks
- Inclusion: inadequate control with topicals
- Outcomes:
  - Area of skin involved
  - Severity of dermatitis
  - Pruritus

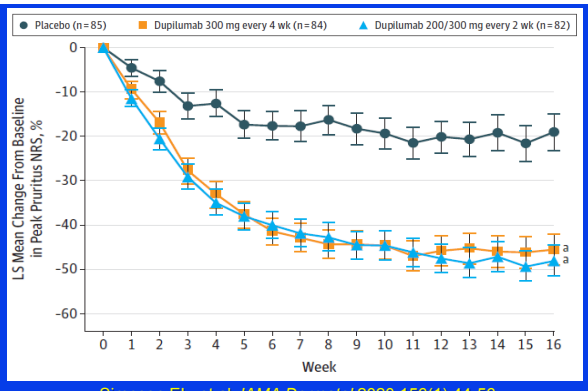
Simpson EL, et al *JAMA Dermatol* 2020;156(1):44-56

Dupilumab: % Δ Eczema Area & Severity



Simpson EL, et al *JAMA Dermatol* 2020;156(1):44-56

Dupilumab: % Δ Pruritus



Simpson EL, et al *JAMA Dermatol* 2020;156(1):44-56

Atopic Dermatitis: Food Allergy

"Food allergy should be considered in infants, young children, and selected older children diagnosed with moderate-severe atopic dermatitis."

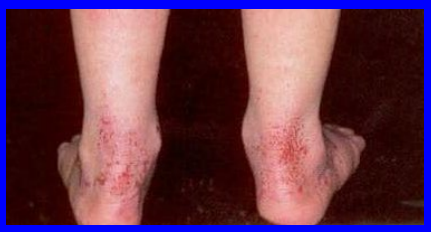
Habif TP Clinical Dermatology 6th Edition 2016 Elsevier

Atopic Dermatitis: Food

"Five foods account for 90% of the positive oral challenges seen in children; in order of frequency they are: eggs, peanuts, milk, soy, and wheat."

Habif T Clinical Dermatology 4th Ed Mosby (Edinburgh) 2004

Flexural Involvement: a 6 y y.o with Achilles Excoriations



Atopic Dermatitis: *Possible* Culprit Foods

+ Skin Tests in 160 AD children

Egg	89%	Wheat	24%
Peanut	81%	Rice	14%
Fish	45%	Rye	14%
Soy	45%	Potato	12%
Pork	44%	Corn	12%
Shrimp	41%	Oats	9%
Milk	39%	Green beans	7%
Beef	31%	Tomato	7%
Pea	30%	Chocolate	5%
Chicken	27%	Strawberry	1%

Sampson HA "The role of food allergy and mediator release in atopic dermatitis" J All Clin Immunol 1988;81(4):635-645

Atopic Dermatitis: *Possible* Culprit Foods

+ DBPC FOOD CHALLENGES in 160 AD children

Egg	48%
Peanut	30%
Milk	14%
Fish	9%
Soy	6%
Wheat	5%
Chicken	2%
Potato	2%
Pork	1%
Beef	1%

Sampson HA "The role of food allergy and mediator release in atopic dermatitis" J All Clin Immunol 1988;81(4):635-645

ODDS & ENDS

Atopic Dermatitis: The Bleach Bath

PREMISES

- Staph Aureus more adherent to keratinocytes in AD
- Antimicrobial peptide expression decreased (β-defensins, cathelicidins)
- Rx: 1/8-1/4 cup bleach per FULL tub soak once daily

Brunk D "Simple Solutions Treat Tough Atopic Dermatitis" Fam Pract News 2003;Dec 1:34

Bleach Bath: 16 y.o. Severe Recalcitrant Atopic Dermatitis

"Despite the vigorous use of topical steroids and basic care, he flared every time his antibiotic discontinued. 'At this point, we introduced a daily bleach bath and it remarkably improved his control…"

Case example
Amy S Paller, MD Professor and Chair of Dermatology
Northwestern University Chicago

Brunk D "Simple Solutions Treat Tough Atopic Dermatitis"
Fam Pract News 2003;Dec 1:34

"A Trial of Oolong Tea in the Management of Recalcitrant Atopic Dermatitis"

- Premise: oral tea (green, oolong, black) suppresses type I and type IV a cutaneous allergic reactions (animal studies)
- Study: Patients with resistant AD (n=121)
  - Mild (20), moderate (74) severe (27)
- Inclusion: adults on standard therapy (steroids, antihistamines, environmental control) for at least 6 months

Uehara M, Sugiura H, Sakurai K Arch Dermatol 2001;137:42-43

"A Trial of Oolong Tea in the Management of Recalcitrant Atopic Dermatitis"

- Rx: 16 g dried oolong tea leaves (Suntory Ltd, Tokyo) in 1000 ml boiling water X 5 minutes, divided at 3 meals
- Metric: comparison photographs at 1 & 6 months
- Comment: "The beneficial effect was first noted after 1-2 weeks"

Uehara M, Sugiura H, Sakurai K Arch Dermatol 2001;137:42-43

Oolong Tea in Atopic Dermatitis: Outcomes

Degree of Improvement	1 month	6 months
Marked (>50%)	17%	8%
Moderate (25-50%)	46%	47%
Slight (<25%)	15%	24%
No Change	19%	18%
Worse	3%	3%

Uehara M, Sugiura H, Sakurai K Arch Dermatol 2001;137:42-43

SELF EVALUATION

Diagnosing and Treating Atopic Dermatitis

1. The diagnosis of atopic dermatitis is made

a. By biopsy of inflamed lesions
b. By serum IGE levels
c. By measurement of interleukin-4 levels
d. Clinically: the diagnosis relies upon typical clinical symptoms and signs

2. Damage to the skin of patients with atopic dermatitis is predominantly due to

a. Antigen-antibody deposits in the dermis
b. Complement-IgE deposits in the dermis
c. Vitamin D deficits
d. Repetitive scratching due to the pruritus of atopic dermatitis

3. The most common site of atopic dermatitis in infants is

a. The face
b. Popliteal fossae
c. Antecubital fossae
d. The diaper region

4. The most consistently identified genetic factor leading to atopic dermatitis is

a. Filaggrin loss-of-function genetic mutation
b. Familial toll-like receptor tolerance to Staph Aureus
c. Anti-transglutaminase antibody excess

5. Which moisturizer should always be co-administered with an occlusive agent such as petrolatum?

a. A humectant (e.g., alpha-hydroxy acids)
b. An emollient (e.g., linoleic acid)
c. An occlusive agent (e.g., mineral oil)
d. A calcineurin inhibitor (eg., pimecrolimus)

Answer Key: 1. D, 2. D, 3. A, 4. A, 5. A

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Financial Intelligence for the Healthcare Practice

Financial Intelligence

The understanding of finance and accounting principles in the business world

1. Ability to prevent/detect fraud
2. Ability to understand how you and your business fits into larger healthcare system
3. Ability to have the practice you desire

GAAP

Quality	Assumptions	Principles	Constraints
Relevance	Separate entity	Historical cost	Materiality
Reliability	Monetary unit	Revenue recognition	Cost/benefit
Comparability	Continuity	Matching	Conservatism
Consistency	Time period	Full disclosure	Industry peculiarities

GAAP

Quality	Assumptions	Principles	Constraints
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Comparability	Continuity	Matching	Conservatism
Consistency	Time period	Full disclosure	Industry peculiarities

Accrual vs Cash

Accrual

- Revenue and expenses are posted when they occur
- Allows for easier matching of revenue to expenses
- GAAP standard. Expensive to set up and use

Cash

- Cash is recorded when it is received or paid out
- Easy to set up and use
- Harder to match revenue with expenses

		Oct	Nov	Dec	Jan	Feb
Accrual	Revenue	$	$$	$$$	$	$
	Expenses	$	$$	$$$	$	$
Cash	Revenue					
	Expenses					

		Oct	Nov	Dec	Jan	Feb
Accrual	Revenue	$	$$	$$$	$	$
	Expenses	$	$$	$$$	$	$
Cash	Revenue	$	$	$$	$$$	$$
	Expenses	$	$$	$$$	$	$

The Financial Health

Must examine the financial reports

1. The income statement
2. The balance sheet
3. The cash flow statement

Three Questions

How much money came in?

Where did the money go?

How much money is left?

Answers to the Three Questions

How much money did we earn and spend?

Income statement

Where did the money really go?

Statement of cash flows

How much money is left?

