THE
2021-22

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 2021-22 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, psychology, and practice management. And their presentations include topics ranging from high conflict patients, type 2 diabetes, professional employment agreements and COPD, to retirement planning, acute cardiac event triggers, the practitioner as a witness, and understanding practice financial statements.

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 2021-22 Medical-Dental-Legal Update*** you should have acquired the knowledge that will better enable you to better:

- Understand cardiovascular risks inherent in **high intensity physical activity** and how to mitigate them.
- Understand the **health impact of sleep** as well as non-medical approaches to engender better sleep.
- Develop and maintain patient and physician **referral relationships**.
- Understand the key elements of a **professional employment agreement**.
- Identify **acute cardiovascular event triggers** and how they're prevented.
- Diagnose and treat **Carpal Tunnel Syndrome**.
- Read and understand **practice financial reports**.
- Glean helpful **practice management data** from financial reports.
- Understand the nature of the **DEA's focus on opioids** and healthcare providers.
- Utilize a variety of **clinically relevant but relatively unknown treatments**.
- Understand the nature and diagnosis of **transthyretin amyloidosis** as well as pharmacologic options.
- Better manage macrovascular risk in **type 2 diabetes**.
- Better **lung cancer screening** decision making
- Better recognize the symptoms of **professional burnout** and take measures to avoid it.
- Understand the diagnosis, nature and treatment of **Non-Alcoholic Fatty Liver Disease & Alcoholic Hepatitis**
- Evaluate and improve **practice processes**.
- Identify strategies for **effective time management**.
- Understand the elements of **effective negotiating and decision making**.
- Appreciate the role of **physician testimony** in a malpractice case as well as witness dos and don'ts.
- Understand the nature of **high conflict patients** and how best to interact with them.
- Explain effective **retirement planning** techniques and vehicles

All learning objectives above address IOM/ACGME core competencies.

THE 2021-22

Medical-Dental-Legal UPDATE

FACULTY DISCLOSURES

The individuals listed below have control over the content of ***The 2021-22 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:

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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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Things I Wish I'd Known Last Year

Alternative Rx of Hypertension

A 62 y.o. man with stage 2 HTN (160/82) is reluctant to take prescription medication. Which intervention below might make a meaningful impact upon his BP

a) Vitamin E 600 IU/d PO

b) Coenzyme Q 60 mg PO

c) Celecoxib (eg, Celebrex) 200 mg PO

d) Bremelanotide 1.75mg SQ

Coenzyme Q for HTN

- Study: HTN pts (n=76)
- Rx: CoQ 60 mg b.i.d. vs placebo
- Rx Groups:
  - HTN
  - Normotensive 'controls'
- Outcome (at 12 weeks): SBP

Burke BE et al *South Med J* 2001;34(11):1112-1117

Coenzyme Q HTN Baseline Characterteristics

	HTN CoQ	HTN Pbo	Control
Age	70	67	65
SBP mmHg	165	164	138
DBP mmHg	81	82	79
CoQ mg/mL	0.47	0.55	0.49

Burke BE et al *South Med J* 2001;34(11):1112-1117

Coenzyme Q for HTN Outcomes

	HTN CoQ	HTN Pbo	Control
SBP mmHg	165→147*	164→162	138→140
DBP mmHg	81→78	82 →82	79→79
CoQ mg/mL	0.47→2.69*	0.55→0.53	0.49→2.50*

* p< 0.01

Burke BE et al *South Med J* 2001;34(11):1112-1117

Coenzyme Q for HTN Outcomes A Closer Look

- "The average reduction in SBP in the … CoQ group after 12 weeks was 17.8 ± 7.3 mm Hg…."
- "Analysis of individual patient data revealed that….45% of patients were non-responders."
- In…responders, the average reduction in SBP was 25.9 ±6.4 mm Hg."

Burke BE et al *South Med J* 2001;34(11):1112-1117

Reducing Smoking: How Much Benefit?

You are speaking to a new patient about smoking cessation. Taken aback, he says "But doc, I've cut down by more than 50% in the last two years and kept it up….isn't that good enough?" Your evidence based response should be

a) Yes, risk of CVD is correspondingly ±50% lower

b) Yes, but CVD risk reduction is only ± 25%

c) No, cutting down has been shown NOT to help

RESEARCH PAPER

Health consequences of reduced daily cigarette consumption

Aage Tverdal, Kjell Bjartveit

Tobacco Control 2006;15:472-480. doi: 10.1136/tc.2006.016246

Cutting Down Smoking: Benefits?

- Study: Prospective study (Norway) heavy smokers (n=51,210) who cut down by >50%
- Inclusion
  - Age at enrollment 20-49 years
  - Smoked >15 cigs/d at baseline
  - ♀ (n=24,959)
  - ♂ (n=26,251)
- Exclusion: Known CHD; pipe smokers
- Followup 1974-1978 thru 2003 (mean 21.2 yrs)

Tverdal A, Bjartveit K *Tobacco Control* 2006;15:472-480

Cutting Down Smoking: Benefits?

Mortality	Reducers vs Sustained Heavy Smokers RR	p
All-cause	1.02 (0.84-1.22)	NS
CVD	1.02 (0.75-1.39)	NS
IHD	0.96 (0.65-1.41)	NS
Lung Ca	0.66 (0.36-1.21)	NS
Smoking-related CA	0.86 (0.57-1.29)	NS

Tverdal A, Bjartveit K *Tobacco Control* 2006;15:472-480

Cutting Down Smoking: Benefits? Conclusions

"Long-term follow-up provides no evidence that heavy smokers who cut down their daily cigarette consumption by >50% reduce their risk of premature death significantly."

Tverdal A, Bjartveit K *Tobacco Control* 2006;15:472-480

Cutting Down Smoking: Benefits? Conclusions

"…it may give people false expectations to advise that reduction in consumption is associated with reduction in harm."

Tverdal A, Bjartveit K *Tobacco Control* 2006;15:472-480

Cosmetic Complaint: Melasma

A 36 y.o. Asian male complains of scattered hyperpigmented macules on his face. Topical 'bleaching agents' and makeup have proven unsatisfactory. Which next step might help?

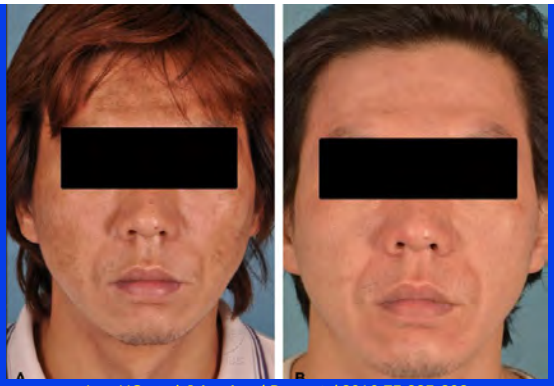
A) Tranexamic acid PO
B) Tamoxifen PO
C) Zoledronic acid IV
D) Amiodarone PO

Oral tranexamic acid (TA) in the treatment of melasma: A retrospective analysis

Hwee Chyen Lee, MRCP, Tien Guan Steven Thng, MRCP, FRCP, and Chee Leok Goh, MD, MRCP
Singapore

Lee HC et al J Am Acad Dermatol 2016;75:385-392

Melasma After Tranexamic Acid X 2 Months



Lee HC et al *J Am Acad Dermatol* 2016;75:385-392

Melasma: Premises

- "Melasma can be psychologically and socially debilitating and Rx remains a challenge."
- Pathogenesis: Unknown
- Genetic predisposition

Lee HC et al *J Am Acad Dermatol* 2016;75:385-392

Melasma: Tranexamic Acid

- Study: Melasma patients in Singapore 3^0 Care Derm clinic (n=561)
- Demographics:
  - ♀ (91.4%)
  - ♂ (8.6%)
  - Mean age of onset = 45
  - Melasma duration = 6 years (median)
- Rx: PO tranexamic acid 250 mg b.i.d x 4 months (median)

Lee HC et al *J Am Acad Dermatol* 2016;75:385-392

Tranexamic Acid for Melasma What About AEs?

"…one patient who developed DVT…was eventually found to have familial protein S deficiency and required warfarin."

Lee HC et al *J Am Acad Dermatol* 2016;75:385-392

Tranexamic Acid for Melasma: Possible Confounders

- Oral contraceptives: 3.7%
- HRT: 1.1%
- IUD (type not specified) : 0.4%

Lee HC et al *J Am Acad Dermatol* 2016;75:385-392

Tranexamic Acid for Melasma: Previous Rx

Topicals	94.5%
Lasers/Intense Pulsed Light	35.5%
Chemical Peels/Alternative Medicine	5.2%

Lee HC et al *J Am Acad Dermatol* 2016;75:385-392

Tranexamic Acid for Melasma: Outcomes

Improved	89.7%
No Change	10.0%
Worse	0.4%
Mean Time to Response (months)	1.9
% improvement (mean)	56.9%
Relapse (Time in months)	27% (8.6)

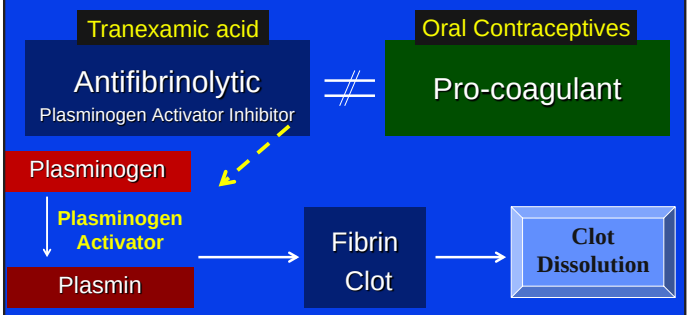
"However. 24.1% patients who used oral tranexamic acid as 1st-line Rx all showed improvement with a 100% response rate."

Lee HC et al *J Am Acad Dermatol* 2016;75:385-392

Tranexamic Acid *Some* Reported Clinical Uses

- Menorrhagia
- Major Trauma: Internal Bleeding
- Epistaxis
- Dental Surgery
- Hemorrhoidal bleeding
- Hemoptysis (Inhaled)
- Post Partum Hemorrhage
- Orthopedic Surgery

What is Tranexamic Acid?



Efficacy of Tranexamic Acid For Oral Surgery

- Study: RDBPCT oral surgery pts (n=94)
- Warfarin NOT stopped
- Rx: tranexamic acid solution 4.8%
  - 10 ml immediately post-op
  - 10 ml q.i.d X 2 mins X 7 days
- Outcome (Bleeding requiring Rx)
  - Rx group: None
  - Placebo group: 10 patients ($p < 0.01$)

Ramstrom G et al J Oral Maxillofac Surg 1993;51(11):1211-1216

Tranexamic Acid: A Way to Reduce Bleeding Associated with Dental Procedures

Dosing

- Tranexamic acid 5% oral solution rinse (500 mg/10 ml)
  - 5 ml 5-10 mins pre-procedure
  - 5 ml t.i.d.-q.i.d. X 24-48 hrs

Douketis JD et al Chest 2012;141;e326-e350S

CRASH-2

Clinical Randomisation of an Antifibrinolytic in Significant Haemorrhage 2

Lancet 2010;376:22-32

Trauma or Major Surgery

Part of normal hemostatic response

Clot Breakdown (fibrinolysis)

Sometimes

Pathologic Clot Breakdown (hyper-fibrinolysis)

Hemorrhage

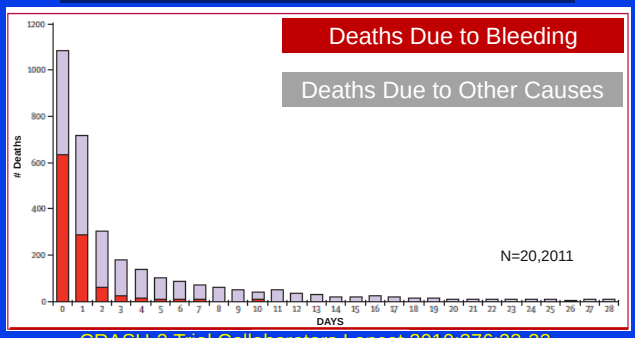
CRASH-2 Trial Collaborators Lancet 2010;376:22-32

Trauma Issues

"Haemorrhage is responsible for about a third of in-hospital trauma deaths.."

CRASH-2 Trial Collaborators Lancet 2010;376:22-32

Post-trauma Mortality: Hemorrhage vs Other



CRASH-2 Trial Collaborators Lancet 2010;376:23-32

What is Tranexamic Acid?

Tranexamic acid

Antifibrinolytic

Plasminogen Activator Inhibitor

≠

Oral Contraceptives

Pro-coagulant

Plasminogen

Plasminogen Activator

Plasmin

Fibrin Clot

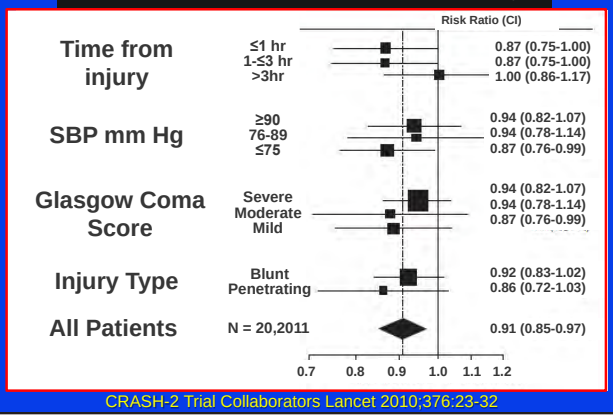
Clot Dissolution

Effects of Tranexamic Acid in Trauma Patients with Hemorrhage

- Study: RDBPCT trauma pts (n=20,211)
- Inclusion:
  - SBP < 90 mm Hg *and/or*
  - Pulse > 110 bpm *and/or*
  - Considered at risk of significant bleed
  - Within 8 hr of injury
- Rx: tranexamic acid IV 1 g load + 1 g 8hr infusion vs placebo

CRASH-2 Trial Collaborators Lancet 2010;376:22-32

Tranexamic Acid vs Placebo: All-Cause Mortality



CRASH-2 Trial Collaborators Lancet 2010;376:23-32

CRASH-2 Thrombotic Outcomes & Transfusions

	Tranx	Placebo	RR	p
MI	35 (0.3%)	55 (0.5%)	0.64 (0.42-0.97)	0.035
Stroke	57 (0.6%)	66 (0.7%)	0.86 (0.61-1.23)	0.42
PE	72 (0.7%)	71 (0.7%)	1.01 (0.73-1.41)	0.93
DVT	40 (0.4%)	41 (0.4%)	0.98 (0.63-1.51)	0.91
Transfusion	5,067 (50.4%)	5,160 (51.3%)	0.98 (0.96-1.01)	0.21

CRASH-2 Trial Collaborators Lancet 2010;376:23-32

The Allure of the Tanning Salon

Anna is a 20 y.o. student at Great Falls College MSU. Considering it is mid-winter, you are surprised by the generous tan that she has achieved by going to the local tanning salon. She wants to "look good for Volley Ball at the Spring Event". You should advise:

A) Go for it: tanning enhances Vitamin D

B) Go for it: tanning has no known AEs

C) Not so fast: risk of melanoma is increased

D) Not so fast: risk of Vitamin D toxicity is increased

For Women, It's All HER Fault

Gabrielle Bonheur Chanel
19 August 1883 – 10 January 1971

Indoor Tanning: Melanoma Risk Premise

"Indoor tanning is associated with increased risk of melanoma, but most evidence comes from case-control studies."

Ghiasvand R et al *Am J Epidemiol* 2017;185(3):147-156

So What's Wrong with a Case-Control Study?

Case-control study

- Observational (no intervention)
- Within an otherwise similar population:
  - Group A: has the outcome, e.g., lung CA
  - Group B: did not get the outcome (lung CA)
- The frequency of a perceived RF (e.g., smoking) in Group A is compared to group B

Wikipedia accessed Jan 9, 2020

So What's Wrong with a Case-Control Study?

"They require fewer resources but provide less evidence for causal inference than a randomized controlled trial."

Wikipedia accessed Jan 9, 2020

Indoor Tanning: Melanoma Risk

- Study: The Norwegian Women and Cancer Study (n= 141,045)
- Method: Prospective Cohort Study 1991-2012
- Variables related to indoor tanning:
  - age at initiation
  - duration of use
  - dose response
- Outcome of interest: melanoma

Ghiasvand R et al *Am J Epidemiol* 2017;185(3):147-156

Indoor Tanning: Melanoma Risk (Based on 861 cases of melanoma)

	RR	CI	p
# sessions Tertile #1 vs Tertile #3	1.32	1.08-1.63	0.006
Initiated age <30	1.31	1.07-1.59	<0.05

Moreover, women who started indoor tanning prior to 30 years of age were 2.2. years younger at Dx, on average, than never users."

Ghiasvand R et al *Am J Epidemiol* 2017;185(3):147-156

Indoor Tanning: Melanoma Risk

"This cohort study provides strong evidence of a dose-response association between indoor tanning and risk of melanoma and supports the hypothesis that vulnerability to the harmful effects of indoor tanning is greater at a younger age."

Ghiasvand R et al *Am J Epidemiol* 2017;185(3):147-156

The Endless Struggle For Beauty

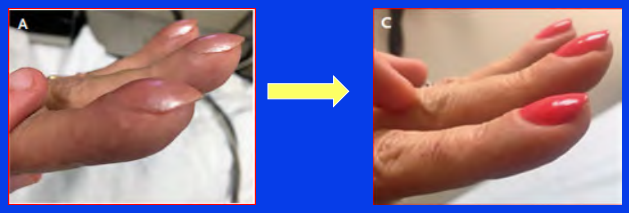
Linda is 59 y.o. woman who recently diagnosed with stage 4 lung CA. She tends to keep her hands hidden because she is "embarrassed by my thick fingers." She is undergoing chemo- and radiation therapy. What can you prognosticate about her clubbing?

A) It will not change

B) It will worsen despite lung CA Rx

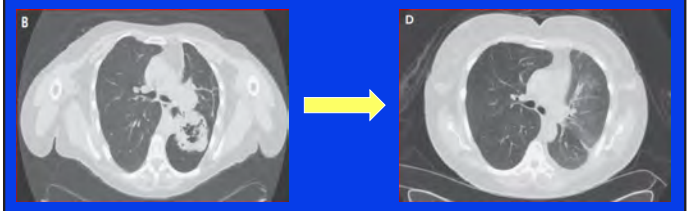
C) It may improve with lung CA Rx

Clubbing: 6 Months Post Lung CA Rx



Ciment AJ, Ciment L *NEJM* 2016;375:12:1171-1171

Lung CA: 6 Months Post Lung CA Rx



Case: Charles M: Reluctant to Start Urate Lowering Therapy

- Charles is a 52 y.o. man who has just completed a course of anti-inflammatory treatment for acute podagra (gout: great toe). His uric acid level was moderately elevated (8.6 mg/dL). He attributes the attack to an ill-chosen drinking binge with his buddies, and hence declines LTULT (Long term urate lowering therapy). What are the chances that this will be his only attack of gout in his lifetime?
  - a) <10%
  - b) 10-20%
  - c) 30-40%
  - d) Its about an even 50:50 chance that he'll get another attack

Charles: Gout Attack #2

- Charles returns for a 2nd occurrence of podagra 3 years later. Although high-dose NSAID (naproxen 500 mg b.i.d.) promptly resolved his last attack, he developed severe GI distress from it despite co-therapy with a PPI. What alternative treatment has shown comparable efficacy?
- A) topiramate 100 mg b.i.d.
- B) prednisone 30-35 mg/d
- C) montelukast 10 mg qd
- D) amitriptyline 25 mg b.i.d.