Balance sheet

Income Statement

Covers a specific period of time

Revenue
- Cost of Goods Sold
= Gross Margin (Gross Profit)

Total of all costs used to create product or service that has been sold

In services, it's the labor, payroll taxes, and benefits of those who generate billable hours (those who do the work)

The amount you earn from the sale of your products and services

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Income Statement

Revenue
- Cost of Goods Sold
= Gross Margin (Gross Profit)
- Operating Expenses
= Operating Income (EBIT)

Any expense associated with the general, sales, and administrative functions of the business

Admin salaries, rent, utilities, office supplies, etc

Income earned from the core operations of the business, excluding financing and tax-related issues

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Income Statement

Revenue
- Cost of Goods Sold
= Gross Margin (Gross Profit)
- Operating Expenses
= Operating Income (EBIT)
+/-Other Income & Expenses
= Net Income

Income in excess of revenues over expenses

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Income Statement
December 31, 2014

Gross Charges:		
Professional Service Charges		1,139,223
Orthopedic Charges		9,101
Injection Charges		101,941
Immunization Charges		147,206
Procedure Charges		115,860
Laboratory Charges		728,329
Radiology Charges		122,113
Hospital Charges		84,383
Nursing Home Charges		20,061
Miscellanous Charges		3,375
	Gross Charges Total:	**2,471,593**
Contractual Adjustments:		**-1,121,820**
	Net Medical Charges:	**1,349,773**
Capitation Revenue		121,245
Other Operating Income		65,262
Adj to Cash Collections		259,478
	Total Net Revenue:	**1,795,757**

Expenses			
Total Professional Exp	189,703	Legal Fees	2,333
		Accounting Fees	2,195
Total EE Exp	398,454	Collection Svcs	0
		Other Purchased Svcs	25,267
Drugs & Meds	86,116	Transcription Svcs	0
Medical Supp	15,030	Storage Exp	50
Office Supplies	6,751	Total Purchased Svcs	29,846
Laundry & Linen	4,485		
Janitorial Supp	2,506	Recruitment	231
Total Supplies Expense	114,887	Employee Relations	533
		Prof Liability Insurance	21,252
Total Computer Expense	21,928	Total EE Related Svcs	22,016
Total Radiology Expense	28,984	Telephone Exp	10,933
		Prof Listings / Promo	12,095
Total Laboratory Exp	89,069	Postage & Freight	8,095
		Bank Fees	9,241
Lab Supplies	49,250	Books, Subscrip, Etc.	890
Outside Lab Fees	21,051	Other G&A Exp	18
Lab Equip Lease / Rent	9,812	Total Gen & Adm Exp	41,272
Lab Equip Maint	2,438		
Other Lab Exp	6,517	Total Operating Exp	1,176,718
Bio-Hazard Waste	3,930	Total Non-Op Rev/Exp	71,493
Building Lease	220,391		
Janitorial Services	8,554	Total Physician Sal/Ben	11,339
Total Building Exp	232,875		
		Total Expenses	1,259,551
Total Furn / Equip Exp	7,685		
		Net Profit	536,206

Balance Sheet

A snapshot in time

Assets = Liabilities + Owners Equity

Assets

What a business owns or is owed

- Real property
- Equipment
- Cash
- Inventory
- Accounts Receivable
- Patents & copyrights

Liabilities

What a business owes

- Debt
- Taxes
- Accounts payable

Equity

Stockholders equity: Amount of financing (cash) provided by owners (shareholders) + retained earnings

Paid-in capital: total amount of cash and other assets paid into the firm by stockholders in exchange for capital stock

Retained earnings: all the money a firm has earned since start-up minus dividends

The money the firm has put back into the business

Timing Matters

Current Assets/Liabilities -operating cycle or one year which ever is longer to convert or conserve cash. Or, the debt is due in less than one year.

Long-Term (non-current) Assets/Liabilities – take longer than one year or operating cycle to convert or conserve cash. Or, the debt is due in more than one year.

Balance Sheet
December 31, 2014

Current Assets		***Current Liabilities***	
Cash in Bank	23,139	Loans Payable—Line Of Credit	$ 44,274
Savings Acct	59,725	Loans Payable—Malpractice	
Patients Receivable	251,944	Loans Payable—Furniture, Furnishings, and Equipment	$ 31,341
Accounts Receivable-Bldg	95,065	FUTA Tax Payable	$ 31
Receipts not Posted	(164)	SUTA Tax Payable	$ 40
Pre-Paid Insurance		**Total Current Liabilities**	**$ 75,686**
Investment Receivables	2,600		
Total Current Assets	**432,309**	***Deferred Revenue***	
		Deferred Accounts Receivable	$ 254,883
Fixed Assets			
Furniture & Fixtures	219,624	**Total Liabilities**	**$ 330,569**
Software	64,093		
Accumulated Depreciation	(266,147)	***Members' Capital***	
Total Property & Equipment	**17,570**	Retained Earnings	$ 53,700
		Members' Capital Accounts	$ 25,470
Other Assets		Members' Curr Yr Capital Contrib.	$ 1,500
Organizational Costs	3,406	General Draws	$ (430,445)
Accumulated Amortization	(3,406)	Draws—Health, Dental	$ (14,574)
Utility Deposit	3,215	Draws—Life & Disability Ins.	$ (6,128)
Inv-TI	5,111	Draws—401(K) Deferral	$ (38,093)
Total Other Assets	**8,326**	Current Yr Net Income	$ 536,206
		Total Members' Capital	**$ 127,636**
Total Assets	**458,205**		
		Total Liabilities & Capital	**$ 458,205**

Statement of Cash Flows

You can go broke making a profit

Cash is the life blood of any business

Cash flow statement can show where cash comes from and where it goes to

30 Days to Get Your Money

	Jan	Feb	Mar	Apr	May	Jun	Jul
Charges	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000
COS	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000
Gross Profit	$ 10,000	$ 10,000	$ 10,000	$ 10,000	$ 10,000	$ 10,000	$ 10,000
Expenses	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500
Net Profit	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500
Cash Flow							
Beginning Cash	$ 10,000	$ (12,500)	$ (10,000)	$ (7,500)	$ (5,000)	$ (2,500)	$ -
Operations							
Cash from Charges	$ -	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000
Cash to Employees	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000
Cash to Expenses	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500
Net Cash Flow	$ (12,500)	$ (10,000)	$ (7,500)	$ (5,000)	$ (2,500)	$ -	$ 2,500

90 Days to Get Your Money

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan
Charges	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000
COS	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000
Gross Profit	$ 10,000	$ 10,000	$ 10,000	$ 10,000	$ 10,000	$ 10,000	$ 10,000	$ 10,000	$ 10,000	$ 10,000	$ 10,000	$ 10,000	$ 10,000
Expenses	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500
Net Profit	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500	$ 2,500
Cash Flow													
Beginning Cash	$ 10,000	$ (12,500)	$ (35,000)	$ (32,500)	$ (30,000)	$ (27,500)	$ (25,000)	$ (22,500)	$ (20,000)	$ (17,500)	$ (15,000)	$ (12,500)	$ 10,000
Operations													
Cash from Charges	$ -	$ -	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000	$ 25,000
Cash to Employees	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000	$ 15,000
Cash to Expenses	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500	$ 7,500
Net Cash Flow	$ (12,500)	$ (35,000)	$ (32,500)	$ (30,000)	$ (27,500)	$ (25,000)	$ (22,500)	$ (20,000)	$ (17,500)	$ (15,000)	$ (12,500)	$ (10,000)	$ 12,500

Statement of Cash Flows

Covers the same period as the income statement

Three sections

- Cash flows from operating activities
  - Cash to/from your core business
- Cash flows from investing activities
  - Cash to/from your investing
- Cash flows from financing activities
  - Cash to/from borrowing and equity

Cash Flow Statement
For year ending Dec 31, 2015

Operating Activiites	
Net Profit	$ 538,455
Change in A/R	$ (32,216)
Net Cash from Operations	$ 506,238
Investing Activities	
Investment Receivables	$ 1,400
Net Cash from Investing	$ 1,400
Financing Activities	
Net Borrowing	$ 69,428
Repayment of Loans	$ (16,627)
Distributions	$ (89,441)
Paid-In Capital	$ 32,190
Draws—Insurance	$ 8,259
Draws—401k	$ 18,801
Med Malpractice Loan	$ (16,122)
Net Cash from Financing	$ 6,488
Change in Cash	$ 1,055
Beginning Cash	$ 82,864
Ending Cash Balance	$ 83,919

Financial Statements	Business Activities
Income statement	Operating activities
Revenues	
Expenses	
Statement of cash flows	
Operating activities	Operating activities
Investing activities	Investing activities
Financing activities	Financing activities
Balance sheet	
Current assets	Operating activities
Long-term assets	Investing activities
Current liabilities	Operating activities
Long-term liabilities	Financing activities
Equity	Financing activities

How Healthy is Your Practice?

Trends in healthcare

- BP
- Blood sugar
- HgB A1C
- PT/INR
- Ankle:brachial Ratio

Financial Analysis

Liquidity ratios

Activity, efficiency or utilization ratios

Profitability ratios

Financial strength or solvency ratios

Vertical and horizontal analysis

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Liquidity

The ability to meet current obligations with cash and other assets that can quickly be converted to cash

More cash, more liquid; less cash, less liquid

Working Capital

Formula: Current Assets - Current Liabilities

Measures: rough indicator of a firm's ability to pay it's bills on time

Interpretation: larger positives indicate a greater "cushion; smaller positives or negatives indicate greater risk

$$\$408,786 - \$75,686 = \$333,100$$

Current Ratio

Formula: Current Assets ÷ Current Liabilities

Measures: indicator of a firm's ability to pay it's bills on time

Interpretation: Target is around 2:1. Higher ratio indicates poor asset management. Lower ratio indicates risk: potential cash flow problems.

$$\frac{\$408,786}{\$75,686} = 5.4$$

Cash Flows to Current Liabilities

Formula: Cash Flows from Operations ÷ Current Liabilities

Measures: ability to pay off debts with operating cash

Interpretation: Target greater than 1.

$$\frac{295,801}{75,686} = 3.91$$

Days in Accounts Receivable

Formula: 365 days ÷ A/R Turnover Ratio

Measures: the length of time it takes to convert a credit account to cash

Interpretation: lower (faster) is better – indicates ability to convert receivables to cash

$$\frac{365 \text{ days}}{5.4} = 68.1 \text{ days}$$

Days in Accounts Payable

Formula: 365 days ÷ A/P Turnover Ratio

Measures: the length of time it takes to pay off a credit account

Interpretation: Should be around 30 days?

$$\frac{365 \text{ days}}{3.4} = 107 \text{ days}$$

Return on Assets

Formula: Net Income ÷ Total Assets

Measures: how successful the firm is

Interpretation: varies. Higher is better. Expressed as a percentage.

$$\frac{1,349,773}{434,682} = 3.1$$

Return on Equity

Formula: Net Income ÷ Total Stockholder's Equity

Measures: how successful the firm is

Interpretation: varies. Higher is better. Expressed as a percentage.

$$\frac{1,349,733}{104,113} = 13.0$$

EBITDA

Formula: Net Income + Interest Expense + Income Taxes + Depreciation + Amortization

Measures: Earnings Before Interest, Taxes, Depreciation & Amortization. A common variant of the profit metric, adds back expenses that some view as uncontrollable in the short-run

Interpretation: Varies. Higher is better.