Charles: Gout Attack #3

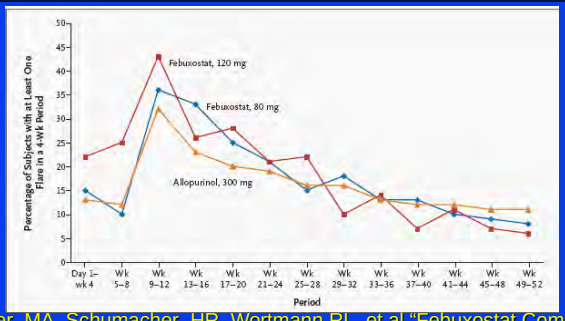
- 2 years later, Charles returns with an attack of gout involving his forefoot and ankle. He is now motivated to try and prevent future flares. Which agent has been shown to best consistently maintain uric acid levels< 6.0 in clinical trials
- A) allopurinol
- B) probenecid
- C) colchicine
- D) febuxostat

'New' Colchicine Dosing for Acute Gout

- TRIAL: Colchicine 1.2 mg + 0.6 mg 1 hr later (Total dose = 1.8 mg) vs Colchicine 1.2 mg + 0.6 mg X 6 (Total dose = 4.8 mg)
- OUTCOME: Equal efficacy, but lower dose much better tolerated

Terkeltaub RA Semin Arth Rheum 2009;38:411-419

Febuxostat vs Allopurinol : Gouty Flares



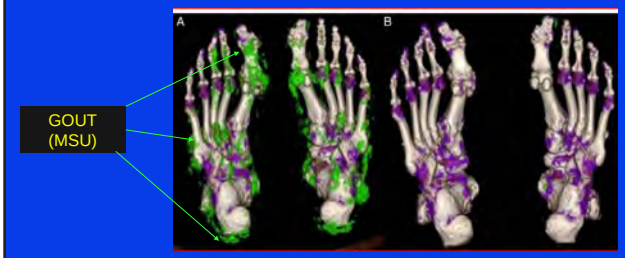
Becker MA, Schumacher HR, Wortmann RL, et al "Febuxostat Compared with Allopurinol in Patients with Hyperuricemia and Gout" N Engl J Med 2005;353(23):2450-61

Table 2. Primary and Secondary End Points.*

End Point	Febuxostat 80 mg/d	Febuxostat 120 mg/d	Allopurinol 300 mg/d
Primary Endpoint			
Urate < 6 mg/dL X last 3 months	136/255 (53%)	154/250 (62%)	53/251 (21%)

Becker MA, Schumacher HR, Wortmann RL, et al "Febuxostat Compared with Allopurinol in Patients with Hyperuricemia and Gout" N Engl J Med 2005;353(23):2450-61

Dual Energy CT Dx of Gout
Rx X 13.3 weeks (mean)



Araujo EG et al *Rheumatic and Musculoskeletal Diseases Open* 2015;1:e000075

Can This Marriage Be Saved: Non-Compliant OSA

Melissa's 48 year old husband has OSA. Despite multiple attempts at CPAP, which does eliminate his operatic class snoring, he cannot tolerate it. Which simple intervention is likely to help?

A) Surgical Uvulopalatoplasty

B) Inhaled corticosteroids

C) A mandibular advancement device

D) Voice training to convert opera snoring to R & B

Paper Mache Cast of My Face for CPAP

Click Image by Unknown Author is licensed under CC BY-NC-ND

Oral Appliances in the Management of Obstructive Sleep Apnea

Jing Hao Ng, BDS (Singapore), MDS Orthodontics (Singapore), MOrth RCS (Edinburgh, UK)*, Mimi Yow, BDS (Singapore), FDS RCS (Edinburgh), MSc (London) (Orthodontics), FAMS (Craniofacial Orthodontics)

Sleep Med Clin 2019;14:109-118

[Contemporary Reviews in Sleep Medicine]

CHEST

Oral Appliances for the Management of OSA
An Updated Review of the Literature

Mona M. Hamoda, BDS, MSc, MHSc; Yuuya Kohzuka, DDS; and Fernanda R. Almeida, DDS, PhD

CHEST 2018;153(2):544-553

Obstructive Sleep Apnea (OSA) Evaluation: AHI

Apnea-hypopnea index (AHI) = Total # apneas + hypopneas / Total sleep time (hrs)

- Severity cutoff levels
  - Mild = 5-15 episodes/hr (with Sxs)
  - Mod = 15-30 episodes/hr
  - Severe = > 30 episodes/hr

Hayes D *Ferri's Clinical Advisor* Elsevier (Philadelphia) 2016:1139-1140

First: The 'Bottom Line"
MAD (Mandibular Advancement Devices)

"…the latest guidelines recommend the use of [MAD] for primary snoring and as an alternative to CPAP for those who prefer [MAD] or those who refuse to use or are unable to tolerate CPAP."

Hamoda MM et al *CHEST* 2018;153(2):544-553

MAD: Does OSA Severity Make A Difference?

"The 2015 guidelines do not specify a particular disease severity of [MAD] use….."

Hamoda MM et al *CHEST* 2018;153(2):544-553

Efficacy vs Effectiveness

- Efficacy: How well an intervention works in ideal circumstances (e.g., clinical trial)
- Effectiveness: How well an intervention works in 'real world' settings

Hamoda MM et al *CHEST* 2018;153(2):544-553

MAD vs CPAP Outcomes

"RCTs comparing CPAP with [MAD] and varying in baseline OSA severity from mild to severe have shown similar results in improving Sx such as sleepiness, QOL, and simulated driving performance."

Hamoda MM et al *CHEST* 2018;153(2):544-553

MAD vs CPAP CVD Outcomes

"Compared with CPAP, the gold standard therapy, oral appliances are less efficacious but are more accepted and tolerated by patients, which in turn, may lead to a comparable level of therapeutic effectiveness."

Hamoda MM et al *CHEST* 2018;153(2):544-553

MAD vs CPAP: Outcomes

"Compared with CPAP, the gold standard therapy, oral appliances are less efficacious ….."

Hamoda MM et al *CHEST* 2018;153(2):544-553

MAD vs CPAP: Efficacy Comparison

Outcome	CPAP	Oral Appliance
AHI	↓ 8.43 AHI/hr >	
Oxygen Saturation	↑ 3.11% SaO_2	
ESS	> 0.8 points	
Function: FOSQ	=	=
Function: SF-36	=	=
BP	=	=
Mortality (Severe OSA)	=	=
Compliance		1.1 hr/night >

Outcome	Normal	Mild-Moderate	Severe
Epworth Score	0-9	11-15	16-24

Ng JG et al *Sleep Med Clin* 2019;14:109-118

I Didn't Show You This Line FIRST

"In terms of CV outcomes, there were no differences between the two Rx with respect to short-term effects on BP, and reducing the risk of mortality in patients with severe OSA."

Hamoda MM et al *CHEST* 2018;153(2):544-553

SNORE Rx

Deep Oropharyngeal Questions

According to a recent CNN publication (1/10/2020), commenting on a just-published article in a well-respected USA journal, which question should each of us be considering about our tongue?

A) Are my lingual papillae clean?

B) Can I touch my nose with my tongue?

C) Can I furrow my tongue into a "U"?

D) Do I have a fat tongue?

About OSA and Weight Loss

Obesity and overweight are associated with OSA. Does weight loss help, as measured by AHI improvements?

A) Yes

B) No

About OSA and Weight Loss

Weight reduction improves the AHI. Why?

A) By reducing abdominal wall fat pad pressure

B) By reducing sympathetic tone

C) By increasing metabolism of free fatty acids

D) By altering oropharyngeal structural configuration

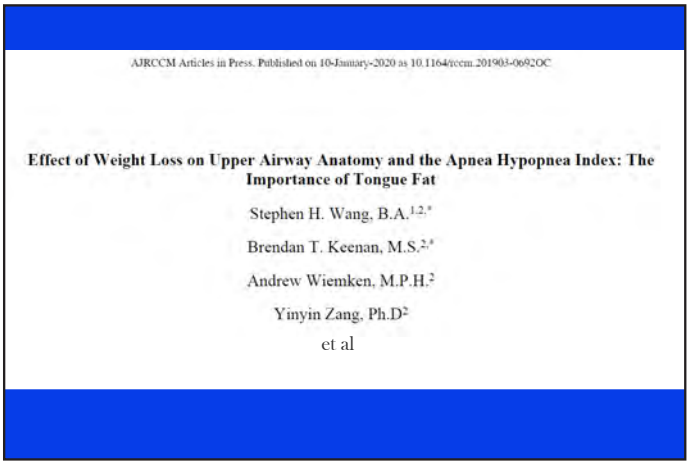
Deep Oropharyngeal Questions

(CNN) – Have you ever asked yourself: Do I have a fat tongue?

It's not a[n] idle query. If you are one of the one billion people globally who suffer from OSA, having a fat tongue could be a key reason you snore, choke, gasp or stop breathing periodically during the night, ruining your sleep and potentially your health.

CNN Health
https://www.cnn.com/2020/01/10/health/tongue-fat-sleep-apnea-wellness/index.html
Accessed Jan 10, 2020

"The questions then was if you reduce the fat in your tongue, does that improve your sleep apnea? And the answer from our paper is 'yes,' said Penn Medicine sleep specialist Dr. Richard Schwab, the lead author of a new study published Friday in the American Journal of Respiratory and Critical Care Medicine



OSA & Tongue Fat Premise

"Why obesity is associated with OSA, why weight loss improves OSA, and why weight gain exacerbates OSA remain unanswered fundamental questions."

Wang SH et al *Am J Resp Crit Care Med* 2020; January 10

OSA, Weight Loss & Tongue Fat Premise

"For example, in the Wisconsin Sleep Cohort, a 1% ↑/↓ in body weight was associated with a corresponding 3% ↑/↓ in AHI and a 10% weight gain was associated with a 6-fold ↑ risk of developing an AHI > 15 events/hr."

Wang SH et al *Am J Resp Crit Care Med* 2020; January 10

OSA, Weight Loss, & Tongue Fat

- Study: Obese OSA Patients (n= 67)
- Intervention: weight loss
  - DPP model (n= 49): ↓5% -10% weight by diet, exercise, & behavior modification
  - Bariatric (n = 18): sleeve, bypass, banding
- Outcome (at 6 months) : AHI change in relation to weight loss and tongue fat

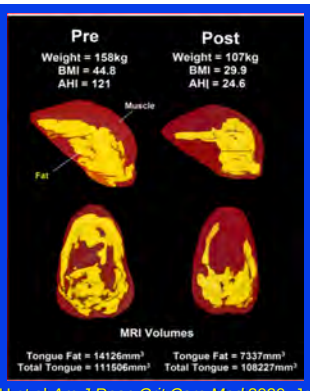
Wang SH et al *Am J Resp Crit Care Med* 2020; January 10

OSA, Weight Loss, & Tongue Fat Results

- Mean weight loss = 9.5%
- Weight loss → ↓tongue fat
- Tongue fat ↓ correlated with AHI reductions
- Minimum weight ↓to affect tongue fat: 2.5%
- "Reduction in tongue fat volume was the primary upper airway mediator of the relationship between weight loss and AHI improvement."

Wang SH et al *Am J Resp Crit Care Med* 2020; January 10

OSA, Weight Loss, & Tongue Fat: Results



Wang SH et al *Am J Resp Crit Care Med* 2020; January 10

Off-Label Issues

OFF-LABEL content in this presentation:

1) Tranexamic Acid for Melasma
2) Cancer chemotherapy for clubbing

SELF EVALUATION

Things I Wish I'd Known Last Year

1. Which of the following supplements has been shown to reduce BP?

a. Niacin
b. Folic Acid
c. Coenzyme Q
d. Biotin

2. Which treatment has been shown to improve melasma in Asians?

a. Vitamin E
b. Methotrexate
c. Tranexamic Acid

3. In a clinical trial comparing allopurinol 300 mg/d to febuxostat 120 mg/d, for the endpoint of ability to maintain target uric acid levels(<6.) in the last 3 months of the trial

a. Allopurinol was superior to febuxostat (twice as efficacious)
b. Allopurinol and febuxostat were equivalent
c. Febuxostat 120 mg/d was superior to allopurinol 300 mg/d (three times as efficacious)

4. Are mandibular advancement devices (MAD) helpful for snoring?

a. MAD show little efficacy compared to CPAP
b. MAD show greater efficacy than CPAP
c. Both tools have similar efficacy, though MAD is typically better tolerated

5. Weight change is associated with changes in AHI (apnea-hypopnea index) scores. Which anatomic factor has recently been recognized to contribute to this

a. Changes in weight are associated with meaningful change in the amount fat in the tongue.
b. CPAP functions better with choanae expansion associated with weight loss
c. The ketosis associated with weight loss enhances pharyngeal tone
d. Diaphragmatic excursion timing is improved by abdominal girth reduction

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

Carole C. Foos, CPA

Carole C. Foos, CPA of Cincinnatti, Ohio is a partner in OJM Group, a physician focused financial planning and asset management firm, and a Certified Public Accountant (CPA) offering tax analysis and tax planning services to the firm's clients. Carole has over 25 years of experience in accounting, tax planning and financial consulting. She is a co-author of numerous books for physicians, including Wealth Management Made Simple and newly published Wealth Planning for the Modern Physician: Residency to Retirement. Carole has authored numerous articles and presented many lectures, webcasts, and podcasts on tax planning and wealth management.

You may contact Ms. Foos with your questions and comments at 513-309-3946, or by email at Carole@OJMGroup.com.

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Understanding Practice Financial Statements - Parts 1 & 2

Carole C. Foos, CPA

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WHY LOOK AT MY FINANCIALS?

- Cash flow and expense review
- Performance indicators
- Trends
- Overall financial health
- Business Plan
- Practice value
- Tax planning

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WHAT REPORTS SHOULD I REVIEW?

- The Basics
  - Profit and Loss
  - Balance Sheet
  - Cash Flow
- Accounts Receivable and collections
- Reports by Physician
- Reports by Location
- Ancillary revenue
- Budget

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INCOME STATEMENT (PROFIT & LOSS)

Shows income and expense and net profit over a period of time

- Method of accounting
  - Accrual
  - Cash
  - Income Tax Basis
- Revenue
  - Net Patient Revenue vs Gross Patient Revenue
    - Who is paying you and at what rates
    - Charity Care vs. Bad Debts
  - Ancillary Revenue (research, consulting, physical therapy, MRI, expert witness, academic)
  - Payment Methodologies

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ACCRUAL BASIS VS CASH BASIS ACCOUNTING

- Accrual Basis
  - Record revenue when earned (bills generated or service provided)
  - Record expenses when incurred
  - Expenses matched to revenue
- Cash Basis (used by most medical practices)
  - Record revenue when collected
  - Record expenses when paid
- Income Tax Basis
  - Similar to cash basis
  - Accrual basis for retirement plan contributions
  - Capitalize prepaid expenses that exceed 12 months

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SAMPLE INCOME STATEMENT (PROFIT & LOSS)

ABC Ortho Group
Profit and Loss
For the Year Ended December 31, 2012

Account	YTD-Actual DEC-12
REVENUE	
Professional Fee Income	
Gross Fees	5,996,198.00
TOTAL	5,996,198.00
Provider Write Downs	(3,294,876.00)
TOTAL	(3,294,876.00)
NET FEE REVENUE	2,701,322.00
Research Revenue	35,868.00
Research Expenses	(16,342.00)
NET RESEARCH REVENUE	19,526.00

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SAMPLE INCOME STATEMENT (PROFIT & LOSS)

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SAMPLE INCOME STATEMENT (PROFIT & LOSS)

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INCOME STATEMENT (PROFIT & LOSS)

Shows income and expense and net profit over a period of time

- Expenses
  - Salaries and benefits
  - Supplies and Outside Services
  - All other expenses
- Non-cash expenses
  - Depreciation and Amortization
- Fixed costs vs. Variable costs

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BALANCE SHEET

Shows Assets, Liabilities, and Equity

- Cash
- Investments
- Receivables
- Fixed Assets and Net Fixed Assets
- Accounts Payable
  - Accounts payable ledger
- Notes Payable
  - Debt Service
- Equity / Partner Capital

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SAMPLE BALANCE SHEET

ABC Ortho Group
Balance Sheet
December 31, 2012

ASSETS	
CURRENT ASSETS	
Cash	572,849.00
Petty Cash	675.00
Accounts Receivable	808,000.00
Total Current Assets	1,375,524.00
PROPERTY & EQUIPMENT	
Computer Hardware	38,000.00
Furniture & Fixtures	57,025.00
Leasehold Improvements	173,588.00
Medical Equipment	242,010.00
Office Equipment	72,454.00
	583,077.00
Accumulated Depreciation	(156,075.00)
Net Property & Equipment	425,002.00
OTHER ASSETS	
Deposits	7,500.00
Investments	225,036.00
Total Other Assets	232,536.00
TOTAL ASSETS	2,037,062.00

LIABILITIES & EQUITY	
CURRENT LIABILITIES	
Accounts Payable	14,754.00
Payroll Taxes Payable	9,237.00
Retirement Plan Contributions Payable	19,750.00
Total Current Liabilities	43,741.00
LONG TERM LIABILITIES	
Note Payable	821,000.00
Total Liabilities	864,741.00
EQUITY	
Common Stock	5,000.00
Net Income	167,963.00
Retained Earnings	999,358.00
Total Equity	1,172,321.00
TOTAL LIABILITIES & EQUITY	2,037,062.00

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STATEMENT OF CASH FLOW

Summarizes cash receipts and cash payments for the period

- Operations
- Investing
- Financing

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SAMPLE STATEMENT OF CASH FLOW

ABC Ortho Group
Statement of Cash Flows
For the Year Ended December 31, 2012

Beginning Cash Balance	531,581.00
Cash Provided by Operations	
Net Income	167,963.00
Expense Not Requiring Cash - Depreciation	2,017.00
Net Cash provided by operations	169,980.00
Cash Used for Investing	
Purchase of Property & Equipment	(21,362.00)
Investments Purchased	(25,000.00)
Net Cash used for investing	(46,362.00)
Cash Used for Financing Activities	
Principal payments on Note Payable	(82,350.00)
Increase in Cash	41,268.00
Ending Cash Balance	572,849.00

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ACCOUNTS RECEIVABLE AND COLLECTIONS

- Often one of practice's largest assets
- Often what a retiring physician re
- Things to evaluate:
  - Turnaround cycle (days in collect
    - May differ by payor
  - Excessive write offs
    - Follow up on denied claims?
    - Coding?
    - Collection attempts

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REPORTS BY PHYSICIAN AND BY LOCATION

- By physician
  - Productivity
  - Overhead
  - Profitability
  - Employee costs
  - Compensation
- By location
  - Profitability
  - Revenue trends
  - Overhead

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ANCILLARY REVENUE

Ancillary Revenue

- Is it profitable?
- Opportunity costs?
- Should it be separated from general practice?

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BUDGETS

- Good budget development and analysis helps monitor expenses
  - Check budget vs. actual on a regular basis
- Will help determine when to add staff / equipment
- Important for your cash flow and retirement planning
- Helps in determining exit strategy

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CASH FLOW AND EXPENSE REVIEW

Review your cash and expenses twice a month by reviewing a payables ledger, your income statement or your cash flow statement

- This will help you:
  - Understand regular and irregular cash flows
  - Monitor cash to ensure you have appropriate cash for operations
  - Focus on vendors whose prices are increasing
  - Review and approve bills to avoid late fees
- Review payroll expenses
  - Are you paying overtime that could be avoided?
  - Are employee costs by physician out of line?

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PERFORMANCE INDICATORS

- Review financials monthly to look for performance indicators
  - "Overhead rate" is the ratio of operating expenses to net revenue and may be a good indicator of how well the practice is operating
  - Analyze profit and overhead by location
  - Analyze by physician
- Review Accounts Receivable
  - Are there collection issues with a particular payer?
  - Are there excessive write offs?
    - If so, is there appropriate follow-up for denied claims?
    - Are claims being properly coded?
    - Are there appropriate attempts to collect from insurers and patients?

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TRENDS

Compare income and expenses over the last several quarters

- Has revenue increased or remained flat?
- How have changes in profit corresponded to revenue changes?
- Are expense increases justified?
- Would it be more efficient to outsource non-key areas?
- Are your marketing efforts bringing in additional revenue?
- Are there expenses that can be reduced through relationships with your local medical society?

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OVERALL FINANCIAL HEALTH

- At year end, review the income statement, balance sheet and cash flow statement.
  - Annual statements will include adjustments for depreciation, profit sharing and pension plan expenses as well as for any outstanding loans
- Compare the annual statements to prior years to evaluate growth and changes.
- Additional reports should also be reviewed annually including collections, receivables, budgets and compensation.
- These reports can also be compared against industry benchmarks.
- Review insurance contracts at this time as you review net patient revenue per carrier.