Total Debt to Total Equity

Formula: Total Liabilities ÷ Stockholder's Equity

Measures: the balance between the two sources of capital – creditors and owners

Interpretation: Higher is riskier.

$$\frac{330,569}{104,113} = 3.2$$

Total Debt to Total Assets

Formula: Total Debt ÷ Total Assets

Measures: the proportion of total assets funded by debt.

Interpretation: Higher is riskier.

$$\frac{330,569}{434,682} = 0.8$$

Payor Mix Analysis

Payer	# Visits	% visits
Other Contractual	686	6.5%
Aetna	203	1.9%
BC/BS	1,801	16.9%
Cigna	81	0.8%
Coventry	1,303	12.3%
Medicare	3,420	32.1%
PHS	766	7.2%
PPK	1,027	9.7%
United	877	8.2%
WPPA	92	0.9%
Non-contractual	382	3.6%

Horizontal & Vertical Analysis

Vertical analysis

- compares line items with a subsection of the report

Horizontal analysis

- compares periods of time

Income Statement Vertical Analysis

for years ending

	12/31/14		12/31/15	
Gross Charges:				
Professional Service Charges	$ 1,139,223	46.09%	$ 1,275,745	48.69%
Orthopedic Charges	$ 9,101	0.37%	$ 8,143	0.31%
Injection Charges	$ 101,941	4.12%	$ 105,328	4.02%
Immunization Charges	$ 147,206	5.96%	$ 104,298	3.98%
Procedure Charges	$ 115,860	4.69%	$ 115,725	4.42%
Laboratory Charges	$ 728,329	29.47%	$ 711,383	27.15%
Radiology Charges	$ 122,113	4.94%	$ 125,539	4.79%
Hospital Charges	$ 84,383	3.41%	$ 124,821	4.76%
Nursing Home Charges	$ 20,061	0.81%	$ 46,825	1.79%
Miscellaneous Charges	$ 3,375	0.14%	$ 2,364	0.09%
Gross Charges Total:	**$ 2,471,593**	100.00%	$ 2,620,171	100.00%
Contractual Adjustments:				
Other Contractual Adjustments	$ (65,177)	5.81%	$ (60,735)	5.69%
Aetna Adjustments	$ (19,267)	1.72%	$ (27,489)	2.58%
BC/BS Adjustments	$ (171,064)	15.25%	$ (159,398)	14.94%
Cigna Adjustments	$ (7,651)	0.68%	$ (6,323)	0.59%
Coventry Adjustments	$ (123,789)	11.03%	$ (120,066)	11.25%
Medicare Adjustments	$ (324,835)	28.96%	$ (350,185)	32.83%
PHS Adjustments	$ (72,798)	6.49%	$ (68,449)	6.42%
PPK Adjustments	$ (97,514)	8.69%	$ (52,775)	4.95%
United Adjustments	$ (83,310)	7.43%	$ (93,140)	8.73%
WPPA Adjustments	$ (8,749)	0.78%	$ (12,683)	1.19%
Non-contractual Adjustments	$ (36,277)	3.23%	$ (17,071)	1.60%

Income Statement Horizontal Analysis

for years ending

	12/31/14	12/31/15	
Gross Charges:			
Professional Service Charges	$ 1,139,223	$ 1,275,745	11.98%
Orthopedic Charges	$ 9,101	$ 8,143	-10.52%
Injection Charges	$ 101,941	$ 105,328	3.32%
Immunization Charges	$ 147,206	$ 104,298	-29.15%
Procedure Charges	$ 115,860	$ 115,725	-0.12%
Laboratory Charges	$ 728,329	$ 711,383	-2.33%
Radiology Charges	$ 122,113	$ 125,539	2.81%
Hospital Charges	$ 84,383	$ 124,821	47.92%
Nursing Home Charges	$ 20,061	$ 46,825	133.42%
Miscellaneous Charges	$ 3,375	$ 2,364	-29.97%
Gross Charges Total:	**$ 2,471,593**	$ 2,620,171	6.01%
Contractual Adjustments:			
Other Contractual Adjustments	$ (65,177)	$ (60,735)	-6.82%
Aetna Adjustments	$ (19,267)	$ (27,489)	42.67%
BC/BS Adjustments	$ (171,064)	$ (159,398)	-6.82%
Cigna Adjustments	$ (7,651)	$ (6,323)	-17.36%
Coventry Adjustments	$ (123,789)	$ (120,066)	-3.01%

Vertical Analysis - Balance Sheet

Balance Sheet Vertical Analysis

	Dec 31, 2014		Dec 31, 2015	
Current Assets				
Cash in Bank	$ 23,139	5.05%	$ 28,602	5.95%
Savings Acct	$ 59,725	13.03%	$ 61,792	12.85%
Patients Receivable	$ 251,944	54.98%	$ 284,160	59.10%
Accounts Receivable-Bldg	$ 95,065	20.75%	$ 95,065	19.77%
Receipts Not Posted	$ (164)	-0.04%	$ (164)	-0.03%
Pre-paid Insurance				
Investment Receivables	$ 2,600	0.57%	$ 1,200	0.25%
Total Current Assets	**$ 432,309**	94.35%	**$ 470,655**	97.89%
Fixed Assets				
Furniture & Fixtures	$ 219,624	47.93%	$ 219,624	45.68%
Software	$ 64,093	13.99%	$ 64,093	13.33%
Accumulated Depreciation	$ (266,147)	-58.08%	$ (280,246)	-58.29%
Total Property & Equipment	**$ 17,570**	3.83%	**$ 3,471**	0.72%
Other Assets				
Organizational Costs	$ 3,406	0.74%	$ 3,406	0.71%
Accumulated Amortization	$ (3,406)	-0.74%	$ (3,406)	-0.71%
Utility Deposit	$ 3,215	0.70%	$ 3,215	0.67%
Inv-TI	$ 5,111	1.12%	$ 3,444	0.72%
Total Other Assets	**$ 8,326**	1.82%	**$ 6,659**	1.39%
Total Assets	**$ 458,205**	100.00%	**$ 480,786**	100.00%

Vertical Analysis - Balance Sheet

Current Liabilities				
Loans Payable—Line Of Credit	$ 44,274	13.39%	$ 113,702	29.76%
Loans Payable—Malpractice		0.00%		0.00%
Loans Payable—Furniture, Furnishings, and Equipmer	$ 31,341	9.48%	$ 14,714	3.85%
FUTA Tax Payable	$ 31	0.01%	$ 32	0.01%
SUTA Tax Payable	$ 40	0.01%	$ 39	0.01%
Total Current Liabilities	**$ 75,686**	22.90%	**$ 128,487**	33.62%
Deferred Revenue				
Deferred Accounts Receivable	$ 254,883	77.10%	$ 253,635	66.38%
Total Liabilities	**$ 330,569**	100.00%	**$ 382,122**	100.00%
Members' Capital				
Retained Earnings	$ 53,700	11.72%	$ 50,557	10.52%
Members' Capital Accounts	$ 25,470	5.56%	$ 57,660	11.99%
Members' Curr Yr Capital Contrib.	$ 1,500	0.33%	$ 3,613	0.75%
General Draws	$ (430,445)	-93.94%	$ (519,886)	-108.13%
Draws—Health, Dental	$ (14,574)	-3.18%	$ (9,340)	-1.94%
Draws—Life & Disability Ins.	$ (6,128)	-1.34%	$ (3,103)	-0.65%
Draws—401(K) Deferral	$ (38,093)	-8.31%	$ (19,292)	-4.01%
Current Yr Net Income	$ 536,206	117.02%	$ 538,455	111.99%
Total Members' Capital	**$ 127,636**	27.86%	**$ 98,664**	20.52%
Total Liabilities & Capital	**$ 458,205**		**$ 480,786**	

Balance Sheet Horiztonal Analysis

	Dec 31, 2014	Dec 31, 2015	
Current Assets			
Cash in Bank	$ 23,139	$ 28,602	23.61%
Savings Acct	$ 59,725	$ 61,792	3.46%
Patients Receivable	$ 251,944	$ 284,160	12.79%
Accounts Receivable-Bldg	$ 95,065	$ 95,065	0.00%
Receipts Not Posted	$ (164)	$ (164)	-0.19%
Pre-aid Insurance			
Investment Receivables	$ 2,600	$ 1,200	-53.85%
Total Current Assets	**$ 432,309**	**$ 470,655**	8.87%
Fixed Assets			
Furniture & Fixtures	$ 219,624	$ 219,624	0.00%
Software	$ 64,093	$ 64,093	0.00%
Accumulated Depreciation	$ (266,147)	$ (280,246)	5.30%
Total Property & Equipment	**$ 17,570**	**$ 3,471**	-80.24%
Other Assets			
Organizational Costs	$ 3,406	$ 3,406	-0.01%
Accumulated Amortization	$ (3,406)	$ (3,406)	-0.01%
Utility Deposit	$ 3,215	$ 3,215	0.01%
Inv-TI	$ 5,111	$ 3,444	-32.62%
Total Other Assets	**$ 8,326**	**$ 6,659**	-20.02%
Total Assets	**$ 458,205**	**$ 480,786**	4.93%

Balance Sheet Horiztonal Analysis

Current Liabilities			
Loans Payable—Line Of Credit	$ 44,274	$ 113,702	156.81%
Loans Payable—Malpractice			
Loans Payable—Furniture, Furnishings, and Equipmer	$ 31,341	$ 14,714	-53.05%
FUTA Tax Payable	$ 31	$ 32	3.23%
SUTA Tax Payable	$ 40	$ 39	-3.31%
Total Current Liabilities	**$ 75,686**	**$ 128,487**	69.76%
Deferred Revenue			
Deferred Accounts Receivable	$ 254,883	$ 253,635	-0.49%
Total Liabilities	**$ 330,569**	**$ 382,122**	15.60%
Members' Capital			
Retained Earnings	$ 53,700	$ 50,557	-5.85%
Members' Capital Accounts	$ 25,470	$ 57,660	126.38%
Members' Curr Yr Capital Contrib.	$ 1,500	$ 3,613	140.87%
General Draws	$ (430,445)	$ (519,886)	20.78%
Draws—Health, Dental	$ (14,574)	$ (9,340)	-35.91%
Draws—Life & Disability Ins.	$ (6,128)	$ (3,103)	-49.37%
Draws—401(K) Deferral	$ (38,093)	$ (19,292)	-49.36%
Current Yr Net Income	$ 536,206	$ 538,455	0.42%
Total Members' Capital	**$ 127,636**	**$ 98,664**	-22.70%
Total Liabilities & Capital	**$ 458,205**	**$ 480,786**	4.93%

Create a Dashboard

Pick the metrics that support your mission and purpose

Use them on a regular basis

Graph the trends

Know Your Costs

Fixed costs

Don't change from period to period

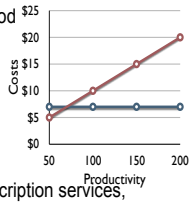
Don't change with activity

Rent, insurance, etc

Variable costs

Change with activity

Hourly labor costs, utilities, transcription services, etc



Determining Your Costs

Accounting Method

You set up the accounting system properly to classify each cost

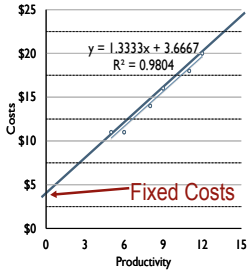
Can be elaborate and expensive

Determining Your Costs

Visual Fit

Plot costs as a function of productivity

Y-intercept is your fixed expenses

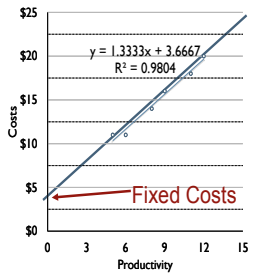


Determining Your Costs

Regression Method

Plot costs as a function of productivity

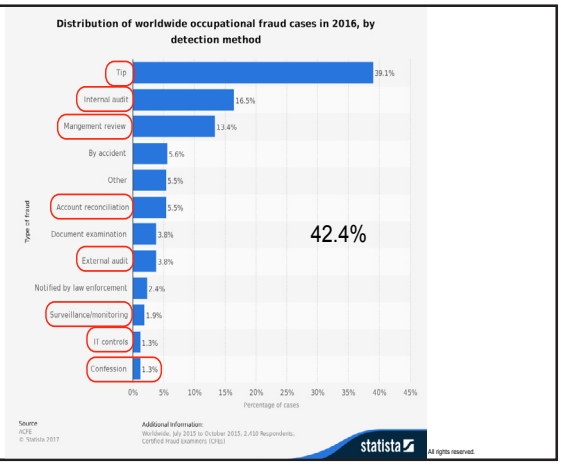
y=mx+b



Fraud

Internal business fraud losses average ~6% of revenue of all US business revenue

Biggest opportunity is small business back office with one or two employees



Preventing Fraud

Cross-training - Rotate jobs so employees are familiar with other aspects of the office - no silos

Mandatory vacation - especially for those who employees who are involved in the cash-conversion cycle

Preventing Fraud

No rubber stamps - Best way is to have owner/officer sign checks

Allows you to verify the amounts, payees, reasons

Consistent, accurate financial reports

This is a MUST! Set the expectation and hold them to it. "I don't have those numbers." might mean "I'm still figuring out a way to hide the money."

Preventing Fraud

Consider **regular** independent **reviews** & **audits**

Create a budget

Not just projecting into the future

Helpful tool for detecting fraud

Refer to the budget each period

Variances are to be expected - must be explained!

Preventing Fraud

Know your line items

Hiring process

Do full, complete background checks (Criminal & financial)

Establish ethical standards - have the frank discussion

Summary

The financial reports tell you

How healthy your practice is

If what you're doing is working

Can help prevent theft

Summary

Do the following:

Examine your reports monthly

Know what each line item represents

Ask questions when you don't understand

Get help

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SELF EVALUATION

Financial Intelligence for the Healthcare Practice

1. Important liquidity ratios you should trend are all of the following EXCEPT:

a. Working Capital
b. Current ratio
c. Return on assets

2. Methods to help detect and prevent fraud include all of the following EXCEPT:

a. Periodic internal and external audits
b. Cross training personnel so that no single individual is knowledgeable for a single portion of the revenue cycle
c. Examining, understanding, and using the financial reports on a regular basis
d. Hiring your sister's cousin without a background check

3. T/F - Cash based accounting systems are preferred because they are easier to understand and show you how much cash you have on hand.

4. Which of the following GAAP standards assumes that the business is separate from its owners or other businesses. Revenue and expense should be kept separate from personal expenses?

a. Going Concern
b. Historical Cost
c. Matching
d. Separate Entity

5. T/F - The accounting formula is ASSETS - LIABILITIES = EQUITY

6. T/F - Current assets or liabilities are all the assets or liabilities that are currently appear on the balance sheet.

7. The type of costs that vary with productivity (i.e. goes up when you're busy and down when you slow) is:

a. Fixed
b. Variable
c. Total

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

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Contraceptive Methods: Efficacy and Mechanisms of Action

Outline

- Definitions
- Key facts about contraception / family planning
- Benefits of family planning and contraception
- Contraceptive methods
- Comparing effectiveness of family planning methods
- Contraceptive use by method

1

What is Contraception?

- The deliberate use of artificial methods to prevent pregnancy as a consequence of sexual intercourse.

2

Definitions

What is contraception?

Contraception is the intentional prevention of pregnancy by artificial or natural means.

What is family planning?

Family planning allows individuals and couples to anticipate and attain their desired number of children and the spacing and timing of their births. It is achieved through use of contraceptive methods and the treatment of involuntary infertility.

What is an unmet need for family planning?

An unmet need for family planning is the number of women that want to stop or delay childbearing but are not using any method of contraception to prevent pregnancy, including also pregnant women whose pregnancies were unwanted or mistimed at the time of conception, and postpartum amenorrhoeic women who are not using family planning and whose last birth was unwanted or mistimed.

3

Training Resource Package for Family Planning – Benefits of Family Planning.
United Nations, Department of Economic and Social Affairs, Population Division. Contraceptive Use by Method 2019: Data Booklet (ST/ESA/SER.A/435). United Nations; 2019.

Key facts about contraception / family planning

Among the 1.9 billion Women of Reproductive Age group (15-49 years) worldwide in 2019, 1.1 billion have a need for family planning; of these, 842 million are using contraceptive methods, and 270 million have an unmet need for contraception.

The proportion of the need for family planning satisfied by modern methods, Sustainable Development Goals (SDG) indicator 3.7.1, was 75.7% globally in 2019, yet less than half of the need for family planning was met in Middle and Western Africa.

Use of contraception prevents pregnancy-related health risks for women, especially for adolescent girls.

Only one contraceptive method, condoms, can prevent both a pregnancy and the transmission of sexually transmitted infections, including HIV.

Use of contraception advances the human right of people to determine the number and spacing of their children.

Contraception offers a range of potential non-health benefits that encompass expanded education opportunities and empowerment for women, and sustainable population growth and economic development for countries.

WHO. Family planning/contraception methods. World Health Organization; 2020.

4

Increased risk of having problems during pregnancy and delivery

Some women have an increased risk of having problems during pregnancy and delivery. They are women who:

- Are under the age of 18, or over age 35
- Become pregnant less than 2 years after a previous live birth
- Become pregnant less than six months post-abortion or post-miscarriage
- Have too many children (high parity)
- Have certain existing health problems
- Do not have access to skilled health care

Problems are more likely in those with multiple risk factors.

5

Training Resource Package for Family Planning – Benefits of Family Planning.

Legal issues

- Legal Age of consent to sexual activity is 16yrs old, regardless of sexual orientation.
- However, contraception can be provided to someone under 16 if a clinician thinks this is in the best interests of that person.
- Anyone attending a sexual health clinic has a right to confidentiality, including those under 16.

6

Benefits of family planning and contraception

- Prevents maternal morbidity and mortality
- Reduces unsafe abortion from unintended pregnancies
- Reduces newborn and infant mortality
- Helps to prevent HIV/AIDS
- Empowers people and enhances education
- Reduces adolescent pregnancies
- Contributes to Economic Growth
- Secures the well-being and autonomy of women

WHO. Contraception: Evidence brief. World Health Organization; 2019.