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BUSINESS PLAN AND PRACTICE VALUE

- Use your financial statements to evaluate where you are in meeting strategic goals
  - Do you have a strategic business plan for the next 3, 5 or 10 years?
  - Is revenue growth on track for the plan?
  - Are profits where they should be according to your strategic plan?
  - Have your assets kept pace? Have you paid down liabilities?
  - What is your practice worth today? Is the value growing according to plan?
- Practice Value
  - Multiple of gross revenue
  - Multiple of net revenue
  - Adding back owner compensation and non-essential expenses

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TAX PLANNING

- Your financial statements are a vehicle that your CPA can utilize to maximize tax planning opportunities.
  - Prior to year end
    - Defer billing?
    - Speed up payment of expenses?
    - Write off equipment
    - Write off bad debts
    - Compensation planning
  - Corporate structure planning

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INTERNAL CONTROL

- The polices and procedures that management puts in place to help protect the business and achieve desired financial results.
  - These practices:
    - Help to create more efficient operational procedures
    - Help to stay compliant with federal, state, and local requirements
    - Help to ensure that your financial information is as accurate and reliable as possible
    - Help to protect your business from fraudulent activities or unnecessary loss
  - Lack of good internal controls can increase business liability vs bank liability if there is an error in a banking transaction

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INTERNAL CONTROL

Separation of Duties – the principle that no single individual is given authority to execute two conflicting duties. Examples:

- Accounts Payable
  - Those entering invoices should not also be responsible for signing checks or making electronic payments or setting up vendors in the AP system
  - The person who signs the checks should not also be responsible for reconciling cash balances each month.
  - Consider requiring 2 signatures on checks over a certain amount.
  - Initiate positive pay with your bank to help reduce the risk of fraudulent checks being drafted.
- Accounts Receivable
  - The person responsible for opening mail and making a bank deposit should not be the same person that records receipts in the AR system.
- Payroll
  - The person who processes payroll should not also do bank reconciliations.
  - Payroll should be periodically reviewed for accuracy and fraudulent activity

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CONTACT ME

- Schedule a free no-obligation consultation
- Contact the presenter:
  - Carole C. Foos, CPA
  - 877.656.4362
  - carole@ojmgroup.com

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DISCLOSURE

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SELF EVALUATION

Understanding Practice Financial Statements - Parts 1 & 2

1. T/F - The Accrual Basis method of accounting records expenses when paid.

2. T/F - Excessive write offs of receivables may be a result of coding errors.

3. Bi-monthly review of cash and expenses will help with which of the following:

a. Understand irregular cash flows
b. Ensure appropriate levels of cash to fund operations
c. Review bill payment to avoid late fees
d. All of the above

4. In order to determine if revenue growth has resulted in increased profit, which of the following should be reviewed?

a. Current income statement
b. Current balance sheet
c. Current income statement compared to previous income statement
d. Cash flow statement

5. T/F - One way to value a medical practice is based on a multiple of gross revenue.

6. T/F - The person entering invoices into the accounting system should also sign checks and enter new vendors.

7. T/F - The person who processes payroll should not also do the bank reconciliations.

8. Financial statements can assist your CPA in tax planning by:

a. Determining if profits are such that billing should be deferred at year end
b. Determining if there are bad debts that should be written off
c. Planning for needed year-end owner compensation adjustments
d. All of the above

9. T/F - Overhead rate is the ratio of operating expenses to gross revenue.

10. T/F - Development of a good budget will not help monitor expenses.

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

Joseph W. Shannon, Ph.D.

Joseph W. Shannon, Ph.D., of Columbus, Ohio, has a doctorate in counseling psychology and over 30 years of clinical experience as a psychologist, consultant and trainer. An expert in understanding and treating a broad range of mental disorders, he has appeared on several television programs including CBS', *Morning Show,* and *PBS: Viewpoint*. Dr. Shannon has developed and presented training programs for medical, allied medical, mental health and substance abuse professionals in the United States and Canada consistently earning exemplary ratings for presenting key insights and practical approaches with clarity, enthusiasm and humor.

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Understanding and Effectively Dealing with High Conflict People

This program is designed to help you deal with noxious people. These individuals have a remarkable ability to precipitate conflict and disharmony in virtually all of their relationships, including their relationships with health care providers. These "high-conflict" people provoke stress-related illnesses, diminish self-worth, keep us awake and upset, enable bad habits and typically lack insight or remorse.

In this new 6-hour program, learn how to reason with "unreasonable" people and develop the art of the possible when dealing with the "impossible" individual. Emphasis will be placed on practical strategies and applications for medical, dental and behavioral settings.

Participants completing this program should be able to:

1. Describe the diagnostic criteria for noxious or high-conflict individuals, including disorders of personality, mood, anxiety, anger modulation and substance abuse;

2. Discuss empirical findings regarding the etiology of the noxious personality, including aspects of social reasoning, atypical brain chemistry, pathological parenting style and the effects of early childhood trauma; and

3. List several strategic, evidence-based approaches that health care professionals can employ in order to deal effectively and ethically with noxious individuals while maintaining their own sense of balance and psychological health.

I. Noxious People: Common Characteristics

- A. Long history of interpersonal conflict, typically dating back to youth
- B. Disruptive, abusive or otherwise pathological childhood relationships
- C. A tendency to view relationships in all-or-nothing, black-or-white terms
- D. Persistent drive to be validated (center of attention)
- E. Tendency to create "psychodramas"
- F. Intense emotions over-rule rational thinking
- G. Mistrust that can border on paranoia
- H. High level of aggressive energy
- I. Profound problems with judgment and/or impulse control
- J. Unconscious distortions and delusions
- K. Will trigger intense confusion, conflict or counter-transference in the care-giver
- L. As they get older, they are prone to be litigious.
- M. Common defenses:
  1. Splitting (e.g., all-or-nothing thinking)
  2. Projection
  3. Persistent drive to control/manipulate others
  4. Blaming others for problems they create
  5. Extremely defensive about any negative feedback
- N. High probability of being diagnosed with an Axis I disorder, e.g. bipolar disorder, agitated depression, obsessive-compulsive disorder
- O. High probability of being diagnosed with an Axis II personality disorder, e.g., borderline or narcissistic disorders

II. Noxious Behavior: Common Types

- A. Inappropriate expression of anger:
  1. Aggressive – e.g., office bullying

2. Passive-aggressive – e.g., protracted divorce litigation
3. Domestic violence – e.g., 1 out of every 3 women and 1 out of every 6 men will be abused by a domestic partner at some point in their life.
4. Aggression/Violence fueled by:
   a. Stress/lack of exercise/poor diet
   b. Substance abuse
   c. Atypical brain chemistry
   d. Mental illness/treatment non-compliance
   e. Toxic relationship dynamics
   f. Desire for revenge
   g. Impulsive anger
   h. Desire to assert a political, religious or other point of view

B. Boundary violations
   physical, emotional, sexual, spiritual abuse

C. Narcissistic behavior
   entitlement/"special"/selfishness

D. Fear-based
   anxiety-driven, e.g., O.C.D.

E. Ignorance/Fear-based
   bigotry, prejudice, homophobia

F. Self-abusive behavior
   1. Cutting
   2. Burning/branding
   3. Compulsive skin-picking
   4. Self-strangulation
   5. Bone-breaking
   6. Excessive tattooing/body piercing

III. Noxious Behavior: Causes/Correlates

A. Dysfunctional family dynamics:
   1. Child's needs, feelings, wants, observations and reactions are ignored/invalidated by parents > NEGLECT
   2. Family shame or secret
   3. At least one parent has a serious psychiatric problem and/or substance abuse problem.
   4. Boundaries are blurred or violated:
      a. Physical abuse
      b. Psychological abuse
      c. Spiritual abuse
      d. Sexual abuse
   5. Poor role models for healthy communication, intimacy and problem-solving
   6. Children tend to develop compulsive behaviors to lessen pain, develop a sense of control, produce positive feelings or block shame.
   7. Family environment is stressful for the child:
      e.g., parents may have a "crisis-orientation" to life
      e.g., active physical, emotional, sexual abuse
      e.g., the impact of poverty
      e.g., parents have abdicated responsibility and a child is expected to take on the role of parent
      e.g., child is punished/rewarded arbitrarily and cannot predict consequences of behavior
      e.g., parent over-indulges the child materially to compensate for emotional neglect.

B. Biological factors:
   1. Biogenetic influences
      a. Atypical brain chemistry, e.g., insufficient levels of serotonin and dopamine
      b. Inherited mental illness, e.g., bipolar disorder
      c. Inherited characterological behaviors, e.g., explosive temper/volatility

2. Pre-birth or post-birth trauma to the central nervous system, e.g., fetal alcohol syndrome
3. Witnessing violence in the home, neighborhood or school can adversely affect brain chemistry.
4. Lousy diet/lack of physical exercise
5. Substance abuse
6. Hormonal changes/imbalances
7. Food/Drug allergies
8. Undiagnosed/untreated medical conditions, e.g., thyroid or pancreatic disease

C. Poor learning/profound social skill deficits
1. Reinforcement contingencies, e.g., being rewarded for inappropriate behavior and punished for healthy behavior
2. Poor/inadequate role models, e.g., violent role models
3. Profound lack of social intelligence, e.g., lack of compassion/empathy

IV. Special Focus: Personality Disorders

A. Definition of "personality"

B. "Personality Disorders"

C. Common characteristics:
1. Adaptive inflexibility
2. Vicious cycles
3. Tenuous stability
4. Profound denial
5. Pathological problem solving
6. Intense transference/counter-transference
7. Highly resistant to treatment

D. Noxious personality types:
1. Paranoid – they are tense, guarded, suspicious, self-righteous, rigid, petty, vengeful and litigious. They hold grudges and are prone to primitive, overt violent acts of aggression. They rarely seek professional treatment and have a very high incidence of domestic violence (as the perpetrator) and substance abuse.
2. Anti-Social (Sociopathic) – they are pervasively dishonest, manipulative, exploitative and disloyal. They have virtually no conscience and experience little or no remorse when they violate rules, behave unlawfully or shatter the lives of others. They are capable of experiencing intense insecurity and anxiety and tend to assuage their insecurity by raising yours. They do not seek treatment voluntarily, have a high rate of substance abuse, A.D.H.D. and are likely to engage in criminal behavior.
3. Borderline – they straddle the border between sanity and psychosis; "they have egos as fragile as spun sugar (and) psyches that are irretrievably fragmented, like a jigsaw puzzle with crucial pieces missing;" they have profound problems with affect regulation and impulse control; their judgment is typically impaired and they will engage in very primitive, oftentimes self-destructive behavior when emotionally upset or frustrated. Others tend to perceive individuals with B.P.D. as frightening black holes of need who quickly erupt in a rage if their dependency needs are in any way thwarted. B.P.D. individuals have a high incidence of substance abuse, self-mutilation and suicide. Prognosis for recovery is good with the proper treatment.
4. Histrionic – they are teen-agers trapped in adult bodies: rapidly-changing but ultimately shallow moods; pathologically vain and flirtatious; pervasive need to be the center of attention ; they demand constant re-assurance and immediate gratification of their every want/need. As they age, they go out of their way to look and act significantly younger than their chronological age. Multiple plastic surgeries are the norm as is multiple marriages and divorces. They are typically referred to treatment by medical doctors; histrionic patients have the highest incidence of psychosomatic/psychogenic pain and other illness. Prognoses for recovery uncertain.
5. Nacissistic (two sub-types)
   a. Treatable type – they are superficially nice, personable but have a severe emotional wound (e.g., sexual abuse) that drives them; they tend to be passive-aggressive, inordinately sensitive to criticism and inordinately needy of praise/validation from others. While capable of empathy, they tend to be pretty self-absorbed and self-centered; they have a high risk for addictions to assuage shame/low self-esteem/depression. They are also prone to jealousy/envy.
   b. Untreatable/Malignant type – these folks truly believe they are superior to just about everybody else on the planet. Accordingly, they demand constant adulation and "special" treatment everywhere they go. They have fantasies of perfection, may be pre-occupied with envy and typically have an insatiable need for power, wealth, prestige and attention. They are excessively sensitive to shame and embarrassment. If you work for them, they will take credit for

your successes and blame you for their failures. When confronted with their short-comings, they will quickly become hostile and defensive and will project blame on to people and circumstances outside themselves. High risk for addictions, sado-masochistic sex and white-collar crime; may have psychopathic tendencies.

6. Compulsive/Perfectionistic – they can be stiff, perfectionistic, aloof, unemotional, unempathic, overly conscientious and controlling; they often have difficulty seeing the "bigger picture" and can become pre-occupied with details. They are riddled with free-floating anxiety and tend to keep this at bay by creating a meticulously-ordered, efficient and, at times, beautiful environment which belies their internal pain/distress. They can be rigid, unforgiving and unyielding when dealing with interpersonal conflict; they don't like or tolerate "mess". They are prone to workaholism and other addictions; also prone to severe depression at mid-life; good prognosis for recovery.
7. Passive-Aggressive – they are inordinately fearful of anger and conflict and tend to deal with their own angry/hurt feelings in covert, often "sneaky" ways; they are exquisitely sensitive to being manipulated or controlled: any request you make of them will likely be seen as an attempt to manipulate/control them and will be resented. They are notoriously late for appointments and other time commitments. They frequently express irritation by brooding, complaining, sulking or by being deliberately inefficient. In more intimate relationships they will withhold affection or sex to "punish" the loved one, but never be open/clear about the source of their upset. Poor prognosis for treatment, largely due to the fact that they derive pleasure/a sense of superiority by being unforgiving.

V. Special Focus: Other Sources of Noxious Behavior

A. Mood-Disordered: Minor and Major Depression and Bipolar-disordered individuals; If untreated, these conditions can have a pervasively negative impact on mood, cognition, impulse control, judgment and social behavior. They can also lead to a host of psychosomatic illnesses, including chronic physical pain, eating disorders, cardiovascular disease and severe gastrointestinal distress.

B. Anxiety-Disordered: Generalized anxiety, pathological perfectionism, obsessive-compulsive disorder; all of these conditions can impair emotional, cognitive and social functioning. "Neurotic stupidity," a common characteristic of anxiety-based disorders, can precipitate vicious cycles of maladaptive behavior and impair insight and social awareness.

C. Post-Traumatic Stress Disorder (PTSD): Horror frozen in memory; intrusive thoughts, dreams and feelings and the risk of secondary, "vicarious" PTSD in caregivers who witness trauma.

VI. De-Toxification Strategies

A. Take excellent care of you:
   1. Diet, exercise
   2. Daily meditation/prayer
   3. Balance work/play/spiritual life/social support
   4. Have you been "shoulding" on yourself?
   5. Learn the basics of Active Empathic Listening
   6. Learn the basics of assertiveness, e.g., D-E-S-K model
   7. Ask yourself: "What is my piece of this noxious situation?", e.g., are you enabling this person?

B. What is the nature of the noxious behavior?
   1. Inappropriate expression of anger?
   2. Boundary violation?
   3. Abuse of power/control?
   4. Behavior related to obvious mental illness? -e.g., agitated depression, bipolar disorder, personality disorder, etc.
   5. Behavior related to substance abuse?
   6. Behavior related to misunderstanding, clash of cultures or some other aspect of communication?
   7. Behavior related to individual's anxiety, fear, ignorance, prejudice?

C. What are your feelings about this behavior?
   anger, outrage, fear, intimidation, disgust, etc.

D. What are your thoughts/beliefs/assumptions about the individual and his/her behavior?
   e.g., "he said that just to embarrass me…"

E. Talk about what you've experienced with a colleague, friend, counselor or supervisor.

F. Develop a plan for dealing with the noxious/stressful situation, especially if the noxious behavior is repetitive/part of a larger pattern.

1. Assertive Model:
   a. Identify the specific behavior which has upset you.
   b. Ask yourself what feelings you have about the behavior in question.
   c. Wait at least 24 hours before confronting the other person with their behavior. During this period of reflection ask yourself (and others) how best to handle the situation.
   d. Pick a time that is convenient for both you and the other individual and express your concern.
   e. Lead with an empathetic or affirming statement.
   f. Use the "D-E-S-K" model to express your concern/feeling.
   g. Negotiate a resolution to the problem once you feel the other person understands the issue/your concern.
   h. Follow through with the agreed-upon changes in behavior.
2. Other strategies:
   a. Paradoxing/Fogging e.g., "That's interesting." (When inwardly you disagree)
   b. Work at accepting the person while not liking their toxic behavior.
   c. Find something to respect and admire about the toxic individual; let them know about this in a genuine, affirming way.
   d. Try to get a better sense of what "sets the other person off"; avoid these buttons, if possible.
   e. Keep your distance from those who seem unsafe; see your fear as a "gift" or warning sign.
   f. Set clear, unambiguous limits with inappropriate behavior; make it clear that you will not tolerate this and will seek help if the situation does not change.
   g. If you feel you are in danger, notify appropriate authorities; take whatever reasonable steps necessary to ensure your safety.

VII. Treatment For the Noxious Individual

A. Treatment components/modalities
   1. Individual psychotherapy, e.g., cognitive-behavioral therapy
   2. Group therapy, e.g., strategic family therapy
   3. Skills training (see M. Linehan, 1993)
   4. Milieu treatment (e.g., in-vivo desensitization)
   5. Pharmacotherapy (e.g., SSRI's and mood stabilizers)

B. Specific recommendations for professional caregivers:
   1. Do a thorough assessment.
   2. Be clear about your role and boundaries.
   3. Set realistic, behavioral treatment goals.
   4. Balance empathy with the technology of change.
   5. Hold the patient accountable without being punitive.
   6. Do not participate in the patient's psychodramas; in particular, resist the desire to rescue or attack the patient; focus instead on the specific maladaptive coping behaviors: "Is this getting you what you really want?" "Would you be willing to learn other ways to get what you want (that are not self-destructive or off-putting/harmful to others)?"
   7. Do not allow yourself to be held hostage by any patient; terminate with the patient and explain your reasons for doing so.
   8. Do not confuse "abandonment" with appropriate termination. Legitimate reasons to terminate:
      a. Patient not appropriate for treatment;
      b. Patient clearly isn't benefitting from treatment;
      c. Continued treatment could prove harmful to the patient; and
      d. Patient is trying to hold practitioner hostage with suicidal threats.
   9. Hospitalize patients who are suicidal/a threat to others.
   10. Document, document, document…
   11. Seek the counsel of colleagues when working with any high conflict patient and document this in the patient's chart.
   12. Be aware of your counter-transference, address it but do not share it with the patient.

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THE TEN COMMANDMENTS OF HOW TO GET ALONG WITH PEOPLE

1. Keep skid chains on your tongue. Always say less than you think. Cultivate a low, persuasive voice. How you say it often counts more than what you say.

2. Make promises sparingly and keep them faithfully, no matter what the cost.

3. Never let an opportunity pass to say a kind and encouraging word to or about somebody. Praise good work, regardless of who did it.

4. Be interested in others; their pursuits, their work, their homes and their families. Make merry with those who rejoice; with those who weep, or mourn. Let everyone you meet, however humble, feel that you regard him/her as a person of importance.

5. Be cheerful. Don't burden or depress those around you by dwelling on your aches and pains and small disappointments. Remember, everyone is carrying some kind of burden.

6. Keep an open mind. Discuss but don't argue. It is a mark of a superior mind to be able to disagree without being disagreeable.

7. Let your virtues, if you have any, speak for themselves. Refuse to talk about the vices of others. Discourage gossip. It is a waste of valuable time and can be destructive and hurtful.

8. Take into consideration the feelings of others. Wit and humor at the expense of another is never worth the pain that may be inflicted.

9. Pay no attention to ill-natured remarks about you. Remember, the person who carried the message may not be the most accurate reporter in the world. Simply live so that nobody will believe him/her. Disordered nerves and bad digestion are a common cause of back-biting.

10. Don't be anxious about the credit due you. Do your best and be patient. Forget about yourself and let others "remember." Success is much sweeter that way.

SELF EVALUATION

Understanding and Effectively Dealing with High Conflict People

1. Which of the following is not a characteristic of the high-conflict individual?
   a. A long history of interpersonal conflict
   b. Pathological childhood relationships
   c. Remarkable empathy for the feelings of others
   d. Aggressive energy

2. Common defenses seen with high-conflict individuals include all but which of the following?
   a. Splitting (e.g., black-or-white thinking)
   b. Projection
   c. Blaming others for problems they create
   d. All of the above are seen with high-conflict people.

3. Which of the following is true of the high-conflict individual?
   a. They trigger defensive reactions in others.
   b. They have an inordinate amount of aggressive energy.
   c. They are prone to be litigious.
   d. All of the above are true.

4. Aggressive behavior can be fueled by which of the following?
   a. Stress
   b. Poor physical health, e.g., lousy diet, lack of exercise, chronic pain, etc.
   c. Atypical brain chemistry, e.g., low in serotonin
   d. Toxic relationship dynamics
   e. All of the above can fuel aggression.