7

Contraceptive methods

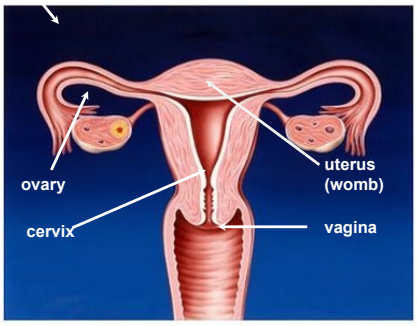
There are different types of contraception. They can be short acting or long acting, reversible or permanent.

The different methods of contraception have varying rates of effectiveness depending on correct usage. (See next few slides)

Health care providers play an important role in helping people find and use a method that is both effective and acceptable.

8

Female Reproductive Organs



Contraceptive methods

Hormonal	Emergency contraception (EC) or postcoital contraception
❑ Progestogen-only contraceptives 1. Progestogen-only pills (POPs) 2. Progestogen-only injectable contraceptives (POIs) 3. Progestogen-only implants 4. Progesterone-Releasing Vaginal Ring ❑ Combined hormonal contraceptives 1. Combined oral contraceptives (COCs) 2. Combined contraceptive patch 3. Combined contraceptive vaginal ring (CVR) 4. Combined injectable contraceptives (CICs)	1. Copper-bearing IUDs (Cu-IUD) for EC 2. Emergency contraceptive pills (ECPs)
	Intrauterine devices (IUDs) 1. Copper-bearing IUDs (Cu-IUD) 2. Levonorgestrel-releasing IUDs (LNG-IUD)
	Permanent methods 1. Female sterilization (tubal ligation) 2. Male sterilization (vasectomy)
	Barrier methods 1. Male and female condoms 2. Other barrier methods
	Spermicides
	Fertility awareness methods 1. Standard Days Method (SDM) 2. Others
	Lactational amenorrhea method

WHO. Contraception. World Health Organization, 2021.

10

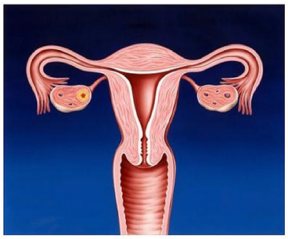
Methods; Hormonal

- Implant
- Patch
- Combined Pill
- Progesterone only pill
- Vaginal Ring
- Injection
- IUS

11

How Hormonal methods work;

- Prevent Ovulation
- Thins uterus lining
- Thickens Mucus around Cervix



100% ?

- Hormonal contraceptive, highly effective
  - Over 99% effective
- Can be affected by;
  - Some medications (Enzyme inducing drugs)
  - St John's wort
  - Vomiting /Diarrhea
  - Not taking it!!

13

Mechanisms of action and effectiveness of contraceptive methods - *1*

Method	How it works	Effectiveness: pregnancies per 100 women per year with consistent and correct use	Effectiveness: pregnancies per 100 women per year as commonly used
Combined oral contraceptives (COCs) or "the pill"	Prevents the release of eggs from the ovaries (ovulation)	0.3	7
Progestogen-only pills (POPs) or "the mini pill"	Thickens cervical mucus to block sperm and egg from meeting and prevents ovulation	0.3	7
Implants	Thickens cervical mucus to blocks sperm and egg from meeting and prevents ovulation	0.1	0.1
Progestogen only injectables	Thickens cervical mucus to block sperm and egg from meeting and prevents ovulation	0.2	4
Monthly injectables or combined injectable contraceptives (CIC)	Prevents the release of eggs from the ovaries (ovulation)	0.05	3
Combined contraceptive patch and combined contraceptive vaginal ring (CVR)	Prevents the release of eggs from the ovaries (ovulation)	0.3 (for patch) 0.3 (for vaginal ring)	7 (for patch) 7 (for contraceptive vaginal ring)
Intrauterine device (IUD): copper containing	Copper component damages sperm and prevents it from meeting the egg	0.6	0.8
Intrauterine device (IUD) levonorgestrel	Thickens cervical mucus to block sperm and egg from meeting	0.5	0.7
Male condoms	Forms a barrier to prevent sperm and egg from meeting	2	13
Female condoms	Forms a barrier to prevent sperm and egg from meeting	5	21

WHO. Family planning/contraception methods. World Health Organization; 2020.

14

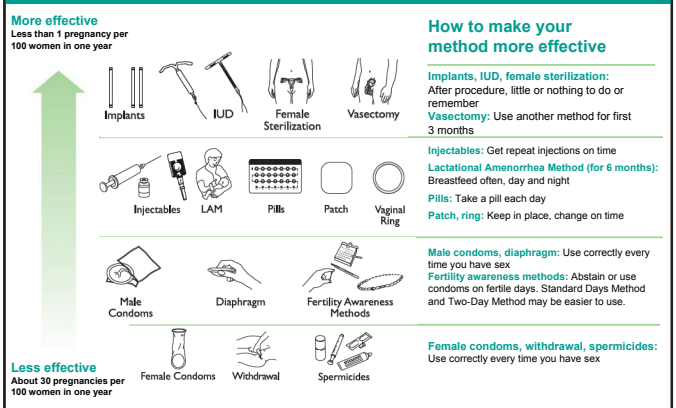
Mechanisms of action and effectiveness of contraceptive methods - *2*

Method	How it works	Effectiveness: pregnancies per 100 women per year with consistent and correct use	Effectiveness: pregnancies per 100 women per year as commonly used
Male sterilization (Vasectomy)	Keeps sperm out of ejaculated semen	0.1	0.15
Female sterilization (tubal ligation)	Eggs are blocked from meeting sperm	0.5	0.5
Lactational amenorrhea method (LAM)	Prevents the release of eggs from the ovaries (ovulation)	0.9 (in six months)	2 (in six months)
Standard Days Method or SDM	Prevents pregnancy by avoiding unprotected vaginal sex during most fertile days.	5	12
Basal Body Temperature (BBT) Method	Prevents pregnancy by avoiding unprotected vaginal sex during fertile days	Reliable effectiveness rates are not available	
TwoDay Method	Prevents pregnancy by avoiding unprotected vaginal sex during most fertile days,	4	14
Sympto-thermal Method	Prevents pregnancy by avoiding unprotected vaginal sex during most fertile	<1	2
Emergency contraception pills (ulipristal acetate 30 mg or levonorgestrel 1.5 mg)	Prevents or delays the release of eggs from the ovaries. Pills taken to prevent pregnancy up to 5 days after unprotected sex	< 1 for ulipristal acetate ECPs 1 for progestin-only ECPs 2 for combined estrogen and progestin ECPs	
Calendar method or rhythm method	The couple prevents pregnancy by avoiding unprotected vaginal sex during the 1st and last estimated fertile days, by abstaining or using a condom.	Reliable effectiveness rates are not available	15
Withdrawal (coitus interruptus)	Tries to keep sperm out of the woman's body, preventing fertilization	4	20

WHO. Family planning/contraception methods. World Health Organization; 2020.

15

Comparing Effectiveness of Family Planning Methods



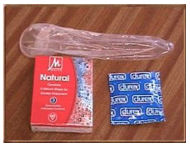
Family Planning: A Global Handbook for Providers (3rd Edition, 2018)

16

Methods; Barrier

- Cap / Diaphragm
- Femidom
- Condom
- Works by;
  - Preventing sperm getting to the egg.





17

Barrier Methods

- Less effective than hormonal contraceptive methods.
  - Condoms (98%)
  - Femidoms(95%)
  - Cap / Diaphragm (92-96%)

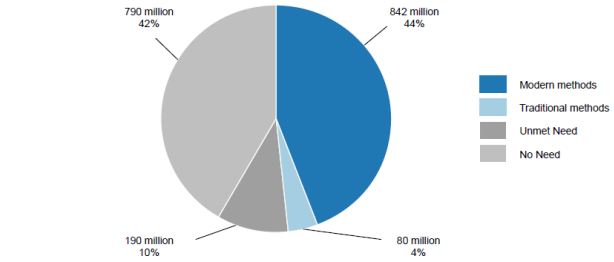
18

Double Dutch!

- Using a combination of methods, ie one barrier and one hormonal method, such as condoms and implant give the best possible protection against unintended pregnancy and STDs

Contraceptive use by method

Estimated numbers of women of reproductive age (15-49 years) using modern and traditional contraceptive methods, having an unmet need for family planning and no need for family planning, worldwide, 2019



Data source: *Estimates and Projections of Family Planning Indicators 2019.*

Contraceptive Use by Method 2019: Data Booklet (ST/ESA/SER.A/435). United Nations; 2019.