5. Which of the following are common behavioral problems with high-conflict individuals?
   a. Boundary violations
   b. Problems managing anger and aggression
   c. Narcissistic behavior
   d. All of the above are behavioral problems with high-conflict individuals.

6. Self-abusive behavior:
   a. Rarely represents a suicide attempt.
   b. Is typically motivated by attention-seeking
   c. Is rarely a serious issue requiring formal intervention
   d. A only

7. Biological factors which may impact the genesis of toxic behaviors include:
   a. Biogenetic influences, e.g., atypical brain chemistry, inherited psychiatric disorders, etc.
   b. Pre-birth or post-birth trauma to the central nervous system.
   c. Chronic or acute substance abuse
   d. Hormonal changes or imbalances
   e. All of the above

8. Borderline personalities:
   a. Straddle the border between sanity and psychosis.
   b. Are typically triggered by real or perceived abandonment.
   c. Have primitive ego defense mechanisms, including splitting and projection of blame.
   d. Rarely seek professional treatment.
   e. A, B, and C are true

9. A serotonin deficiency can cause which of the following symptoms?
   a. Problems with affect regulation, e.g., depression
   b. Anxiety-based disorders, e.g., OCD
   c. Problems with impulse control and judgment
   d. All of the above

10. Health professionals who treat high-conflict patients should:
   a. Be clear about your role and boundaries
   b. Set realistic treatment goals collaboratively with the patient.
   c. Strive to balance the technology of acceptance with the technology of change.
   d. Not allow themselves to be held hostage by any patient.
   e. All of the above.

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

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Successful Negotiating and Effective Decision Making

The Agenda for Today

Learn

- Mindset for effective negotiations
- Factors that can derail your negotiation
- A system that will ground you in safe decision making

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Jim Camp

1946 - 2014

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August 16, 1987

Romulus, MI

NWA FL 255

Passengers: 149

Crew: 6

Fatalities: 156

Only one passenger survived

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The NationalTransportation Safety Board determines that the probable cause of the accident was the flight crew's failure to use the taxi checklist to ensure that the flaps and slats were extended for takeoff.

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The Why

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The Why

We negotiate everything in life

- Spouse
- Children
- Patients
- Contractors and Suppliers
- Partners, Co-workers, Bosses

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The Why

We negotiate everything in life

Patients

Contractors and Suppliers

Partners, Co-workers, Bosses

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Decision Making

Every person has a unique path to how they reach decisions. This is based on their biology, beliefs, experiences, habits and biases

Up to 90% of the decisions we make do not use active thinking

They are automatic and can obscure reality

We do this to conserve energy and increase speed

We are programmed to make 'good enough' decisions

We can improve our decision-making ability by being aware of our and our respected opponent's decision path

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The Four Negotiation Strategies

Win-Win: people who believe that compromise is a requirement and have an overriding need to be friends at the end of the negotiation

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Amateurs: people who don't know what they or they other side really wants and behave unpredictably during the negotiation

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The Four Negotiation Strategies

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Amateurs: people who don't know what they or they other side really wants and behave unpredictably during the negotiation

Bullies: people who don't care about their opponent and just want the best deal for themselves possible

Professionals: people who are happy with what they get, pursue their objectives systematically, and would be welcomed to participate in a future negotiation

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The Case Against Win-Win

Assumes you need to compromise before you start

Can not be objectively measured until the agreement is implemented which may be years in the future

It's an emotion based strategy that puts emphasis on being friends vs being effective and respected

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What is a Negotiation?

A negotiation is the effort to arrive at an agreement between two or more parties, with all parties having the **right to veto**.

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Predators

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Predators Prey on Weakness

What makes you weak?

Desire for

Money

Power

Status

They want you to be afraid of saying "no"

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Tactic vs Principle

Tactic (n) - an action or method that is planned and used to achieve a particular goal

Principle (n) - a basic truth or theory: an idea that forms the basis of something.

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Start with "NO"

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Start with "NO"

Not about saying “NO”

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Start with "NO"

Not about saying “NO”

It’s about inviting “NO”

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Start with "NO"

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Lowers DEFENSES

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Start with "NO"

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It’s about inviting “NO”

Lowers DEFENSES

Builds credibility

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Start with "NO"

Not about saying “NO”

It’s about inviting “NO”

Lowers DEFENSES

Builds credibility

Shows where you differ on issues

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Allow Yourself to Hear NO

If they say NO, it means they don’t like me

If they say NO, my feelings might be hurt

If they say NO, it’s over

If they say NO, I’ve failed

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Allow Yourself to Hear NO

If they say NO, it means they don't like me

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If they say NO, it's over

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Allow Yourself to Say NO

If I say NO, I'll be disliked

If I say NO, I'll hurt their feelings

If I say NO, I might really damage relationship

If I say NO, I'll come across as being mean

If I say NO, it's all over

If I say NO, the deal is lost and then I've failed

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If I say NO, the deal is lost and then I've failed

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What's Worse…

No Deal
Bad Deal

No deal is better than a bad deal
No hire is better than a bad hire
No contract is better than a bad contract

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Signs of a Poor Negotiation

They accepted your first offer

You offered, they countered and you split the difference

You didn't ask any questions

They didn't ask any questions

Neither side tried to tweak the deal

You negotiated only one issue (such as price)

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The Effective Negotiator

Effective decision making

Mission and purpose driven

Set valid activity/behavior goals and objectives

ID and plan to solve "real problem"

Focused

Growth mindset

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Mindset

Thoughts & Feelings ➡ Actions & Behaviors

Fixed Growth

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Let us never negotiate out of fear.
But let us never fear to negotiate.

- John F Kennedy

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What We Really Manage

What is it that we actually control?

The Results

The Systems

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What We Really Manage

What is it that we actually control?

The Results

The Systems

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Protection From Our Emotions

Systems work to provide guidance in decision making

Systems help to reduce and control emotions

Systems help reduce errors and provide safety

Using a **system** consistently can work to change your mindset

A **system** helps you create a plan

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Fear

Fixed (Scarcity) ➡ Focused on us

Rejection Losing

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Their Tactics

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Powerful Psychology

Framing Effect

Prospect Theory

Loss Aversion

Certainty Effect

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Framing Effect

People respond differently to same choice based upon how it is presented to them

You're offered the opportunity for a 10% change

90% → 100% 10%

45% → 55% 10%

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Framing Effect

People respond differently to same choice based upon how it is presented to them

You're offered the opportunity for a 10% change

90% → 100% 10%

45% → 55% 10%

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Prospect Theory

People are drawn to sure things over probabilities even when the probability is a better choice

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Loss Aversion

People will take greater risk to avoid losses than to achieve gains

Gain		Lose	
Probability	Amount	Probability	Amount
95%	$10,000	95%	$10,000
100%	$9,500	100%	$9,500
Gain less		Lose more	

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Probability	Amount	Probability	Amount
95%	$10,000	95%	$10,000
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Gain less — Lose more

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Certainty Effect

People are drawn to sure things over probabilities even when the probability is a better choice

Probability	Amount
95%	$10,000
100%	$9,500

Gain less

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The Relationship

"They won't like us if we don't discount or give them want they want"

They will likely bring up relationship as a leverage tool - induce your fear and neediness

Never take responsibility for the other side's decisions. Never "save the relationship."

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RESPECT

"I can't be your friend here. I'd prefer you respect me and I think that's probably what you would prefer too. Because I respect you, I'm going to be straight with you. We simply cannot do what you've requested."

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The System

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The System

- Mission and Purpose
- Behaviors
- Questions
- Budgets
- Checklist
- Log

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Mission & Purpose

What

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Mission & Purpose

What Why

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Mission & Purpose

What Why

Concise Always written

Rooted in their world

Their problems

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Bad Behaviors

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Neediness

Is a way of thinking

It's a story you tell yourself

It's the emotions you feel

The emotions you display

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Neediness

Talk too much

Vocabulary

Rush to close

You get excited about the success of the deal

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Dangerous Behaviors

Come from fixed mindset

Assumptions

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Dangerous Behaviors

Come from fixed mindset

Assumptions

Expectations

No negative or positive expectations are allowed in a professional negotiation.

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Good Behaviors

No Talking

Never answer the unasked question

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Good Behaviors

No Talking

Never answer the unasked question

3+

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Good Behaviors

No Talking

Never answer the unasked question

Listen

3+

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Good Behaviors

No Talking

Never answer the unasked question

Listen

3+

Be less okay

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Good Behaviors

No Talking

Never answer the unasked question

Listen

3+ Be less okay

Steady Emotions

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Good Behaviors

No Talking

Never answer the unasked question

Blank Slate

Listen

3+ Be less okay

Steady Emotions

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Good Behaviors

No Talking Take good notes

Never answer the unasked question

Blank Slate

Listen

3+ Be less okay

Steady Emotions

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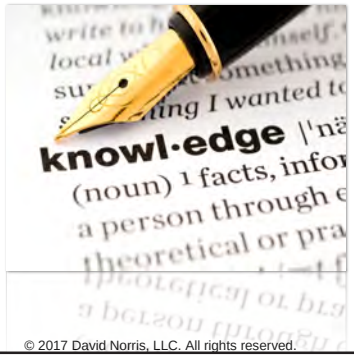
Gather Info



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Where to Look

Web searches
Business papers and magazines
Financial statements and annual reports
10-K, 10-Q, 8-K, Schedule 13D
Form 990 - guidestar.com
Industry & trade organizations and magazines
The marketplace as a whole

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Questions

The other side expects a fight - an argument
Asking questions throws them off their game
Gets you out of the offer-counter-offer game

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Asking Questions

Good questions are key to effective negotiating

Two types

- Verb-led
  - Yield answers : Yes, No, Maybe
- Interrogative
  - Who, What, When, Where, Why, How

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Asking Questions

Good questions are key to effective negotiating

Two types

- Verb-led
  - Yield answers : Yes, No, Maybe
- Interrogative
  - Who, What, When, Where, Why, How

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Ask Questions

WHY?

Use why carefully

- Can see to be an accusation at times
- Why would you ever change/leave/move?
- Why would you want to work for/with us?

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Labeling

Spot their feelings, turn them into words - repeat their emotions back to them

- It seems like…
- It looks like…
- It sounds like…
- Avoid "I"

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The F-Word

Don't assume they have the same yardstick when measuring what is **FAIR**

Avoid projecting your values onto them

You may hear

- "I just want what's fair…"
- Respond with "OK Sorry. Let's stop and go back to where I starting treating you unfairly"
- "We've given you a fair offer…"
- "It seems like you're ready to provide the evidence to support that claim."

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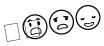
Email

Hard to negotiate via email

- Gives them too much time to think, calm down, recenter themselves
- They can really control the amount of information they reveal
- 7/38/55



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Email

If you're being ignored - provoke a no

Have you given up on this opportunity?

Don't be afraid to use your right to veto

Sometimes you have to force them into "no" to get them to listen and engage

Mislabel their actions, emotions, desires

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If They Seem To…

Go off the rails they might be

Ill-informed - have bad information

Constrained - something you don't know about is holding them back

Have other interests

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If They Seem To…

Go off the rails they might be

Ill-informed - have bad i

Constrai you don't know

them back

Have other interests

Remember - NO ASSUMPTIONS

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Budgets

Time **1x**

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Budgets

Time **1x**

Energy **2x**

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Budgets

Time **1x**

Energy **2x**

Money **3x**

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Budgets

	Time	**1x**
	Energy	**2x**
	Money	**3x**
	Emotion	**4x**

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The Medical Record of the Negotiation

Before the event,

Create a checklist/prep sheet

Everyone on the team shares and uses it

After the event,

Create a log

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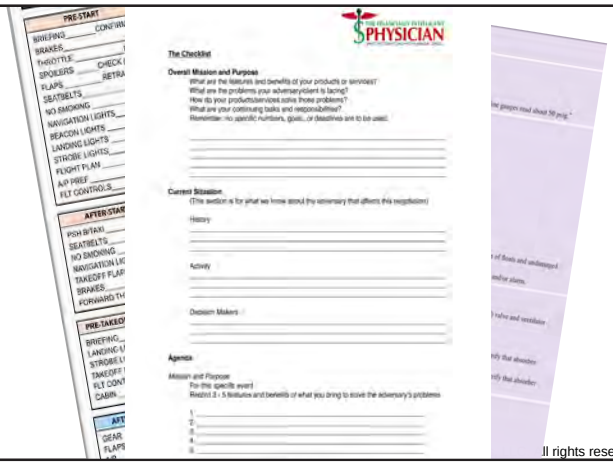

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Checklist

1. Mission & Purpose

Our Overall Mission and Purpose

Must be:

Based in their world to solve their problem and for their benefit. Big picture.

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Checklist

2. Current Situation

Changes

What has happened since last meeting?

History

What has led up to this point?

Activity

What have we done? What have they done?

Decision-Makers

What is their decision-making process?

Who is involved on their side?

Who is involved on our side?

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Checklist

3. Agenda
   A. Mission & Purpose for this Specific Event
      This Events Mission and Purpose
      Must be:
      Based in their world to solve their problem and for their benefit. Focused on details.

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Checklist

3. Agenda
   B. Problems
      Anything that holds us back from a successful conclusion
      When we ID a problem, we must deal with it in the upcoming negotiation.

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Checklist

3. Agenda
   C. Baggage
      Our collected life experiences and observations
      Our baggage
      Their baggage

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Checklist

3. Agenda
   D. What We Want
      If you don't know what you want, you will likely wind up getting what someone else wants.

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Checklist

3. Agenda
   E. What Happens Next
      Have a plan for the next step.
      Leads to next negotiation event.

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Checklist

4. Activities & Goals
   Team Behaviors
      Avoid neediness.
      Connect with them as people. Nurture.
      Be silent and take good notes.
   Assignments
      Let the experts talk in their expert area.
      Assign who will speak about what.
   Questions
      Create 3 to 5 interrogative questions that will help build vision of their pain.

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Log

1. Participants
   - Who was present
     - This side
     - Our side
2. Their Pain
   - What is their identified pain or problem(s)?
   - What new problems did we identify?
   - Summarize your perception of their pain

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Log

3. Budgets

	Theirs	Ours
Time	_____	_____
Energy	_____	_____
Money	_____	_____
Emotion	_____	_____

- Keep track of the budgets.
- Know if your emotional is getting too high.
- Know how high their emotional budget is.

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Log

4. Decision Process
   - What new information about their decision making process was discovered?
   - Who else might we need to involve?
5. Summary of Event
   - Write down a summary of your thoughts about how the session went. Be honest. Do this as soon as possible.
6. Next Potential Agenda
   - Use this log information to create your next negotiation agenda.

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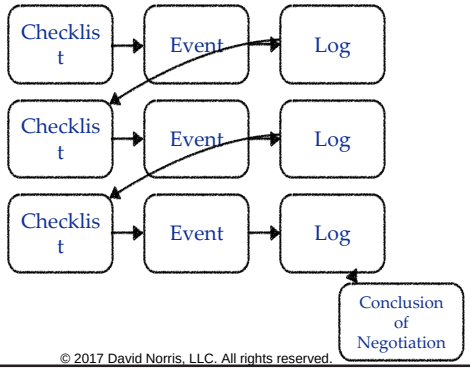
The Cycle



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But Wait, We Can't Say No…

Why?

- Financial burden
- Operational obligations
- Market share
- Public relations
- Fear

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Fear

What are you afraid of?

- The loss of revenue
- Why are you wanting to be paid more?
- Are you losing money?
- What is your ethical duty to your family, employees, their families?

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Fear

What are you afraid of?

The loss of revenue

Why… …g to be paid

Remember - NO DEAL > BAD DEAL

Are you losing money?

What is your ethical duty to your family, employees, their families?

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Fear

What are you afraid of?

The public relations

What's you mission and purpose?

Does the community know it?

Do you live it?

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The Internal Negotiation

Might be the most important negotiation of all

Leadership must be on-board with plan

Use the system to uncover

- The fear/pain/problems of your organization
- The decision makers
- Reach a negotiated plan internally **before** negotiating with the adversary

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The Internal Negotiation

Begin by defining and agreeing upon the M&P

Define the problems that you face internally

Know your decision making process

Know what you want

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The Adversary Has Needs

They sold a piece of paper to the patient/employer/plan

They have a contract to fulfill

Is there capacity in the market space to accommodate your volume so you exercise your right to veto?

They will use fear and predatory practices to grind you down and establish fear in you

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Imagine…

Imagine what you could do if…

- You could control your emotions
- You were prepared for the negotiation
- You didn't feel fear
- You didn't show fear
- You knew what you wanted

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Fastest Way to Get What You Want

Professional athletes use coaches to help them improve their performance

- How do you plan to improve your performance?
- Get negotiations consulting help today
- Contact me to negotiate stronger deals
- david@davidnorrismdmba.com
- 316-200-2785

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Summary

- It all starts with mindset
- Be mindful of your behaviors
- Write down a checklist and log
- Create a negotiation plan and avoid missteps

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Session Objectives

- Describe the need for a structured approach to negotiations
- Recognize the impact of mindset on the negotiation encounter
- Formulate a solid and successful model for negotiations

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Learn More

www.davidnorrismdmba.com/negotiation-resources

david@davidnorrismdmba.com

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SELF EVALUATION

Successful Negotiating and Effective Decision Making

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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Understanding, Diagnosing and Managing Transthyretin Amyloidosis

Objectives

- Understand the pathophysiology of ATTR as a member of the protein-misfolding disorders
- Recognize clinical presentations suspicious for ATTR as encountered in the primary care setting
- Become familiar with the non-invasive diagnosis of ATTR cardiomyopathy
- Learn the fundamentals of some currently available pharmacotherapies for ATTR

Where to Start?....What is Amyloidosis? The Pathologist's Point of View

"…a condition associated with a number of inherited and inflammatory disorders in which extracellular deposits of fibrillar proteins are responsible for tissue damage and functional compromise."

Robbins and Cotran Pathologic Basis of Disease (10th Ed); Elsevier: 2021

ATTR: Where to Start? The PCP Point of View

GUIDELINES

Avoiding misdiagnosis: expert consensus recommendations for the suspicion and diagnosis of transthyretin amyloidosis for the general practitioner

Gertz M et al *BMC Family Practice* 2020;21:198:1-12

ATTR: Where to Start?: The PCP Perspective

"…a systemic life-threatening disease characterized by TTR fibril deposition in organs and tissues….a definitive Dx….is often a challenge…because of its heterogeneous presentation….cardiac and peripheral neurons are most frequently involved…also…GI and other systemic manifestations….often misDx as a more common disorder leading to significant delays in the initiation of Rx."

Gertz M et al *BMC Family Practice* 2020;21:198:1-12

ATTR: Why Bother?

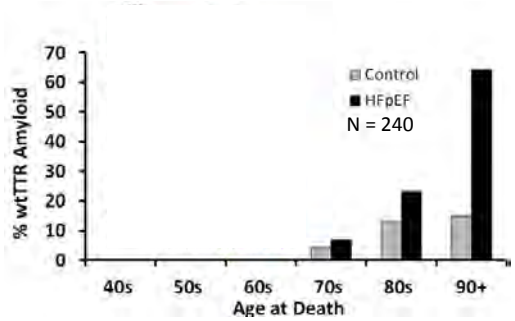
- Epidemiologic Burden
- Pathophysiology Well Described
- Cardiac ATTR; Highly Consequential
  - CHF (HFpEF)
  - Rx →↓ Mortality & Morbidity
- Diverse non-cardiac targets
- Genetic Counseling (hereditary form)

ATTR: Why Bother?

"…. ATTR…almost certainly the most common cause of cardiac amyloidosis…potentially accounting for up to 10% of elderly patients with HF."

Witteles RM Bokhari S, Damy T, et al "Screening for Transthyretin Amyloid Cardiomyopathy in Everyday Practice" *JACC* 2019;7(8):709-16

Autopsy Analysis: wtATTR in HFpEF
(No Prior Amyloidosis Manifestations Noted)



Mohammed SF et al *JACC: Heart Failure* 2014;2:113-22

ATTR: Why Bother?

"ATTR deposition is seen in up to…17% of patients with HFpEF."

Kittleson MM Maurer MS, Ambardekar AV, et al "Cardiac Amyloidosis: Evolving Dx and Management" *Circulation* 2020:142:e7-e22

Epidemiologic Burden of ATTR-C

"Amyloid cardiomyopathy should be suspected in any patient who presents with heart failure and preserved ejection fraction."