20

Most Effective Contraception Methods:

Progesterone IUD
NexplanonImplant

21

Progesterone IUD

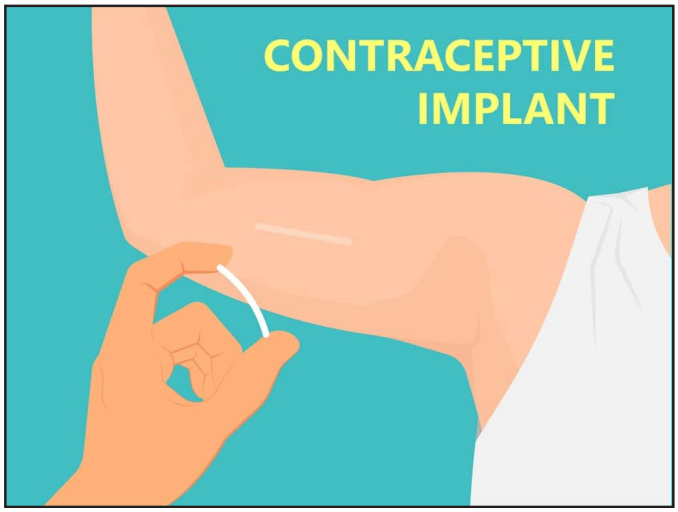
Mirena
Kyleena
Liletta
Skyla

22

Progesterone Implant

Nexplanon

23



SELF EVALUATION

Contraceptive Methods: Efficacy and Mechanisms of Action

True/False

1.___ The contraception with the lowest failure rate aside from abstinence is the Mirena IUD.

2.___ Sperm can survive for a maximum of 3 days inside the female reproductive tract.

3.___ An IUD can only be inserted in females over the age of 18.

4.___ The mechanism of action of the progesterone IUD is to thicken mucus in the cervix to stop sperm from reaching or fertilizing an egg. It also thins the lining of the uterus and partially suppresses ovulation.

5.___ Only one method of contraception can prevent both pregnancy and sexually transmitted infections, the condom.

6.___ The legal age to consent to sex is age 18.

7.___ Taking St. John's Wort can interfere with the mechanism of action of the birth control pill and make it less effective.

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

Dr. Gerald Levine, MD, CCFP

Dr. Gerald Levine, MD, CCFP (Canadian College of Family Physicians), of Barrie, Ontario, graduated from the University of Toronto Medical School and the University of Toronto Family Medicine School. He was a family practitioner for over 30 years and since 2006 has focused on stress management, burnout prevention and mindfulness facilitation offering training to physicians, dentists, and their staffs as well as for dental and medical associations throughout Canada including the Simcoe Muskoka District Health Unit, the General Practitioner Psychotherapy Association of Canada, the Canadian Mental Health Association York Region and many others. Dr. Levine has also authored an e-book, *52 Mindful Weeks, Cultivating Awareness and Resilience* available on his website, www.ManageStress.ca.

You may contact Dr. Levine with you questions or comments at geraldlevine@rogers.com, or by phone at 705-721-3130.

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Employing Mindfulness to Reduce Stress and Avoid Burnout

Learning Objectives :

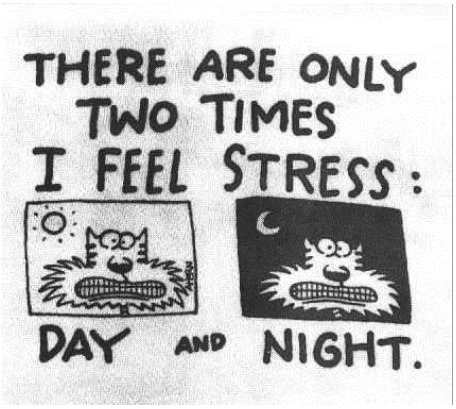
Understand current stress research

Identify and assess stress and burnout symptoms

Apply mindfulness concepts and skills to manage stress and burnout

THINGS TO REMEMBER

Awareness, Acceptance
Breath, Body
Curiosity, Compassion
70 %
5 %



Definition of Stress

- Mind and body reaction to an actual or PERCEIVED threat
- -designed for short-term physical survival, not joy nor calm problem-solving
- -chronic stress state from constant threats to actual or emotional safety
- -emotional safety threatened by discrepancy between conditioned expectations and lived reality

Topics:

Stress physiology/research
Managing Stress
Professional Burnout:Problems
Professional Burnout:Solutions
Self Awareness
Self Care
Mindfulness
Mindful Self Compassion

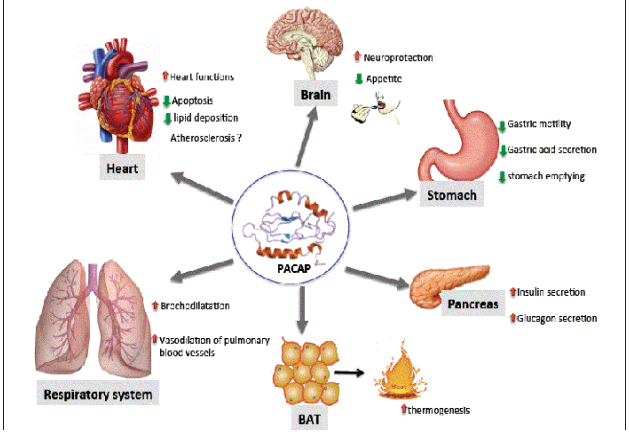
Stress physiology/research

- PACAP
- Neurotransmitter role in stress tolerance
- Telomeres and resilience/aging
- Immune system: cancer, infections: Covid, URTI (N of 1)
- Inflammatory markers (interleukins, CRP)
- Memory and stress
- Neuroplasticity-fMRI studies

PACAP

Pituitary Adenylate-Cyclase-Activating Polypeptide

- Master regulator of adaptation to stress
- Part of glucagon/secretin/Vasoactive intestinal peptide (VIP) superfamily
- mediates via 3 G-protein-coupled receptors in the limbic system
- Regulates H-P-A axis-works w Ach, epinephrine, norepinephrine to maintain homeostasis
- dysregulated in PTSD
- Future pharmacologic possibilities



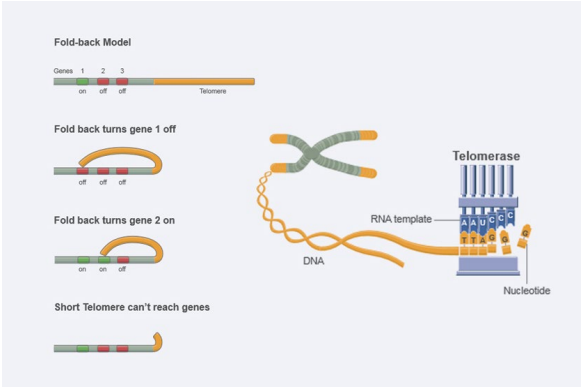
Neurotransmitters Role in Stress Tolerance

- **Dopamine**: neuronal signaling and circuit activation
- Dopamine-related genes, neuron structure, firing patterns relate to variations in stress response during development and in adulthood
- **Serotonin:** mood, anxiety
- **Glutamate:**
- excitatory: activates Ca2+ influx, kinases
- stress=excess of glutamate: Ca2+ toxicity, necrosis, apoptosis-HPA axis activation=increase in glutamate sensitivity
- **Natriuretic peptides:**
- Atrial: inhibits HPA axis =decreased anxiety
- C-type:(vascular-derived) ACTH increases=increased anxiety
- Brain-derived: stress-neutral

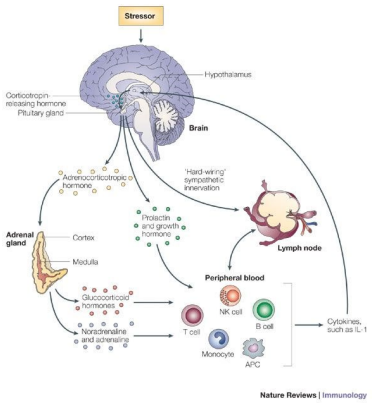
Telomeres

Drs. E. Blackburn, E. Epel: The Telomere Effect (2017)

- Chromosomal end cap health via telomerase
- Chronic stress unwinds telomeres
- Premature aging, lowers resilience
- Stress management, meditation: increases telomerase
- Telomerase replenishes telomeres



Immune System and Stress



Memory and Stress

Case:35 year old patient: "doc, I'm sure I have Alzheimer's"

- Catecholamines and cortisol act in the hippocampus, amygdala, pre-frontal cortex
- Stress decreases neurogenesis in dentate gyrus of hippocampus
- Reduces spatial and working memory
- Stress hormones consolidate memory during stressful events
- Stress hormones reduce memory retrieval

Neuroplasticity

Dr Norman Doidge "The Brain that Changes Itself" 2007

- Neurons that fire together, wire together
- Brain training "10,000 hours" concept at any age
- fMRI studies: 20" daily of mindfulness meditation X 3 months measurably increases glucose uptake in pre frontal cortex
- cultivates ability to place attention when and where needed most
- promotes calmness, connection with others, complex problem solving

Topics:

Stress physiology/research

Managing Stress

Professional Burnout: Problems

Professional Burnout: Solutions

Self Awareness

Self Care

Mindfulness

Mindful Self Compassion

Managing Stress

REACT Flight/fight/freeze

vs.

RESPOND Calm, aware, skilled

Managing Stress

"Stress is inevitable, suffering is optional"

Unskilled , reactive, automatic behaviour

vs. Skilled, flexible, adaptive behaviour

Topics:

Stress physiology/research

Managing Stress

Professional Burnout: Problems

Professional Burnout: Solutions

Self Awareness

Self Care

Mindfulness

Mindful Self Compassion

Professional Burnout: WHO (2020)
"occupational syndrome associated with unmanaged stress at work"

- June 2014 CMAJ: Flegel, et al: soaring rate of burnout in family docs=MD illness, decreased patient care
- HCP suicide rate 2X general population
- HCP students:15-30% higher rate of depression than general population
- 46-51% of HCPs report significant burnout symptoms (2015) (emedcert.com Jan. 2016)
- Anxiety, depression, substance abuse, suicide (in Barrie alone, aware of at least 3 MD suicides)
- CMAJ April 2019 issue: burnout blogs, podcasts, articles
- WORSE SINCE PANDEMIC

Professional Burnout...from the American Dental Association:

….You are not alone. In the 2015 Dentist Well-Being Survey report by the American Dental Association, 2,122 dentists described their stress levels and triggers. Over two-thirds of them, 79%, reported moderate to severe stress. More than a quarter of them, 26%, also reported moderate to high levels of depression.

Empathy Fatigue/Burnout: Secondary Traumatic Stress

mirror neurons in mammalian brain

Empathy: pre-verbal resonance with others; "interpersonal synchrony"; does not necessarily involve concern source of vicarious trauma

Compassion: empathy plus a wish to help; rewarding, energizing, inexhaustible

Empathy fatigue or Secondary Traumatic Stress (STS): gradual lessening of empathy and capacity for compassion over time.

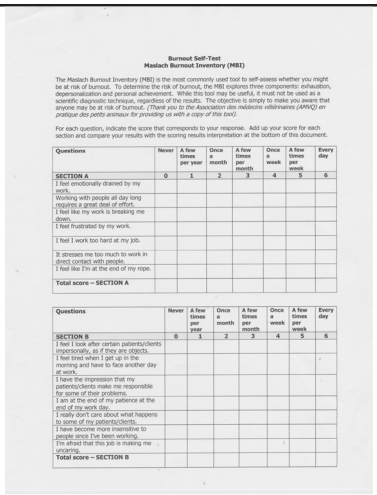
Common with front line workers who work directly with trauma victims

Professional Reactions to Empathy/Compassion Fatigue or Secondary Traumatic Stress (STS)

- **Job Performance** – decrease in quality or quantity of work, low motivation, avoidance of job tasks
- **Morale** – decrease in confidence, loss of interest, dissatisfaction, negative attitude, apathy, burnout
- **Relationships with Peers** – impatience, decrease in quality of relationships, poor communication, staff conflicts
- **Behaviour** – absenteeism, exhaustion, faulty judgment, irritability, tardiness, overwork

Professional Burnout:
Personal factors: perfectionism, self-sacrifice, lack of self care
Professional factors: pandemic, lack of "agency", forms, IT, crises (covid, lifestyle disease, political, climate change, inequality, leadership)

- burnout not in DSM, but in WHO ICD-10
- Symptoms of reactive depression that improves when not working
- physical (insomnia, fatigue, headaches, GI upset)
- psychological: (irritability, cynicism, decreased concentration)
- emotional: (exhaustion, depersonalization, perception of lack of accomplishment)
- Maslach Burnout Inventory



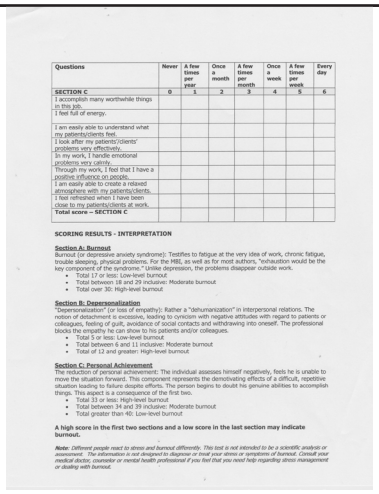
Burnout Self-Test
Maslach Burnout Inventory (MBI)

The Maslach Burnout Inventory (MBI) is the most commonly used tool to self-assess whether you might be at risk of burnout. To determine the risk of burnout, the MBI explores three components: exhaustion, depersonalization and personal achievement. While this tool may be useful, it must not be used as a scientific diagnostic technique, regardless of the results. The objective is simply to make you aware that anyone may be at risk of burnout. *(Thank you to the Association des médecins vétérinaires (AMMQ) en pratique des petits animaux for providing us with a copy of this tool).*

For each question, indicate the score that corresponds to your response. Add up your score for each section and compare your results with the scoring results interpretation at the bottom of this document.

Questions	Never	A few times per year	Once a month	A few times per month	Once a week	A few times per week	Every day
SECTION A	0	1	2	3	4	5	6
I feel emotionally drained by my work.							
Working with people all day long requires a great deal of effort.							
I feel like my work is breaking me down.							
I feel frustrated by my work.							
I feel I work too hard at my job.							
It stresses me too much to work in direct contact with people.							
I feel like I'm at the end of my rope.							
Total score – SECTION A							

Questions	Never	A few times per year	Once a month	A few times per month	Once a week	A few times per week	Every day
SECTION B	0	1	2	3	4	5	6
I feel I look after certain patients/clients impersonally, as if they are objects.							
I feel tired when I get up in the morning and have to face another day at work.							
I have the impression that my patients/clients make me responsible for some of their problems.							
I am at the end of my patience at the end of my work day.							
I really don't care about what happens to some of my patients/clients.							
I have become more insensitive to people since I've been working.							
I'm afraid that this job is making me uncaring.							
Total score – SECTION B							



Questions	Never	A few times per year	Once a month	A few times per month	Once a week	A few times per week	Every day
SECTION C	0	1	2	3	4	5	6
I accomplish many worthwhile things in this job.							
I feel full of energy.							
I am easily able to understand what my patients/clients feel.							
I look after my patients'/clients' problems very effectively.							
In my work, I handle emotional problems very calmly.							
Through my work, I feel that I have a positive influence on people.							
I am easily able to create a relaxed atmosphere with my patients/clients.							
I feel refreshed when I have been close to my patients/clients at work.							
Total score – SECTION C							

SCORING RESULTS - INTERPRETATION

Section A: Burnout
Burnout (or depressive anxiety syndrome): Testifies to fatigue at the very idea of work, chronic fatigue, trouble sleeping, physical problems. For the MBI, as well as for most authors, "exhaustion would be the key component of the syndrome." Unlike depression, the problems disappear outside work.

- Total 17 or less: Low-level burnout
- Total between 18 and 29 inclusive: Moderate burnout
- Total over 30: High-level burnout

Section B: Depersonalization
"Depersonalization" (or loss of empathy): Rather a "dehumanization" in interpersonal relations. The notion of detachment is excessive, leading to cynicism with negative attitudes with regard to patients or colleagues, feeling of guilt, avoidance of social contacts and withdrawing into oneself. The professional blocks the empathy he can show to his patients and/or colleagues.

- Total 5 or less: Low-level burnout
- Total between 6 and 11 inclusive: Moderate burnout
- Total of 12 and greater: High-level burnout

Section C: Personal Achievement
The reduction of personal achievement: The individual assesses himself negatively, feels he is unable to move the situation forward. This component represents the demotivating effects of a difficult, repetitive situation leading to failure despite efforts. The person begins to doubt his genuine abilities to accomplish things. This aspect is a consequence of the first two.

- Total 33 or less: High-level burnout
- Total between 34 and 39 inclusive: Moderate burnout
- Total greater than 40: Low-level burnout

A high score in the first two sections and a low score in the last section may indicate burnout.

***Note:** Different people react to stress and burnout differently. This test is not intended to be a scientific analysis or assessment. The information is not designed to diagnose or treat your stress or symptoms of burnout. Consult your medical doctor, counselor or mental health professional if you feel that you need help regarding stress management or dealing with burnout.*

Topics:

Stress physiology/research

Managing Stress

Professional Burnout: Problems

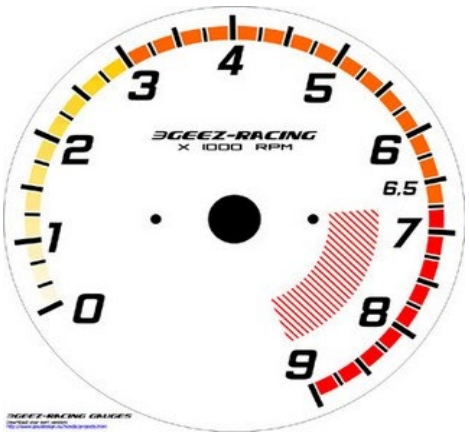
Professional Burnout: Solutions

Self Awareness

Self Care

Mindfulness

Mindful Self Compassion



Self-Awareness

Internal stress o meter

Frequent "check in"

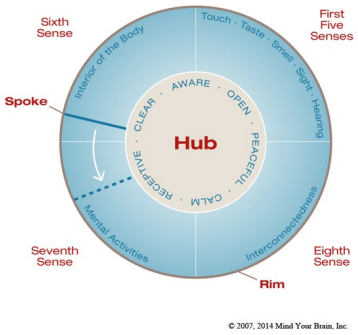
Time and space for inventory: "I'm too busy"

Recognizing your personal stress triggers

Recognizing your own stress reaction

. Cultivating "3rd person" perspective,
. awareness of inner dialogue

Dr Dan Siegel's Wheel of Awareness



SOLUTIONS:

Self Awareness

Self Care

Mindfulness
Mindful Self Compassion

SELF CARE
"enlightened self interest"

self-awareness/self assessment
-"70% rule": leave room for contingencies
-releasing **conditioned** habits-"5% rule"

. Increases efficiency and effectiveness
. reduces burnout

Basic self care

common sense,but not common practice
Routine (especially during pandemic)
Sleep
Food
Exercise/fresh air
Relationships
Vacation
Hobbies/interests
Meditation/Spiritual connection

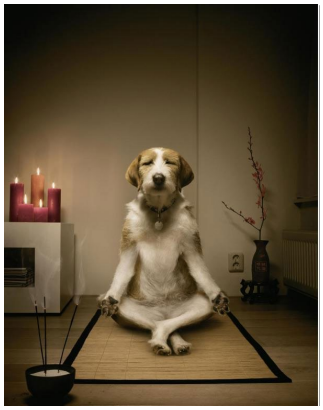
.Caffeine, alcohol, drugs, screen time, overworking….not!