Gertz MA et al *J Am Coll Cardiol* 2015;66:2451-2466

Nomenclature: ATTR

- ATTR = Transthyretin amyloidosis
- Transthyretin: a protein transport carrier for
  - thyroid hormones T_3 and T_4 (the 'thy' of transthyretin)
  - retinol (the retin of transthyretin)
- *Transthyretin*

= *trans*ports *thy*roxine and *retin*ol

Whence 'Amyloid' ?: The Persistent Misnomer

German botanist, anatomist, lawyer, and physician (1804-188

- **1814**: (Colin & Gaultier de Claubry): starch stains blue with iodine/sulphuric acid application
- **1838**: (Schleiden): reports iodine-sulphuric acid test reaction in plants
- **1842**: (Schleiden): Publishes the term 'amyloid' for 'starch-like'(from latin amylym = starch)
- **1854** (Virchow): first publishes article using 'amyloid'

Tanskanen M *Amyloidosis Intech* 2013

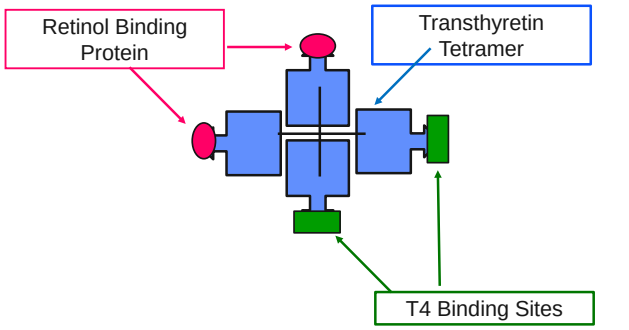
Amyloidosis:
One of the Protein Misfolding Disorders

"What the Heck is
a
'Protein Misfolding Disorder'?"

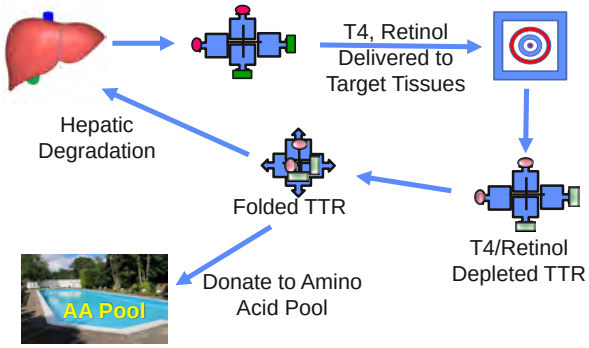
Protein Misfolding Disorders: Examples

Alzheimer's Disease	Cystic Fibrosis
Parkinson's Disease	Lewy Body Dementia
TTR Cardiomyopathy	ALS
AL Amyloidosis	Marfan's Syndrome
α-1-antitrypsin deficiency	Huntington's Disease

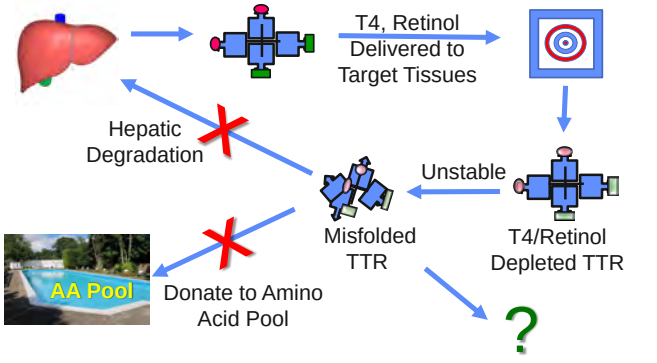
Transthyretin: Normal Configuration



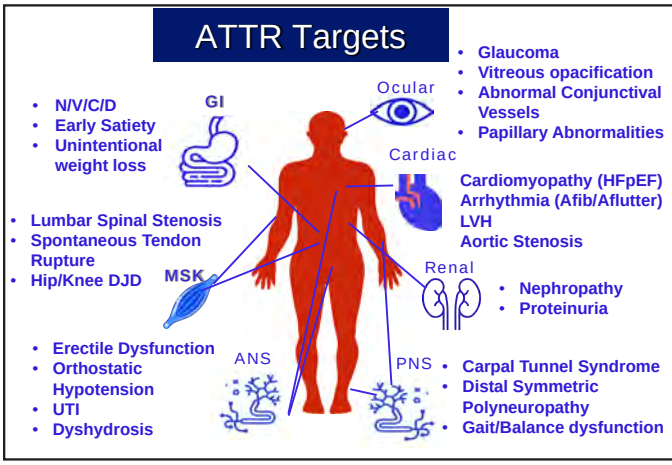
Transthyretin Metabolism: Normal Folding



Unstable Transthyretin Metabolism: Misfolding



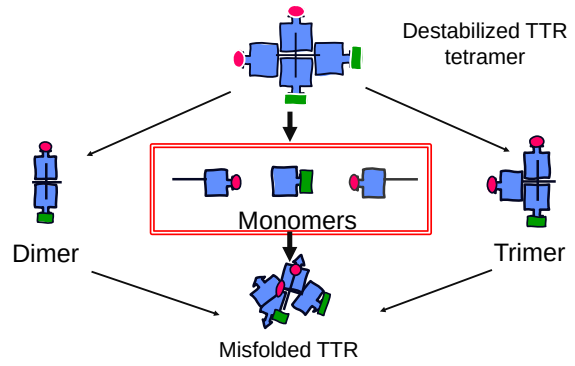
ATTR Targets



What Leads to Misfolded Proteins?

Protein Instability
Oversupply

Unstable Transthyretin Can Misfold
Destabilized TTR Fragments to Smaller Oligomers



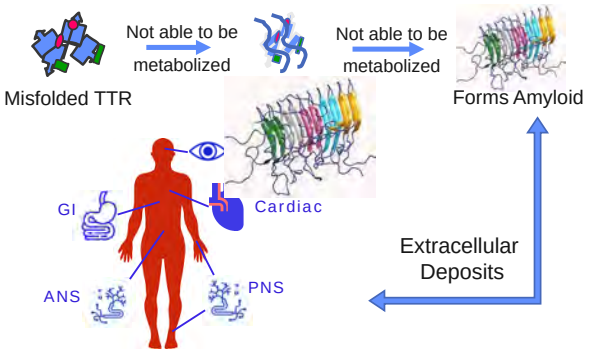
Why Leads to Proteins Instability?

Genetic Defects (eg, Amino Acid Substitutions)

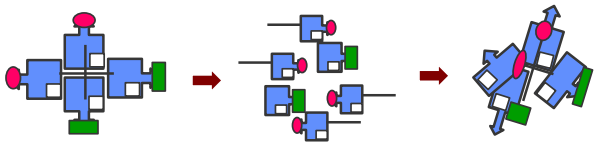
Protein Senescence (Age Concordant)

Over-Supply
(e.g., Multiple Myeloma, Light Chain Disease)

The Fate of Misfolded TTR



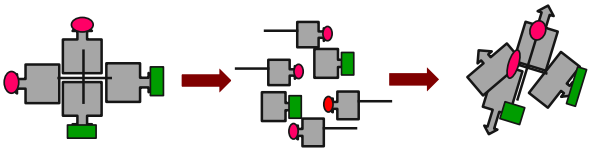
Unstable Transthyretin Can Misfold
Genetic Defects: Amino Acid Substitution



AA-Substituted TTR → TTR Monomers → Misfolded TTR

□ = Substituted Amino Acid

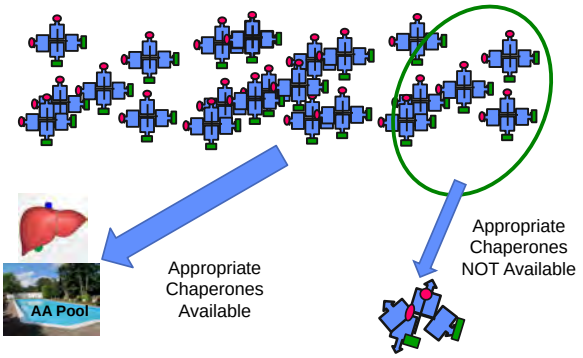
Unstable Transthyretin Can Misfold Senescent TTR



Senescent TTR → TTR Monomers → Misfolded TTR

■ = Senescent TTR

Excess Transthyretin Can Misfold Overproduction Outpaces Chaperone Process



Some Other Important Amyloidoses

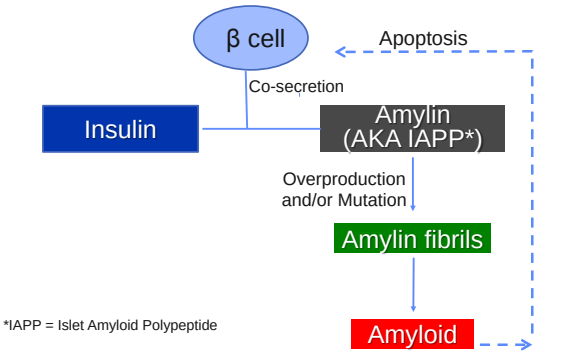
Light Chain Amyloidosis (AL)
Plasma Cell Dyscrasia → ↑↑IgG Light Chain Production
Common Targets: Cardiac, Renal

β-amyloid Protein Amyloidosis (Aβ)
Amyloid precursor protein proteolytic product accumulation
Common Targets: CNS (Alzheimer Disease)

IAPP (amylin) Amyloidosis
Amylin induced amyloid generation
Common Targets: Pancreatic β cell (T2DM)

Robbins and Cotran Pathologic Basis of Disease (10th Ed); Elsevier: 2021

Is T2DM Actually β-Cell Amyloidosis?

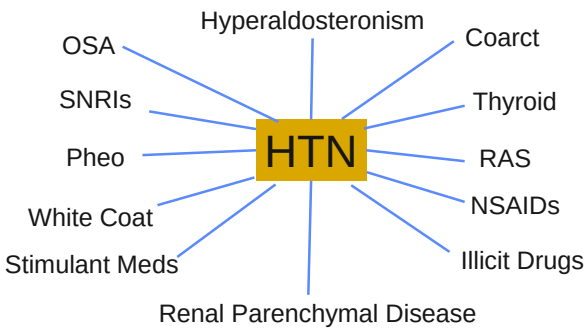


*IAPP = Islet Amyloid Polypeptide

Ponce-Lopez T, Sorsby-Vargas M, et al "DM and Amyloid Beta Protein Pathology in Dementia" *Intertech Open 2019; DOI: http://dx.doi.org/10.5772/intechopen.84473*

So, Is Amyloidosis ONE DISEASE or MANY?

Well, Is HTN One Disease or Many?

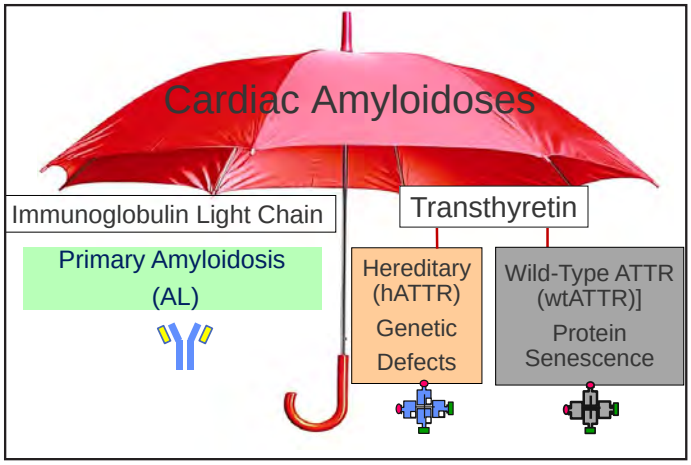


So, Like HTN, Amyloidosis is…

"…Amyloidosis is not a single disease, but rather a group of diseases having in common the deposition of similar appearing proteins."

Robbins and Cotran Pathologic Basis of Disease (10th Ed); Elsevier: 2021

Focus on ATTR-C
(Transthyretin Amyloidosis Cardiomyopathy)



Hereditary ATTR: Valine-122-Isoleucine

- Most common genetic ATTR-C in US
- 3.43% Black Americans (1.5 million persons)
- Clinical penetrance age dependent
- ↑Risk of HF (RR 2.62)
- ↑mortality rate with ATTR-C

[1]Buxbaum J, et al. *Am Heart J.* 2010 159 (5): 864-870
[2]Shah K, et al. Circ Heart Fail. 2017. 9(6): p 5

Wild-type ATTR (wtATTR): Not so Rare…

- MORE common than hereditary ATTR
- Increases with Age; Male Predominance
- 25% >80yo with Bx evidence of cardiac wtATTR[1]
- Spanish study (n=120): 13% of pts ≥60yo admitted for HFpEF found to have wtATTR[2]

[1]Mohammed SF et al *JACC: Heart Failure* 2014 p 4
[2]González-López E, et al. Eur Heart J. 2015 Oct. p 2589

ATTR: Why So Often Unrecognized?

Generally, ATTR presenting signs/SxR *much* more commonly explained by other etiologies:

- Carpal Tunnel Syndrome (CTS) ≈ Repetitive Use
- HFpEF ≈ Hypertensive heart disease
- ED ≈ Vasculopathy
- Spinal Stenosis ≈ DDD

ATTR Clinical Presentations

	hATTR	wtATTR
Onset	**Variable** (per Genotype); >20yo	Median age **> 70yo**
Gender	Male = Female	Male > Female
Clinical Presentations	**Cardiac** & **PNS**	**Cardiac** & **Tenosynovial**
	Heart Failure (HFpEF) **Arrhythmia (Afib / Aflutter)** **Aortic Stenosis** **Conduction System Disease/Ventricular Arrhythmias**	
	Bilateral CTS **Polyneuropathy** **Autonomic Neuropathy**	**Bilateral CTS** **Lumbar Spinal Stenosis** **Hip/Knee DJD**
Dx Delay	~ 3 years	~2 years

Ruberg FL, et al. J Am Coll Cardiol. 2019;73(22):2872-2891

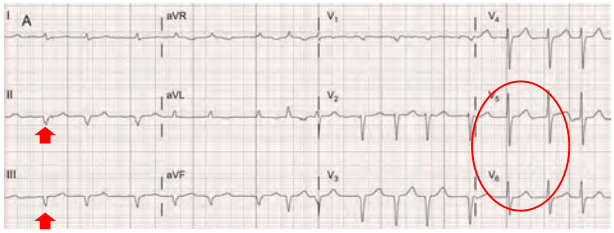
Wt-ATTR Clinical Cues: Precede or Concomitant with ATTR-C

- Carpal Tunnel Syndrome (esp Bilateral)
- Lumbar Spinal Stenosis
- Hip/Knee DJD
- Spontaneous Tendon Rupture
- β-blocker/CCB Exaggerated Response
- Myo-Electric Gap: Discordant ECHO vs ECG LVH
- Elevated Cardiac Biomarkers (troponins, BNP)
- Atrial Fibrillation/Flutter (69%)
- Aortic Stenosis (6-12%)

[1]Ruberg, *J Am Coll Cardiol*, 2019. p2875-2878
[2]Donnellan E, et al. *J Am Coll Cardiol EP*. 2020 Sep 6 (9): p1120.

ECG: ATTR-C

- Myo-Electric Gap: Low voltage pattern in limb leads (25-40% meet low voltage criteria)[1]
- Pseudo-infarct pattern
- Conduction disease (AV block, fascicular/BBB; Atrial fib)[2]



[1]Rapezzi C, et al. *Circulation* 2009;120:1206
[2]Witteles M, et al. *J Am Coll Cardiol HF* 2019;7(8):713

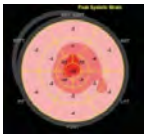
Echocardiogram: ATTR-C

Traditional Echo

- ↑ LV thickness (>12mm)
- Diastolic dysfunction
- Diffuse cardiac hypertrophy

Strain Imaging Echo

- Global longitudinal LV strain
- Apical sparing
- "Cherry-on-the-top" sign
- "Bullseye Map" sign



[1]Dorbala S, et al. *J Car Failure*. 2019. 25(11): E1-E39.
[2]Lee SP, et al. *J Cardiovasc Imaging*. 2019;27(1):p 4. (Image)
[3]Witteles RM, et al. *JACC Heart Fail*. 2019; 7:709–716.

hATTR: Ladder of Initial Presentation

Progressive Symmetric Sensorimotor Neuropathy – 62%

✚ ≥ 1 ← When to 'Pull the Trigger" for ATTR search

Family History
Carpal Tunnel (esp. bilateral) – 33%[2]
Early Autonomic Dysfunction & GI– 29%
Unexplained weight loss – 8%
Cardiac: CHF, arrhythmia, LVH – 10%
Renal, Ocular, Fatigue - <10%

*data from 5 pooled data sets (n = 833)

[1]Conceicao, *J Periph Nerv System*, 2016 p7
[2]Kapoor, et al. *J Neuromuscul Dis*. 2019;6(2):189-199

Carpal Tunnel Syndrome: Sometimes a Harbinger of ATTR-C

Carpal tunnel release pts (n =98):

- Median age = 68
- 51% male
- + tenosynovial amyloid Bx = 10.2%
- hATTR = 2
- Cardiac Amyloidosis = 2

Sperry B.W., et al. *J Am Coll Cardiol*. 2018. 72:2040-2050.

Diagnosis of ATTR-C

1. Exclusion of Plasma Cell Disorder (AL Amyloidosis)
2. Identification of amyloid deposits by histology or non-invasive NM imaging
3. TTR gene sequencing to determine presence of hATTR

Ruberg, *J Am Coll Cardiol*, 2019

Ruling out AL Amyloidosis

Must rule out AL Amyloidosis to reliably dx ATTR-C

1. Serum Free Light Chain levels (k, l, and k/l ratio)
2. Serum and Urine Immunofixation Electrophoresis (*NOT UPEP/SPEP*)

- If Positive → Prompt referral to hematology

Falk RH, et al. *JACC* 2016;68(12): p 1335

ATTR-C Diagnostic Algorithm

Hx, Lab, ECG, Echo, Cardiac MRI: ATTR-C Suspect

↓

Rule out AL Amyloidosis
- Serum Free Light Chains with k/l ratio
- Serum / Urine Immunofixation Electrophoresis

\+ → Hematology Referral

\- → ^{99m}TY-PYP Bone Scan

\+ → Cardiology Genetic Screen

\- → Endomyocardial Biopsy

Kittelson M, et al *Circulation* 2020;143(1):e10.

ATTR: Non-Cardiac Presentation

ATTR Clinical Signals
(Progressive neuropathy, CTS, GI Sx, Spinal stenosis, ED, dysautonomia)
(+) Family History

↓

Exclude Other Potential Dx
NCS if Neuropathy present

↓

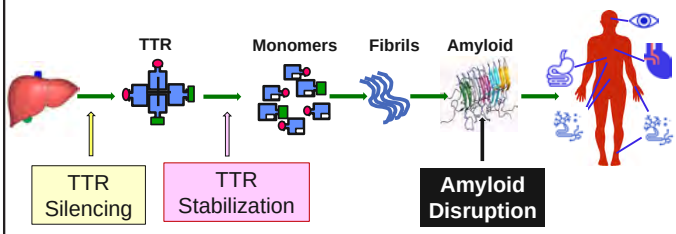
Biopsy of involved organ

↓

TTR Genetic Testing

Potential Approaches to Rx ATTR

- Liver Transplantation
- Targeted Therapeutics



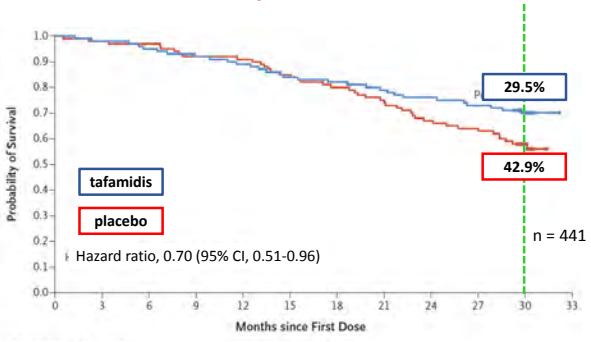
Targeted Therapeutics

ATTR Stabilizers	• Diflunisal • **Tafamidis (*FDA ATTR-C)***
ATTR Silencers	• Inotersen • Patisiran
Amyloid Disruptors	• Doxycycline/TUDCA • Monoclonal Antibodies

Tafamidis Treatment for Patients with Transthyretin Amyloid Cardiomyopathy

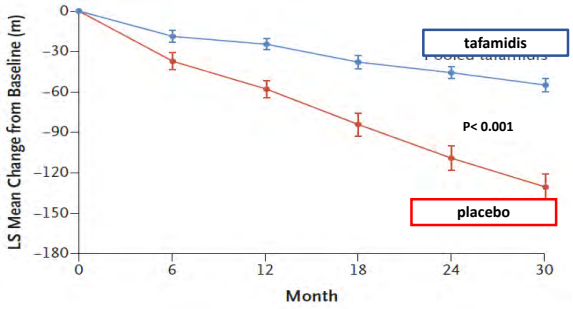
Maurer MS, Schwartz JH, Gundapaneni B et al
NEJM 2018;379(11):1007-1016

Tafamidis in ATTR Cardiomyopathy
All Cause Mortality



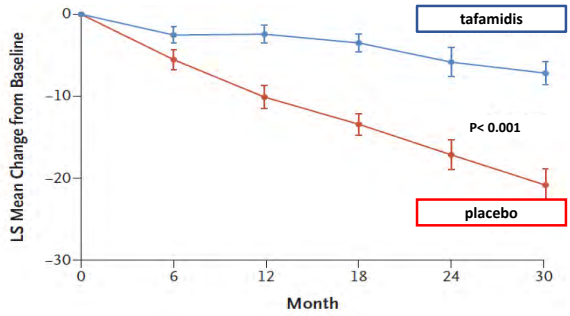
Maurer MS, Schwartz JH, Gundapaneni B et al *NEJM* 2018;379(11):1007-1016

Tafamidis in ATTR Cardiomyopathy:
6-Minute Walk



Maurer MS, Schwartz JH, Gundapaneni B et al *NEJM* 2018;379(11):1007-1016

Tafamidis in ATTR Cardiomyopathy:
Kansas City Cardiomyopathy Questionnaire



Maurer MS, Schwartz JH, Gundapaneni B et al *NEJM* 2018;379(11):1007-1016

What About Tafamidis Tolerability?

"The safety profiles of tafamidis and placebo were similar….Adverse events that emerged during Rx were generally mild to moderate in severity, and permanent discontinuation of tafamidis or placebo as a result of adverse events was less common in tafamidis than in the placebo group."

Maurer MS, Schwartz JH, Gundapaneni B et al
NEJM 2018;379(11):1007-1016

Tafamidis: What the PCP Needs to Know
(or…. did you expect the Cardiologist to practice OB, Pharmacology, and Rheumatology also?)

- **Contraindications**: NONE
- **Drug Interactions**: BRCP inhibitor (may increase BRCP substrates, e.g., methotrexate, rosuvastatin, imatinib)
- **P450 Activity:** Induces P-450 system enzymes 2B6 and 3A4
- **Pregnancy**: no human data. Animal studies indicate fetal harm
- **Lactation**: no human data. Animal studies show presence in breast milk

Vyndaqel, Vyndamax (Tafamadis) Prescribing Information 2020

In Closing…..

"Advances in noninvasive dx, coupled with concurrent demonstration of efficacy and … approval of specific ATTR-CM therapies, has shifted ATTR-CM from a rarely encountered and untreatable "zebra," to a condition that clinicians should consider on a daily basis."

Ruberg F, et al. *JACC* 2019 73(22):2872-2891.

SELF EVALUATION

Understanding, Diagnosing and Managing Transthyretin Amyloidosis

1. What is the most appropriate test to evaluate a 75 y.o. heart failure patient for ATTR-C?

a. Myocardial perfusion imaging stress test
b. Technetium pyrophosphate bone scan (Tc99m-PYP) imaging
c. Serum plasma electrophoresis
d. Electrocardiogram and NT-pro-B-type natriuretic peptide

2. Of the known TTR genetic variants that cause ATTR amyloidosis and are reported in commercially available tests, which is the most common in the USA?

a. Val122Ile also known as V122I or pV142I
b. Thr60Ala also known as T60A or pT80A
c. Val30Met also known as V30M or pV50M

3. The primary source of plasma transthyretin is:

a. The liver
b. The choroid plexus
c. The retinal pigment epithelium
d. The thyroid

4. Which of the following pairs of compounds are transported by transthyretin

a. Trans fatty acids and thyroid hormone
b. Thyroid hormone and retinol
c. Thiopentanol and albumin
d. Prealbumin and Postalbumin

5. Tafamadis, an oral TTR stabilizer, has shown which benefits in Heart failure treatment?

a. Reduced mortality
b. Improved six-minute walk
c. Improved quality of life
d. All of the above

Answer Key: 1. B, 2. A, 3. A, 4. B, 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.

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Reducing Financial Stress through Smart and Safe Retirement Planning

David B. Mandell, JD, MBA

ABOUT ME

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TODAY'S PRESENTATION

1. Background on physician financial stress
2. Best retirement planning tools for physicians and dentist in private practice
3. Avoiding liabilities in retirement plans
4. Success factors in selling a medical or dental practice

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DOCTORS UNDER FINANCIAL STRESS* - EVEN PRE-COVID

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

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

FINANCIAL PREPAREDNESS* - INADEQUATE EVEN PRE-COVID

- Providing a comfortable retirement for themselves and spouse/partner is the #1 financial goal – having enough to retire is their #1 personal financial concern (unchanged over 5 years)
- 2016: 61% of physicians stated that they were on track of ahead for retirement; 39% were behind. (improvement from 2013/14 numbers)
- Physicians reports gaps in personal financial knowledge in a wide array of areas including retirement savings, life and disability insurance, and estate planning.

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* 2013, 2014 and 2016 Reports on U.S. Physicians Financial Preparedness, conducted by AMA Insurance. Over 4,000 total respondents.

BENEFIT PLANNING:
HOW DOCTORS IN PRIVATE PRACTICE SHOULD MAXIMIZE THEIR RETIREMENT SAVINGS

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WHAT IS A RETIREMENT PLAN?

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

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TAX DIVERSIFICATION

ORDINARY INCOME	CAPITAL GAINS	TAX FREE
37.0% FEDERAL + 6.6% STATE + 3.8% ACA	20% FEDERAL + 6.6% STATE + 3.8% ACA	
(47.4% TAX)	(30.4% TAX)	(0% TAX)
WITHDRAWAL: $100,000	WITHDRAWAL: $100,000	WITHDRAWAL: $100,000
LESS TAX: $47,400	LESS TAX: $30,400	LESS TAX: $0
NET AFTER TAX: $52,600	NET AFTER TAX: $69,600	NET AFTER TAX: $100,000

QRP GROUND RULES

- Two different categories
- Asset protection is excellent
- Must cover all eligible employees
- **Full deduction for contributions/income taxation on withdrawals**
- Penalties on withdrawals before 59$^{1}/_{2}$
- Funds left in estate taxed up to 70%

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QRP: DEFINED CONTRIBUTION PLANS

- IRS defines the contribution amount
- 401(k)s, 403(b), and 457 plans
  - $19,500 employee deferral amount
- PS: Defined contribution maximum $58,000
- Flexibility on funding
  - No penalties for underfunding or termination
- **Proper plan design is key**

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QRP: DEFINED BENEFIT PLANS

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

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QRP GROUND RULES: REVISITED

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

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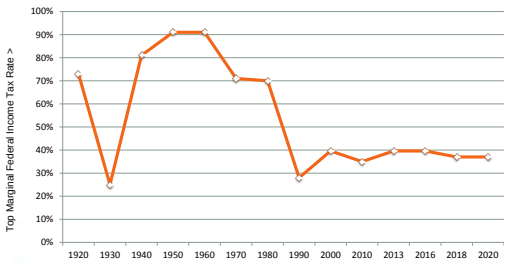
QRPs: A GOOD BET TO TRADE TODAY'S DEDUCTION FOR TOMORROW'S TAX?



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USING BENEFIT PLANS TO HEDGE YOUR LONG-TERM TAX BET

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

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NON-QUALIFIED PLAN AS OPTION

- No limitations on contributions – reasonable compensation
- In addition to 401k, profit-sharing, pension
- Owners can vary how much/if they participate
- Employee participation not required
- No tax deduction, tax-free growth and on withdrawal
- **Ideal hedge against future income/cg tax increases**
- **Next 5 years: Ideal time for funding Non-Q plans**

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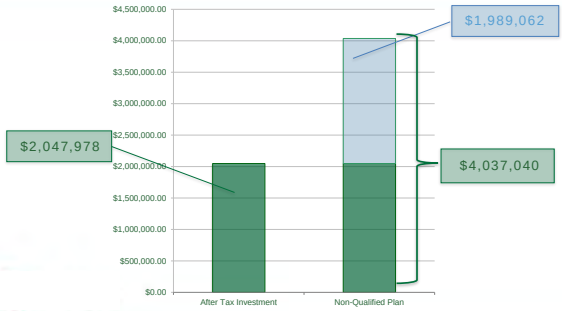
ASSUMPTIONS FOR CASE STUDY

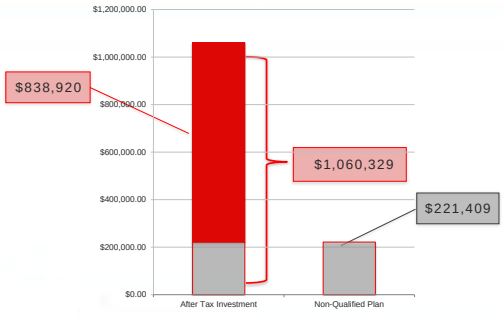
Example taken from Actual OJM Group Client:

- 45-Year-Old Male
- Ohio Resident
- $100,000 Annual Contribution for 10 Years
- Growing at 6.0% annual gross rate of return
- Investment management fee of 1%
- Assuming taxed at 20% Short Term Rates/80% Long Term Rates
- 37% Federal & 6.0% State
- 20% Long Term Capital Gains & 3.8% ACA Tax
- Distributions at age 65 for 20 years

NON-QUALIFIED PLAN
AFTER-TAX RETIREMENT DISTRIBUTION



NON-QUALIFIED PLAN
TAXES AND FEES VS. POLICY EXPENSES



WHAT LARGEST FIRMS DO

Percentage of Banks that Own BOLI

Asset Size	Banks	Banks with BOLI	% of Banks with BOLI
Greater than $50 Billion	40	28	70.00%
$5 Billion- $50 Billion	169	137	81.07%
$1 Billion - $5 Billion	540	446	82.59%
$750 Million - $1 Billion	246	190	77.24%
$500 Million - $750 Million	430	320	74.42%
$250 Million - $500 Million	1,122	836	74.51%
$100 Million - $250 Million	1,807	1,085	60.04%
Less than $100 Million	1,501	621	41.37%
Total	5,855	3,663	62.56%

Source: March 31, 2017 Bank Call Reports - Schedules RC & RC-F

AVOIDING LIABILITY IN YOUR QUALIFIED PLAN

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ARE YOU OVERPAYING AND EXPOSED?

- Parties involved in QRP administration
  - Recordkeeper
  - Third Party Administrator
  - Investment advisor
- "Bundled" services often lead to conflicts, kick-backs, expensive fund lineups
- Many small practice plans have not been reviewed
- As plan sponsor/trustee, you have fiduciary liability to employees
  - You can be sued for underperformance; high expense funds
    - U. of Chicago, MIT
    - MassMutual, Ameriprise, Nationwide settlements. Goldman Sachs ongoing.
  - **Solution: have your plan audited independently with benchmarks**

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CASE STUDY: OVERPAYING AND EXPOSED

- Employees: 1 physician, 4 employees, including spouse ($600,000 p
- Fees: 1.50% Investment Advisory
  - 2.41% across mutual fund expenses, TPA/Recordkeeping, and Investment Advisory
- This was a pooled investment account, meaning all participant investments are managed in the same manner. This can cause liability for the plan since not all participants will be comfortable taking the same level of risk.

Solution

- Plan design changed to allow each participant to direct his/her individual investments, including target-date retirement options
- Per industry benchmarking, the advisory fee was dropped to 0.60% for the plan. Total fees dropped from 2.41% to 1.63%, which saved the plan $4,000 annually.

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FOUR SUCCESS FACTORS IN SELLING A MEDICAL OR DENTAL PRACTICE

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#1: PREPARING THE PRACTICE FINANCIALLY
MAXIMIZING VALUE

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KEY DETERMINANTS OF VALUE: MEDICAL/DENTAL PRACTICE

- Retention of key doctors and staff after transaction close
- A significant dollar amount of Adjusted EBITDA
  - Adjusted EBITDA = Practice Earnings Before Interest Expenses, Income Taxes, Depreciation and Amortization Expense + adding back non-recurring expenses + owner-related expenses + excess owner compensation
- Diversified sources of revenue (Medical and Cosmetic, Ancillaries)
- Adjusted EBITDA margins that are consistently greater than 20%
- Highlighted growth opportunities (organic and add-on)

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#2: DETERMINING THE RIGHT TRANSACTION FOR YOU

ONE SIZE DOES NOT FIT ALL

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STRATEGIC OPTIONS

- **Status Quo**
  - Continue to execute on the practice's current operating plan.
  - Maintain existing ownership structure.
- **Majority Equity Sale Options**
  - **Add-On Scenario** – Sale to a Strategic Buyer
    - Sell a 100% or majority equity position to a current industry player, which could be owned by a private equity group.
    - A practice would likely operate as a subsidiary within the larger strategic platform.
  - **Standalone** – Sale to a Private Equity Group
    - Typically sell a majority equity stake to a private equity group and serve as the platform investment.
    - Partner would provide capital and expertise to help grow the practice.
- **Debt & Minority Equity Sale Options**
  - **Investment from a Debt & Equity Group**
    - Sell a minority equity stake in the practice to a Debt & Equity investment group and serve as the platform investment.
    - Partner would provide capital and expertise to help grow the practice.

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#3: FINDING THE RIGHT ADVISOR TEAM

EXPERIENCE & EXPERTISE MATTER

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FINDING THE RIGHT TEAM

- **Wealth Advisor** – how does a transaction impact future financial life?
- **Practice Accountant** – know the books
- **Transaction Accountant** – may be the practice accountant or one who has experience in deals
  - identify strengths and weaknesses
  - to review financials before going to market
- **Experienced M&A Attorney** – ideally with experience in these transactions
- **Investment Banker –** key to create maximum value in deal, field competitive offers, negotiate terms.
  - Compensation should be tied to success/value creation
  - Better off, net of fee

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#4: PREPARING MENTALLY

UNDERSTAND & ACCEPT HOW THINGS WILL BE DIFFERENT

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PREPARING MENTALLY

- Motivation is the fundamental factor to any deal: the WHY?
- Are you prepared to become an employee? Have bosses?
- How will this impact your daily life as a doctor in the practice – managerially, clinically?
- How will this impact you financially?
  - Liquidity event
  - Lower annual income
- How does this jive/not jive with your life goals?

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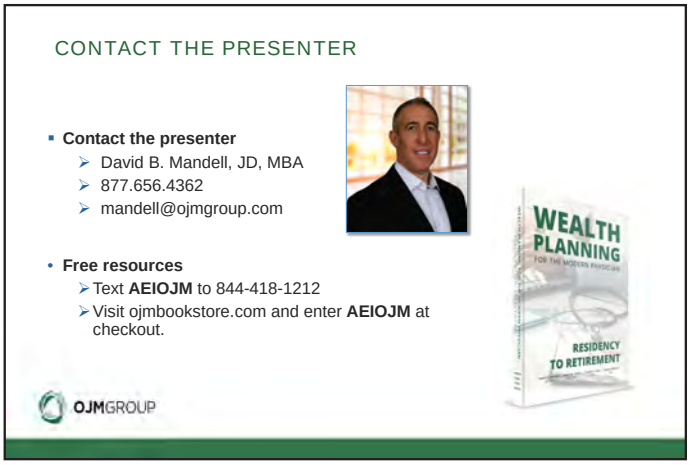

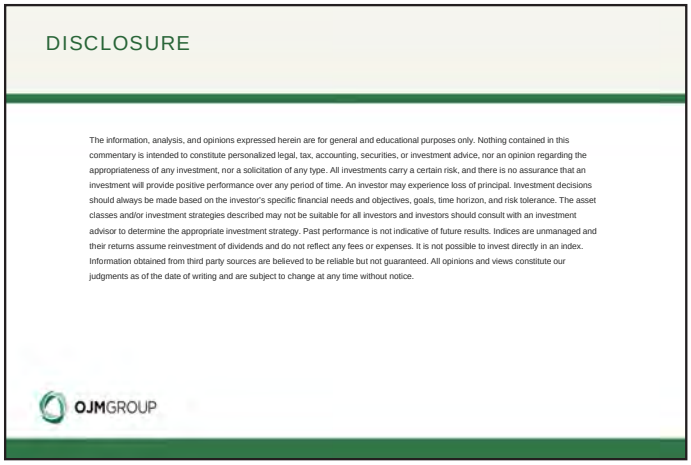

SELF EVALUATION

Reducing Financial Stress through Smart and Safe Retirement Planning

1. T/F - Providing a comfortable retirement for themselves and spouse/partner is the #1 physician financial goal.

2. According to the 2016 AMA survey, the percentage of physicians who are behind where they would like to be in terms of retirement preparedness was:

a. a. 10%
b. b. 25%
c. c. 39%
d. d. 50%

3. T/F - Tax diversification is crucial for all physicians' long term financial plans.

4. Which of the following are considered "defined contribution" plans?

a. Profit sharing plans
b. 401(k)s
c. 403(b)s
d. All of the above

5. T/F - Non-qualified plans can be offered to only physicians or dentists in a practice, employees do not have to participate.

6. T/F - The largest U.S. banks use over $160 billion of corporate owned life insurance (COLI).

7. The following are NOT firms involved in qualified retirement plan administration:

a. Attorney
b. Recordkeeper
c. Third Party Administrator
d. Investment advisor

8. T/F - EBITDA means "Practice Earnings Before Interest Expenses, Income Taxes, Depreciation and Amortization Expense".

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

Barry A. Franklin, PhD

Barry A. Franklin, PhD, of Royal Oak, Michigan, serves as Director, Preventive Cardiology and Cardiac Rehabilitation, at Beaumont Health, as well as Professor, Internal Medicine, Oakland University William Beaumont School of Medicine. He is past president of both American Association of Cardiovascular and Pulmonary Rehabilitation and American College of Sports Medicine.

Dr. Franklin is past editor in chief of the *Journal of Cardiopulmonary Rehabilitation and Prevention* and serves on the editorial boards of 15 other scientific and clinical journals. He has written or edited more than 700 scientific and clinical publications, including 26 books, and has given over 1000 invited presentations worldwide. In 2015, he was listed among *The World's Most Influential Scientific Minds (Clinical Medicine)*.

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Barry A. Franklin, PhD
Director of Preventive Cardiology and Cardiac Rehabilitation

Extreme Exercise and Cardiac Health: Is More Really Better?

High Volume and Intensity Endurance Training/Competition: Is More Exercise Better ?*

In 2015, there were ~ 2.5 million marathon participants in the U.S., as compared with 25,000 in 1976. There has been a similar exponential growth in other endurance events with, for example, 4.2 million triathlon competitors in the U.S. last year – a doubling since 2011.