Einstein's definition of insanity: doing the same thing and expecting a different outcome!

. Is what I am doing working?
. What needs to change?
. Overcoming barriers to change:
. ego, pride, fear, conditioned expectations
. **Individua**l stress "sweet spot" (70% of capacity)

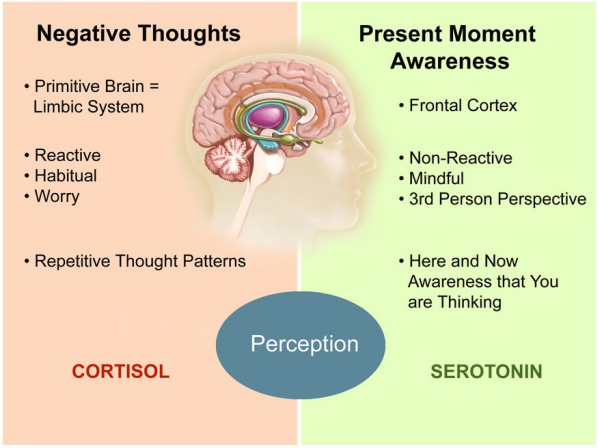
SOLUTIONS:

Self Awareness
Self Care
Mindfulness
Mindful Self Compassion



Mindfulness:

- paying attention to the here and now with attitudes of curiosity and acceptance
- Intentional focus on the present
- Repeated shifting of attention from the past or future to the present moment
- Awareness of what you are doing as you are doing it



Neurobiology of Mindfulness

Mindfulness: "awareness of the present moment, with acceptance" (Chris Germer)

- **Default mode network (DMN):** -midline brain structures
- (medial prefrontal cortex/posterior cingulate cortex (PCC)
- highly active when NOT paying attention (Dr. Ron Siegel)
- =mind wandering/rumination/worry/sense of self projected into past and future
- -built for survival, not joy or happiness
- -mindfulness meditation deactivates the PCC/DMN (Brewer, 2011)
- -mindfulness increases activity in the insula=increased empathy
- -bypasses automatic pilot in the medial prefrontal cortex, increases activity in the L prefrontal lobe=neural integration (cortex, limbic areas, brainstem, body, social world) (Dr Dan J Siegel)

Mindfulness: Myths and Facts

- **Myths:** trying to empty the mind, religious doctrine, passive, isolating, waste of time

- **Facts:** scientifically proven concentration/attention training
- rewires the brain for calm, clear problem-solving,
- wise responses, presence, connection with others

Mindful Principles/Attitudes

- Kindness
- Non-judgment
- Acceptance
- Patience
- Curiosity
- Trust
- Non-striving
- Letting go/reduced attachment

"Live each moment. Practice being mindful.
Be present in… Hold on, I have to take this."

Mindful Practices

Formal: breathing, body scan, yoga:1"-20"
Informal:
STOP
sense and savor nature walk

Informal Practice:STOP

- STOP
- TAKE SOME BREATHS
- OBSERVE
- PROCEED

Mindfulness for Busy Practitioners

Morning: few deep breaths before getting up
shower meditation

. Middle of Day: "disinfect" between patients
. soles of feet reset, STOP,
. gratitude practice

. End of Day: boundaries, mindful driving,
. hand on house door knob, attitude reset,
. gratitude while lying in bed, body scan for EMW

SOLUTIONS:

Self Awareness
Self Care
Mindfulness
Mindful Self Compassion

Mindful Self Compassion (MSC)

Drs. Chris Germer and Kristin Neff 2003

"two wings of the mindfulness bird"

Mindful Self Compassion

. Managing our conditioned inner critic
. Kind, instead of harsh, inner coaching
. Mindfulness vs over identification
. Self kindness vs self criticism
. Common humanity vs isolation, shame

Mindful Self Compassion: physiology

THREAT/DEFENSE	INNER CRITIC	SELF-COMPASSION
Fight	self-critic	self kindness
Flight	isolation	common humanity
Freeze	self-absorption	mindfulness

Mindful Self Compassion

. Including yourself equally in the circle of care
. Treating yourself as you would a good friend
. Preventing depletion with self kindness, self-care
. **Myth**: weakness, self indulgent, selfish
. **Facts**: promotes strength, resilience, connection, helping others effectively

Managing Secondary Traumatic Stress/Empathy Fatigue

Reduced attachment to outcome

Reduced attachment is that we simply do our very best and accept the outcome.

Remain caring, present and connected but less attached to how things turn out

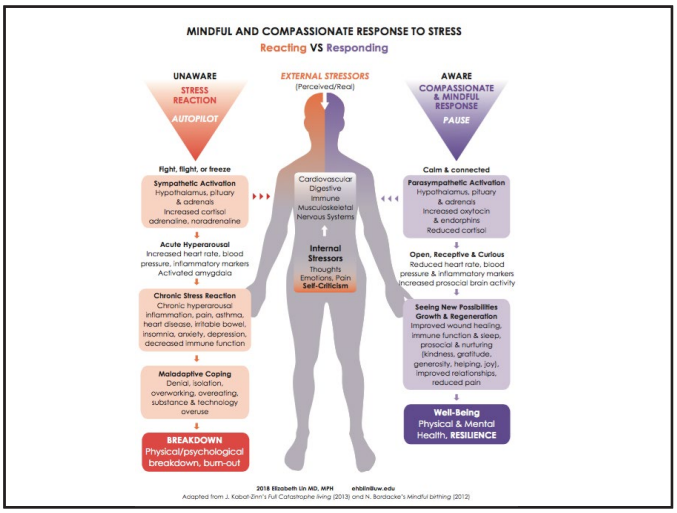
Do not try to change the things beyond our sphere of influence:

Most outcomes are far beyond our control

Managing Secondary Traumatic Stress

Mindful self compassion

"This a moment of difficulty"
"One for me, one for you"
Including yourself equally in the circle of care
Treating yourself as a good friend



Ultimate Courage: Seeking help

Barriers: Pride: "I can bully my way through"

Ego: "I'm indispensable"

Fear: "I can't afford to slow down"; "My peers and patients will think I'm incompetent."

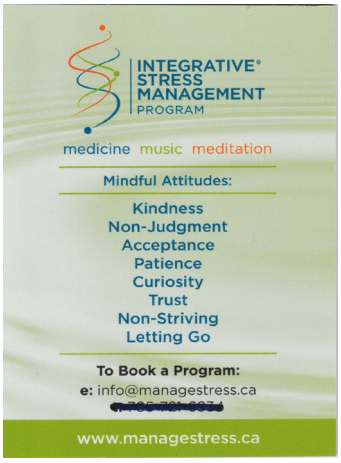
Facts:

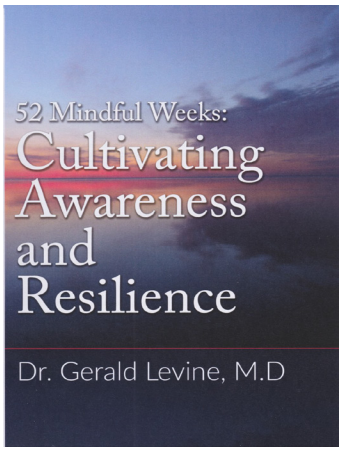
seeking help requires strength and courage; works out better in the long run (N of 1)

NEED TO CULTIVATE A SUPPORTIVE WORKPLACE

THINGS TO REMEMBER

Awareness, Acceptance
Breath, Body
Curiosity, Compassion
70 %
5 %





CONTINUED PRACTICE/RESOURCES

Dr Gerald Levine: www.managestress.ca

eBooks: 52 Mindful Weeks

Stress Physiology: Handbook of Stress v 3 by George Fink

Mindfulness: Full Catastrophe Living by Dr. Jon Kabat-Zinn

The Mindful Brain by Dr. Daniel J. Siegel

The Mindfulness Solution by Dr. Ronald D. Siegel

Resilient by Dr. Rick Hanson

Meditation for Fidgety Skeptics by Dan Harris

Burnout: Drs. Maslach, Shanafelt, Bodenheimer

Time to Care by Dr. Robin Youngson

Dr. Jonathan Fisher: https://www.mindheartnow.com/Self-Compassion:

Wisdom and Compassion in Psychotherapy by Dr. Chris Germer

Center for MSC.org Dr. Kristen Neff

APPS: 10% Happier, Insight Timer, Calm, Headspace

SELF EVALUATION

Employing Mindfulness to Reduce Stress and Avoid Burnout

1. Chronic stress negatively effects:

a. our immune system function
b. working memory
c. problem solving capabilities
d. chromosomal telomeres, causing premature aging
e. all of the above

2. T/F - Health Care Professional burnout is rare because of high pay and work satisfaction

3. T/F - fMRI neuroplasticity studies show that 3 months of 20 minutes mindfulness training per day improves prefontal cortex function

4. T/F - Mindfulness involves being more efficient at multi tasking

5. Mindful self compassion reduces burnout by:

a. reducing attachment to outcomes beyond our control
b. nourishing ourselves during difficult professional encounters to helping to manage secondary traumatic stress
c. treating ourselves as we would a good friend
d. all of the above

6. T/F - 70% rule means we need to find and maintain our stress levels to 70% of our limit

7. T/F - 5% rule means that we need at least 5% average annual returns on our investments

8. T/F - Health Care Practitioners have no time for self care, mindfulness and mindful self compassion

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