* 2015 Marathon, half marathon and state of the sport reports. Running USA, 2015 (http://www.runningusa.org/statistics/reports)

Outline *(8 topics)*

Topic 1

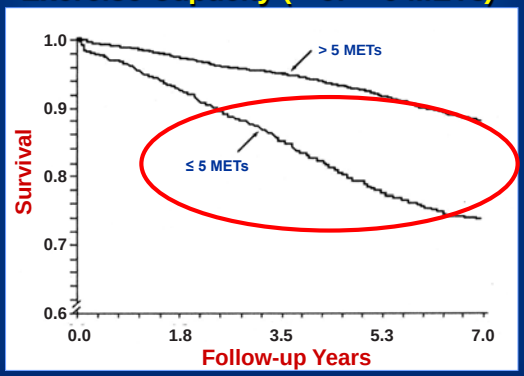
- Cardiorespiratory Fitness, Walking Pace and Mortality: Protective Mechanisms ?
- Exercise-Related Cardiovascular Events: Risk of Marathon/Triathon; Impact of Regular Exercise on Exercise Risk
- Marathon Running and "Immunity to Heart Disease"
- Exercise: Too Much of a Good Thing ?
- Physical Activity, Fitness & Atrial Fibrillation: Reverse J-Curve Pattern

Metabolic Equivalents (METs): A Measure of Energy Expenditure

- 1 MET* = amount of O2 your body uses at rest
- Average adult has a fitness level of 6 – 10 METs; heart failure patients 2 – 5 METs; elite endurance athletes ~ 20 – 25 METs
- Each 1 MET increase in cardiorespiratory fitness is associated with a 15% reduced risk of dying from an acute cardiac event
- A treadmill test is the most accurate way to assess your MET capacity

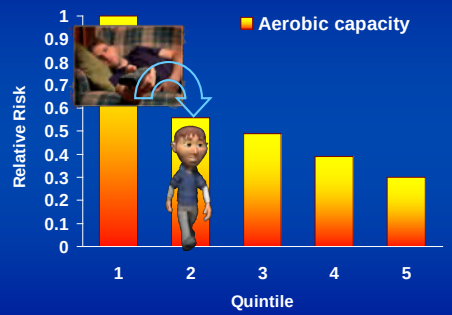
** 3.5 mL O2/kg/min*

Poor Survival Associated with Low Exercise Capacity (< or = 5 METs)

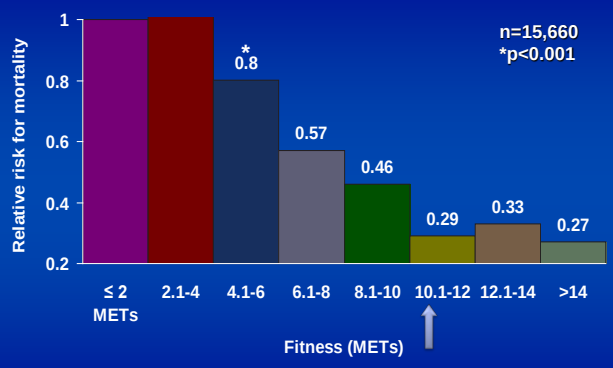


Myers J et al. Am J Med 2004;117:912

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



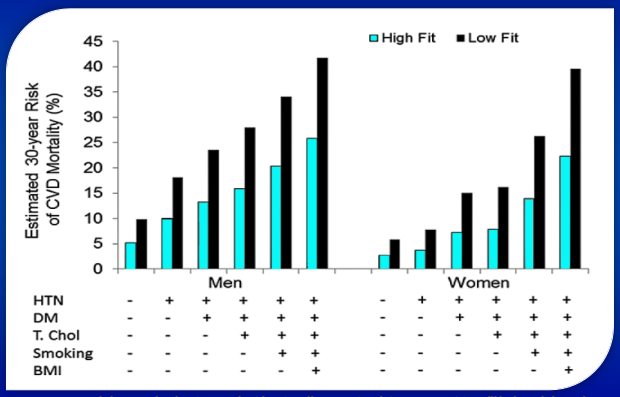
Blair SN et al. JAMA 1996;276:205
Williams PT Med Sci Sports Exerc 2001;33:754
Franklin B et al. Mayo Clin Proc 2013;88:431



Circulation 2010;122:1637

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.

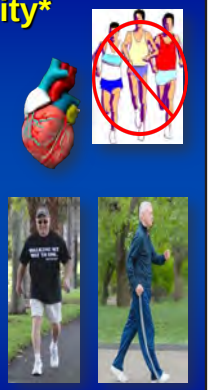
Regardless of the Risk Factor Profile, Low Fit Men and Women have ~ 2x the Mortality



Wickramasinghe CD et al. Circ Cardiovasc Qual Outcomes 2014 (lifetimerisk.org)

Summary: Cardiorespiratory Fitness (CRF) and All-Cause Mortality*

Conclusion: Men & women who are unable to achieve 5 METs (1.7 mph, 10% grade) during treadmill testing are at high risk for CV and all-cause mortality. In contrast, the risk of CVD-death is very low in those with a CRF of > or = 10 METs (3.4 mph, 14% grade).



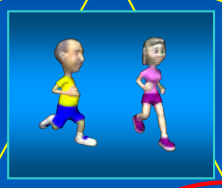
* Blair SN et al. JAMA 1989;262:2395. Myers J et al. Am J Med 2004;117:912 † Gulati M et al. Circ 2003;108:1554. Kodama S et al. JAMA 2009;301:2024. Kokkinos P et al. Circ 2010;122:1637. Fine NM, et al. Mayo Clinic Proc 2013;88:1408. Bourque JM et al. J Am Coll Cardiol 2009; 54:538. Feldman DJ et al. J Am Coll Cardiol 2015;65: 629.

Reduced Walking Speed: A Harbinger of the Approaching Grim Reaper ?

At a minimum, routinely assess physical activity and simply observe your patient's gait speed the next time he/she leaves your office. A tortoise-like pace (slower than 2 miles per hour) may provide the most telling "vital sign" of your physical exam that day.

Stanaway FF et al. BMJ 2011 ; Studenski S, et al. JAMA 2011

Cardiovascular Benefits of Regular Exercise/Fitness



Anti-atherosclerotic
- Improved lipids
- Lower BPs
- Reduced adiposity
- ↑ Insulin sensitivity
- ↓Inflammation

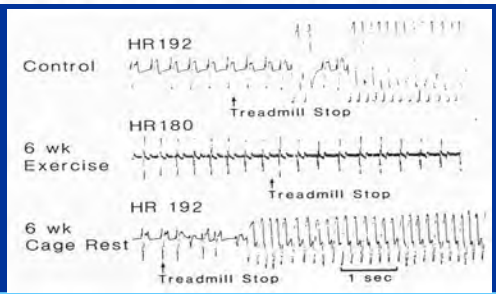
Anti-thrombotic
- ↓ Platelet adhesiveness
- ↑ Fibrinolysis
- ↓ Fibrinogen
- ↓ Blood viscosity

Anti-ischemic
- ↓Myocardial O_2 demand
- ↑ Coronary flow
- ↓Endothelial dysfunction
- ↑ EPCs and CACs

Anti-arrhythmic
- ↑ Vagal tone
- ↓ Adrenergic activity
- ↑ HR variability

The effects of daily exercise on susceptibility to sudden cardiac death

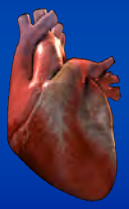
George E. Billman, Ph.D., Peter J. Schwartz, M.D., and H. Lowell Stone, Ph.D.



Billman GE et al. Circ 1984;69:1182

Aerobic Exercise Conditioning: A Nonpharmacological Antiarrhythmic Intervention*

Aerobic exercise conditioning can improve cardiac autonomic balance by both increasing cardiac parasympathetic tone and decreasing cardiac sympathetic activity, thereby enhancing cardiac electrical stability and preventing sudden cardiac death.



*Billman GE. J Appl Physiol 2002;92:446

Outline

Topic 2

- Cardiorespiratory Fitness, Walking Pace and Mortality: Protective Mechanisms ?
- Exercise-Related Cardiovascular Events: Risk of Marathon/Triathlon ; Impact of Regular Exercise on Exercise Risk
- Marathon Running and "Immunity to Heart Disease "
- Exercise: Too Much of a Good Thing ?
- Physical Activity, Fitness & Atrial Fibrillation: Reverse J-Curve Pattern

AHA Scientific Statement

Exercise and Acute Cardiovascular Events
Placing the Risks Into Perspective
A Scientific Statement From the American Heart Association Council on Nutrition, Physical Activity, and Metabolism and the Council on Clinical Cardiology

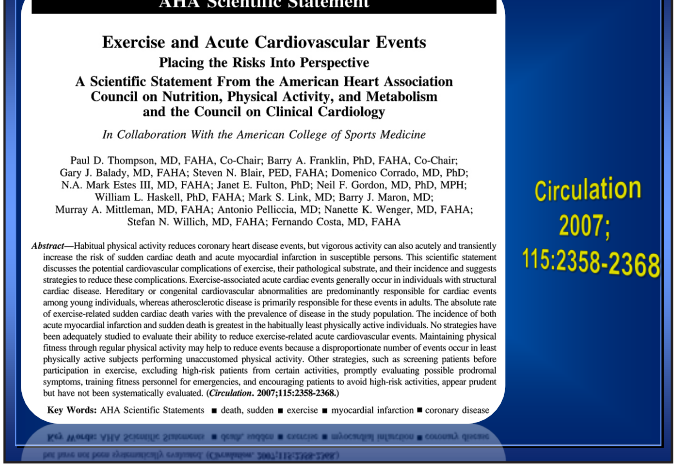
In Collaboration With the American College of Sports Medicine

Paul D. Thompson, MD, FAHA, Co-Chair; Barry A. Franklin, PhD, FAHA, Co-Chair; Gary J. Balady, MD, FAHA; Steven N. Blair, PED, FAHA; Domenico Corrado, MD, PhD; N.A. Mark Estes III, MD, FAHA; Janet E. Fulton, PhD; Neil F. Gordon, MD, PhD, MPH; William L. Haskell, PhD, FAHA; Mark S. Link, MD; Barry J. Maron, MD; Murray A. Mittleman, MD, FAHA; Antonio Pelliccia, MD; Nanette K. Wenger, MD, FAHA; Stefan N. Willich, MD, FAHA; Fernando Costa, MD, FAHA

Abstract—Habitual physical activity reduces coronary heart disease events, but vigorous activity can also acutely and transiently increase the risk of sudden cardiac death and acute myocardial infarction in susceptible persons. This scientific statement discusses the potential cardiovascular complications of exercise, their pathological substrate, and their incidence and suggests strategies to reduce these complications. Exercise-associated acute cardiac events generally occur in individuals with structural cardiac disease. Hereditary or congenital cardiovascular abnormalities are predominantly responsible for cardiac events among young individuals, whereas atherosclerotic disease is primarily responsible for these events in adults. The absolute rate of exercise-related sudden cardiac death varies with the prevalence of disease in the study population. The incidence of both acute myocardial infarction and sudden death is greatest in the habitually least physically active individuals. No strategies have been adequately studied to evaluate their ability to reduce exercise-related acute cardiovascular events. Maintaining physical fitness through regular physical activity may help to reduce events because a disproportionate number of events occur in least physically active subjects performing unaccustomed physical activity. Other strategies, such as screening patients before participation in exercise, excluding high-risk patients from certain activities, promptly evaluating possible prodromal symptoms, training fitness personnel for emergencies, and encouraging patients to avoid high-risk activities, appear prudent but have not been systematically evaluated. (*Circulation*. 2007;115:2358-2368.)

Key Words: AHA Scientific Statements ■ death, sudden ■ exercise ■ myocardial infarction ■ coronary disease

Circulation 2007; 115:2358-2368



Malignant Ventricular Arrhythmias: A Potential Complication of Vigorous Exercise

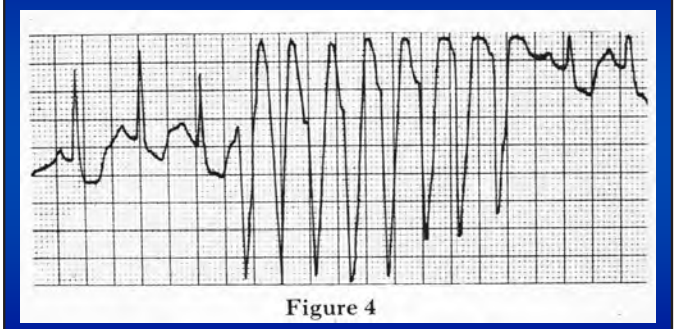
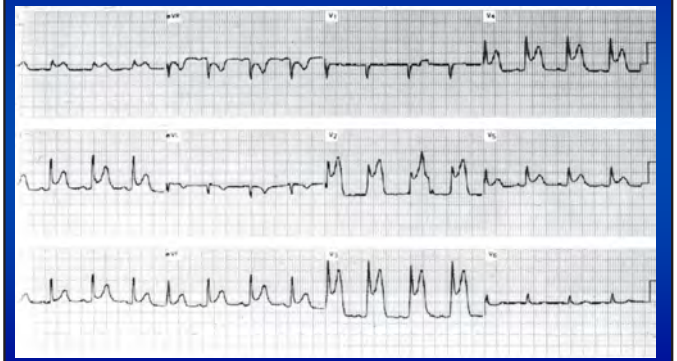


Figure 4

Exercise May Provoke Plaque Rupture and Coronary Thrombosis



Thompson P. Arch Intern Med 1996;156:2297

REVIEW | CLINICIAN'S CORNER

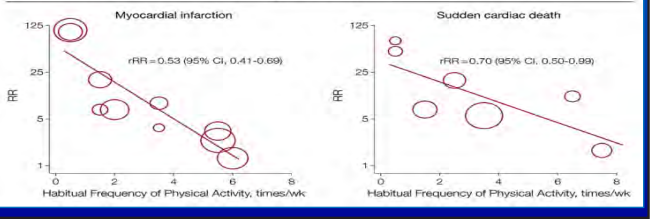
Association of Episodic Physical and Sexual Activity With Triggering of Acute Cardiac Events

Systematic Review and Meta-analysis

JAMA 2011;305(12):1225-1233

Conclusion: This meta-analysis reported a 5-fold increased risk of SCD and a 3.5-fold increased risk of AMI during vigorous-intensity physical activity (> 6 METs); however, these associations were markedly attenuated among persons with high levels of habitual physical activity.

Meta-regression Graph of Triggering Relative Risks for Myocardial Infarction and Sudden Cardiac Death Over Habitual Physical Activity Levels



Cardiac Arrest During Long-Distance Running Races*

To clarify the risk of cardiac arrest associated with marathon and half-marathon races in the U.S. from January 1, 2000, to May 31, 2010, investigators reported on the incidences and outcomes of events among 10.9 million registered marathon runners. Of the 59 cases of cardiac arrest (mean ± SD age, 42 ± 13 years; 51 men), 42 (71%) were fatal (~4 fatalities/year). Conclusion: Marathoners are at a low risk for acute cardiac events. The final mile, < 5% of the 26.2 mile marathon distance, accounts for ~ 50% of the sudden cardiac deaths.

The most frequent clinical and autopsy findings were hypertrophic cardiomyopathy and atherosclerotic CVD, respectively.

**Kim JH et al. NEJM 2012;366:130-140*

Annals of Internal Medicine — ORIGINAL RESEARCH

Death and Cardiac Arrest in U.S. Triathlon Participants, 1985 to 2016

A Case Series

Harris K et al.
Ann Intern Med
2017;167:529-535

Death and Cardiac Arrest in U.S. Triathlon Participants*

- > 9 million participants over 30 years
- 135 sudden cardiac deaths(SCDs, 86% men; 13 survivors); incidence of 1.74/100,000 participants versus 1.01/100,000 for marathon running
- Women ~ 15% of the study population, and their incidence of SCD was 3.5 – fold less than men
- Most SCDs occurred during the swim (n=90; 67%) followed by the bicycle, run, and post-race periods, 22, 15, and 8 respectively
- Many of the SCDs (38%) were competing in their first triathlon
- Autopsies performed on 61 of the 135 victims, revealed that 27 (44%) had atherosclerotic CAD and/or cardiomyopathy

Harris KM et al
Ann Intern Med
2017
167:529-535

Outline

Topic 3

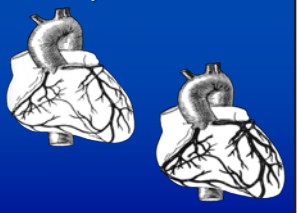
- Cardiorespiratory Fitness, Walking Pace and Mortality: Protective Mechanisms ?
- Exercise-Related Cardiovascular Events: Risk of Marathon/Triathlon; Impact of Regular Exercise on Exercise Risk
- Marathon Running and "Immunity to Heart Disease"
- Exercise: Too Much of a Good Thing ?
- Physical Activity, Fitness & Atrial Fibrillation: Reverse J-Curve Pattern

SPECIAL ARTICLE

HALF A CENTURY OF RUNNING*

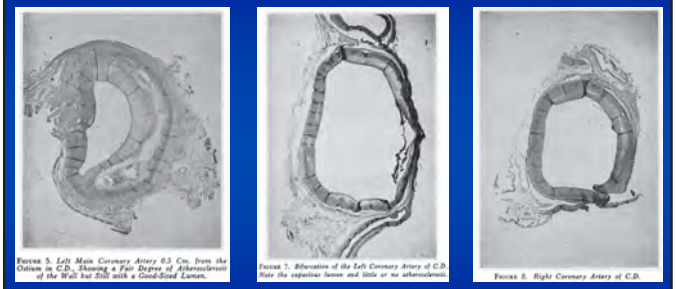
Clinical, Physiologic and Autopsy Findings in the Case of Clarence DeMar ("Mr. Marathon")

The striking anatomic finding in the heart was the relative size of the coronary arteries, which were estimated to be 2 or 3 times the normal diameter. Atherosclerosis of the coronary arteries was present but was relatively mild in degree, i.e., lumen was estimated to be reduced by 30% at several sites.



Currens JH, White PD.
NEJM 1961;265:988-993

Coronary Arteries of Clarence DeMar at Autopsy



Currens JH, White PD. NEJM 1961;265:988-993

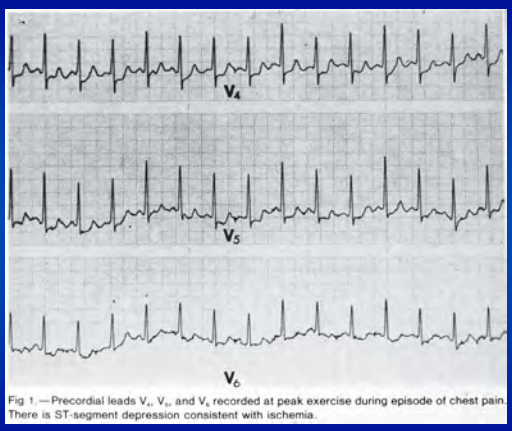


Fig 1.—Precordial leads V_4, V_5, and V_6 recorded at peak exercise during episode of chest pain. There is ST-segment depression consistent with ischemia.

This patient represents unequivocal evidence that long-distance marathon running and an unremarkable risk factor profile are not necessarily protective against the progression of coronary atherosclerosis.

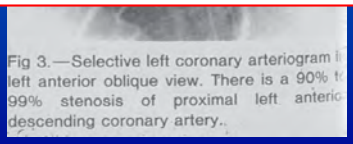
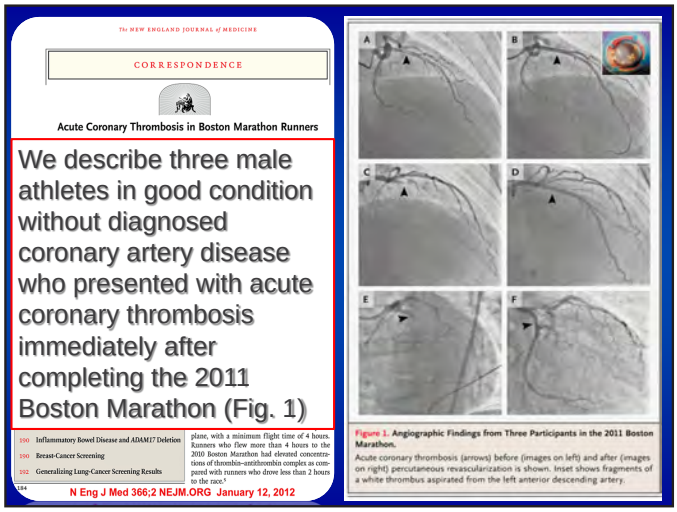


Fig 3.—Selective left coronary arteriogram i left anterior oblique view. There is a 90% t 99% stenosis of proximal left anteric descending coronary artery..



THE NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

Acute Coronary Thrombosis in Boston Marathon Runners

We describe three male athletes in good condition without diagnosed coronary artery disease who presented with acute coronary thrombosis immediately after completing the 2011 Boston Marathon (Fig. 1)

190 Inflammatory Bowel Disease and *ADAM17* Deletion
190 Breast-Cancer Screening
192 Generalizing Lung-Cancer Screening Results

plane, with a minimum flight time of 4 hours. Runners who flew more than 4 hours to the 2010 Boston Marathon had elevated concentrations of thrombin–antithrombin complex as compared with runners who drove less than 2 hours to the race.[5]

184

N Eng J Med 366;2 NEJM.ORG January 12, 2012

Figure 1. Angiographic Findings from Three Participants in the 2011 Boston Marathon.

Acute coronary thrombosis (arrows) before (images on left) and after (images on right) percutaneous revascularization is shown. Inset shows fragments of a white thrombus aspirated from the left anterior descending artery.

Outline

Topic 4

- Cardiorespiratory Fitness, Walking Pace **and** Mortality: Protective Mechanisms ?
- Exercise-Related Cardiovascular Events: Risk of Marathon/Triathlon; Impact of Regular Exercise on Exercise Risk
- Marathon Running and "Immunity to Heart Disease"
- Exercise: Too Much of a Good Thing ?
- Physical Activity, Fitness & Atrial Fibrillation: Reverse J-Curve Pattern

Clin Cardiol 2012;35:69-73

Abnormalities Following Ultra-Endurance Exercise

27 athletes competing in a triathlon

↑ cardiac troponin and B-type natriuretic peptide in the immediate post-race setting; echocardiographic evidence of both left and right ventricular dysfunction. Evidence of myocardial damage resolved after 7 days.

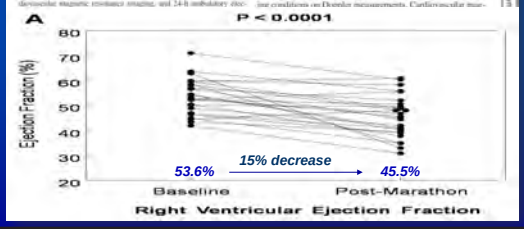
Significance? Cardiac injury seen after intense exercise represents a potential for generation of scar tissue → malignant cardiac arrhythmias.

LaGerche A et al. Heart, Lung & Circulation 2007;16:S102

J Appl Physiol 2010;108:1148-1153

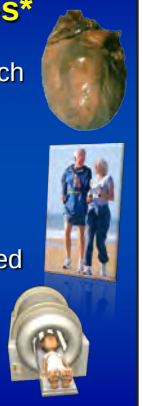
Acute cardiac effects of marathon running

Marathon running causes dilation of the right atrium and right ventricle, reduction of right ventricular ejection fraction, and release of cardiac troponin I and B-type natriuretic peptide but does not appear to result in ischemic injury to any chamber.



Myocardial Fibrosis in Veteran Endurance Athletes*

Newer tissue characterization techniques such as delayed gadolinium enhancement on cardiovascular magnetic resonance imaging have now been used to describe diverse patterns of myocardial fibrosis in highly trained veteran endurance athletes (6 of 12, 50%).



*Wilson M et al. J Appl Physiol 2011;110:1622-1626

Outline

Topic 5

- Cardiorespiratory Fitness, Walking Pace and Mortality: Protective Mechanisms ?
- Exercise-Related Cardiovascular Events: Risk of Marathon/Triathlon; Impact of Regular Exercise on Exercise Risk
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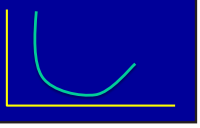
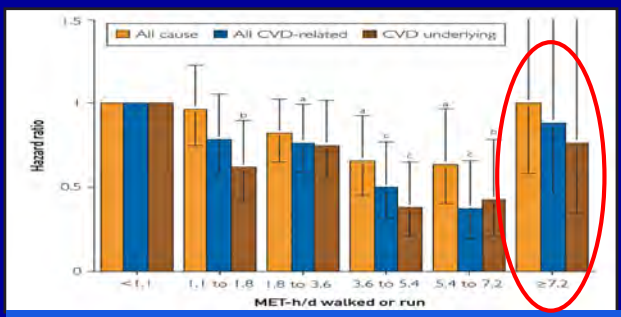
- Exercise: Too Much of a Good Thing ?
- Physical Activity, Fitness, Mortality and Atrial Fibrillation: Reverse J-Curve Pattern



	Events	Person-years	Incidence/mortality rate (95% CI) per 1000 person-years
Cardiovascular mortality			
Daily	14	1481.9	9.5 (5.6 to 16.0)
5–6×/week	10	1617.9	6.2 (3.3 to 11.5)
2–4×/week	19	4188.1	4.5 (2.9 to 7.1)
1–4×/month	15	1849.8	8.1 (4.9 to 13.5)
Rarely/never	23	789.8	29.1 (19.4 to 43.8)
All-cause mortality			
Daily	24	1481.9	16.2 (10.9 to 24.2)
5–6×/week	14	1617.9	8.7 (5.1 to 14.6)
2–4×/week	32	4188.1	7.6 (5.4 to 10.8)
1–4×/month	26	1849.8	14.1 (9.6 to 20.6)
Rarely/never	35	789.8	44.3 (31.8 to 61.7)

Mons U et al. Heart May 14, 2014



Chronic running or walking (MET-h/d) was associated with progressively lower cardiovascular mortality (up to 63%), that is, cohorts walking ~40 miles/week or running ~ 25 miles/week, beyond which much of the survival benefit of exercise was lost (in a reverse J-curve pattern).

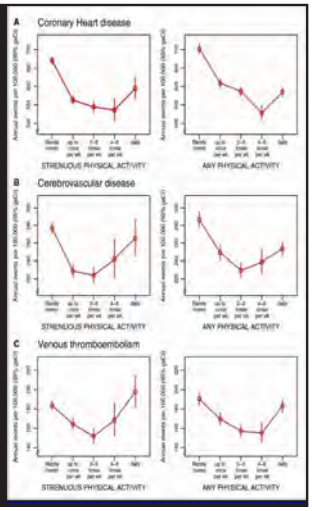
Williams P et al. Mayo Clin Proc Sept 2014

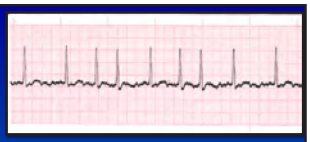
Exercise Physiology

Frequent Physical Activity May Not Reduce Vascular Disease Risk as Much as Moderate Activity
Large Prospective Study of Women in the United Kingdom

Miranda E. G. Armstrong, MPhil(Cantab), PhD; Jane Green, BM(Oxf), DPhil; Gillian K. Reeves, MSc, PhD; Valerie Beral, DSc, AC, FRS; Benjamin J. Cairns, PhD; on behalf of the Million Women Study Collaborators

METHODS & RESULTS: In 1998, on average, 1.1 million women without prior vascular disease reported their frequency of physical activity. Over a 9 year follow-up, as compared with inactive women, those reporting moderate activity had significantly lower risks of all 3 conditions (p<0.001 for each). However, women reporting strenuous physical activity daily had higher risks of coronary heart disease (p=0.002), cerebrovascular disease (p<0.001), and venous thromboembolic events (p<0.001) than those reporting doing such activity 2 to 3 times/week.



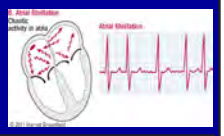


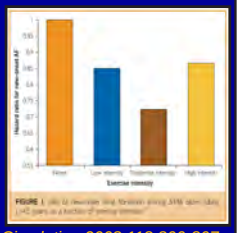
Extreme Exercise Increases the Risk of Atrial Fibrillation (5x)*

* O'Keefe JH et al. Mayo Clin Proc 2012;87:587-595

Older Adults, Exercise and Atrial Fibrillation

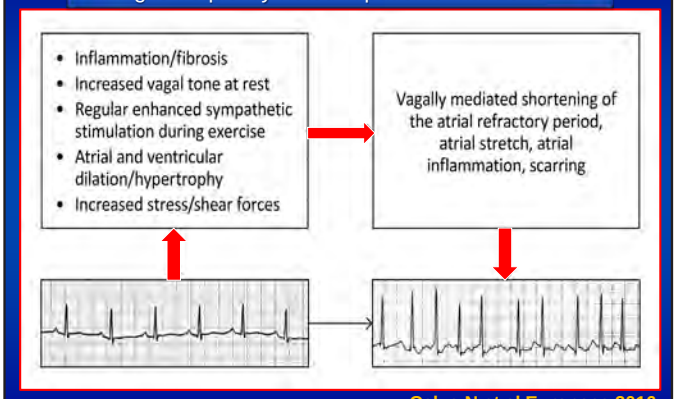
A prospective observational study of older men and women (mean age 73 years) reported that moderate-intensity physical activity such as walking was associated with a reduced risk of atrial fibrillation by about one-third. Still, high-intensity exercise showed the familiar reverse J-shaped relationship with the risk of atrial fibrillation.





Mozaffarian D et al. Circulation 2008;118:800-807

A history of ≥ 2000 hours of vigorous endurance-training is frequently noted in patients with Lone-AF.



Calvo N,et al Europace 2016

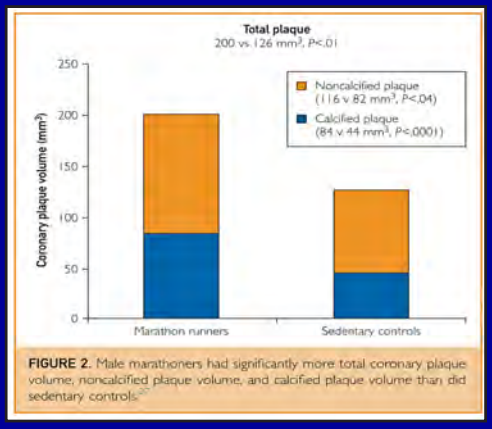


FIGURE 2. Male marathoners had significantly more total coronary plaque volume, noncalcified plaque volume, and calcified plaque volume than did sedentary controls.[20]

Schwartz RS et al. Missouri Med 2014;111:85

BACKGROUND: A robust literature demonstrates that coronary artery calcification (CAC) and cardiorespiratory fitness (CRF) are independent predictors of cardiovascular disease (CVD) events. Much less is known about the joint associations of CRF and CAC with CVD risk.

Results From the Cooper Center Longitudinal Study

METHODS: We studied 8425 men without clinical CVD who underwent preventive medicine examinations that included an objective measurement 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 (hazard ratio, 0.89; 95% CI, 0.84 – 0.94).

CONCLUSIONS: In a large cohort of generally healthy men, there is an attenuation of CVD risk at all CAC levels with higher CRF.

Circulation 2018;137:1888-1895

Table 3. Estimated Hazard Ratios for Total Cardiovascular Disease Events (N=8120, 5–15 METs)

Effect	Base Model		Adjusted Model†	
	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

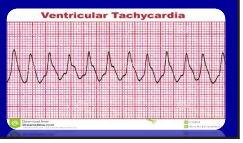
CAC indicates coronary artery calcium; CI, confidence interval; CRF, cardiorespiratory fitness; HR, hazard ratio; and MET, metabolic equivalent of task.
*Modeled as linear effects.
†Base model plus smoking, body mass index, systolic blood pressure, history of hypertension, glucose, history of diabetes mellitus, cholesterol, and statin therapy.

Circulation 2018;137:1888-1895

Outline

Topic 6

- Activities Associated with an Increased Risk of Acute Cardiac Events
- Pre-participation Screening: Prophylactic Interventions; Establishing a Cardiovascular Performance Clinic
- Case Studies: Medical Marvels



Cardiac Demands of Heavy Snow Shoveling

Barry A. Franklin, PhD; Patrick Hogan, MA; Kim Bonzheim, MSA; Donovan Bakalyar, PhD; Edward Terrien, MD; Seymour Gordon, MD; Gerald C. Timmis, MD

JAMA 1995;273:880

Acute Myocardial Infarction After Manual or Automated Snow Removal

Barry A. Franklin, PhD, Peter George, MD, Richard Henry, DO, Seymour Gordon, MD, Gerald C. Timmis, MD, and William W. O'Neill, MD

AJC 2001;87:1282

Sudden Cardiac Death After Manual or Automated Snow Removal

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

AJC 2003;92:833

Cardiorespiratory Measurements During Treadmill Testing and Snow Shoveling (Means ± SD)

Variable	Treadmill Testing	Snow Shoveling
Heart rate (beats/min)	179 ± 17	175 ± 15
Systolic blood pressure (mm Hg)	181 ± 25	198 ± 17
Rate-pressure product (mm Hg x beats/min x 10^{-2})	322 ± 40	342 ± 34
Oxygen consumption (METs)	9.3 ± 1.8	5.7 ± 0.8
Rating of perceived exertion (6-20 scale)	17.9 ± 1.5	16.7 ± 1.7

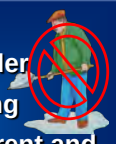
Cardiovascular Clinical Data in the 5 Sedentary Men*

Patient	Age (Years)	SH	CS	↑C	Previous AP	Previous AMI	Previous PTCA	BMI (kg/m²)	Snow Removal Technique: Shoveling	Snow Removal Technique: EST	Symptoms During Snow Removal: Substernal CP	Symptoms During Snow Removal: Sweating	Confirmed AMI	Time of AMI
1	55	0	+	0	0	0	0	34.6	+	0	+	0	+	pm
2	58	0	0	+	0	+	+	30.7	0	+	+	+	+	am
3	64	0	0	0	+	0	0	33.8	0	+	+	0	+	am
4	70	0	0	0	0	0	+	27.7	+	0	+	0	+	am
5	77	+	+	+	0	0	0	30.8	+	0	+	+	+	am

*Persons not participating in a regular exercise program or meeting the minimal physical activity recommendations from the U.S. Surgeon General's report.[13]
AP = angina pectoris; BMI = body mass index; C = cholesterol; CP = chest pain; CS = cigarette smoker; EST = electric snow thrower; PTCA = percutaneous transluminal coronary angioplasty; SH = systemic hypertension.

AJC 2001;87:1282

Habitually sedentary middle-aged and older patients at risk for heart disease, including obese and/or overweight individuals, current and former smokers, those with a history of hyper-cholesterolemia and/or systemic hypertension, as well as those with previous AMI or coronary revascularization, should be cautioned regarding the risk of AMI following manual or even automated snow removal, especially during the early morning hours.



Sudden Cardiac Death After Manual or Automated Snow Removal

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

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

(Am J Cardiol 2003;92:000)

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

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

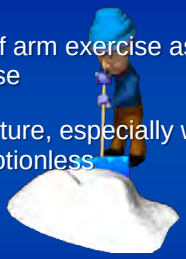
* Snow removal related deaths: *1 of 2; †22 of 24; ‡13 of 17.

snowfall, were obtained from the National Weather Service database.

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

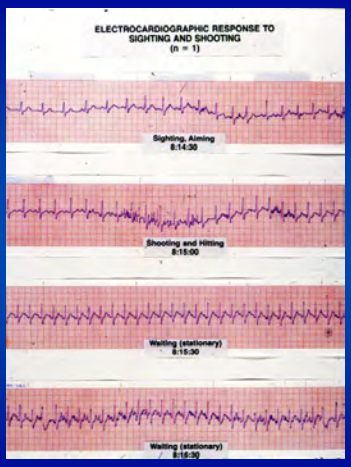
Counseling implications--TOTLSS

Why Snow Shoveling Wreaks Cardiac Havoc*



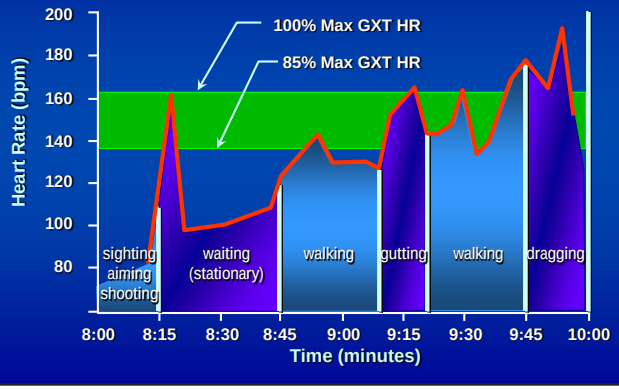
- The relative inefficiency of arm exercise as compared with leg exercise
- Working in an upright posture, especially when the legs are frequently motionless
- Isometric (static) exertion
- Expiratory strain (Valsalva maneuver)
- Inhalation of and exposure to cold air

** Franklin BA. Am J Med Sports 2001;3(6):339*



Heart Rate Response to Varied Deer Hunting Activities Compared with GXT Results

(n=1)

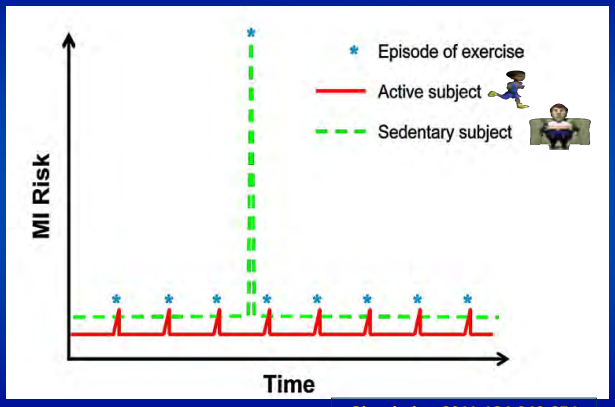


Outline

Topic 7

- Activities Associated with an Increased Risk of Acute Cardiac Events
- Prophylactic Interventions; Establishing a Cardiovascular Performance Clinic
- Case Studies: Medical Marvels

PROPHYLACTIC INTERVENTIONS: Vigorous Exercise-- Who is at Greatest Risk ?



Circulation 2011;124:346-354

Advise Patients to Walk Before Running

When previously sedentary individuals initiate an exercise program, level walking (2-3 METs) is strongly recommended, gradually increasing the speed or intensity of exertion (3-5 METs) over time (2-3 months), provided the individual remains symptom-free.

This strategy will ↓ injury and ↑fitness without going through a period during which each bout of vigorous exercise (>6 METs) is associated with large spikes in relative cardiovascular risk.

PTP

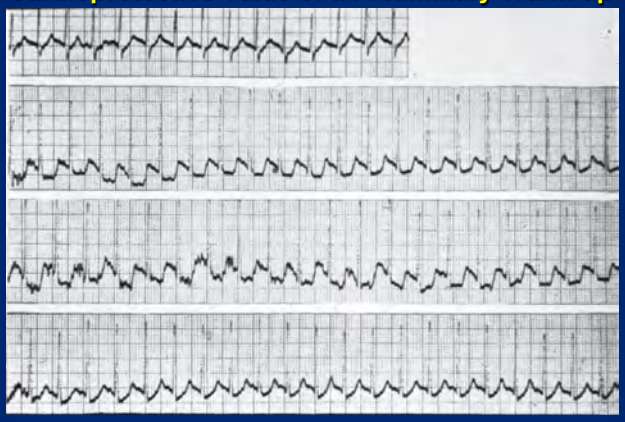
Riebe D et al. Med Sci Sports Exerc, Vol 47, No 8, pp 2473

Neither superior athletic ability, habitual physical activity, nor the absence of cardiac risk factors guarantees protection against an exercise death.

FOREWARNING SYMPTOMS APPEARED TO PRESENT THE ONLY CLUE TO IMPENDING CARDIOVASCULAR EVENTS.

Thompson PD et al. JAMA 1979;242:1265

Cardioprotective Value of a Preliminary Warm-up*



** Barnard RJ, et al. Circulation 1973;48:936*

AHA/ACSM Scientific Statement

Automated External Defibrillators in Health/Fitness Facilities

Supplement to the AHA/ACSM Recommendations for Cardiovascular Screening, Staffing, and Emergency Policies at Health/Fitness Facilities

Writing Group
Gary J. Balady, MD, Chair; Bernard Chaitman, MD; Carl Foster, PhD; Erika Froelicher, PhD; Neil Gordon, MD; Steven Van Camp, MD

Circulation 2002;105:1147-1150

Cardiovascular Performance Clinic

All CPC Participants Undergo the Following Tests

- H & P exam by Cardiovascular Specialist (ie, MD)
- 12-lead Electrocardiogram (ECG)
- Echocardiogram
- *Cardiopulmonary Exercise Test (V02 max, Anaerobic Threshold) (Cost : $370)

- Nutritional Consultation
- DXA Scan (body fatness)

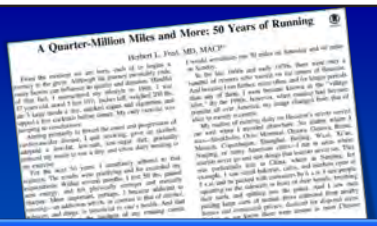
If age > 40 years or CHD risk factors

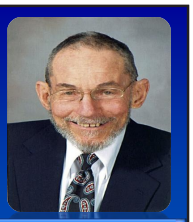
- Coronary Calcium Scoring by CT (Cost: $100)

Additional Testing as Appropriate including: Blood Chemistry Studies, Cardiac MRI; Coronary CT Angiography; Referral to Specialist; 7 for $70

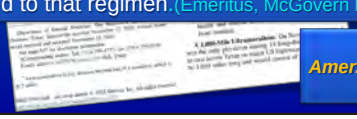
Final Evaluation and Training/Competition Recommendations

* Fitness consultation: Maximal aerobic capacity, anaerobic threshold, optimal training/race pace


A Quarter-Million Miles and More: 50 Years of Running



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

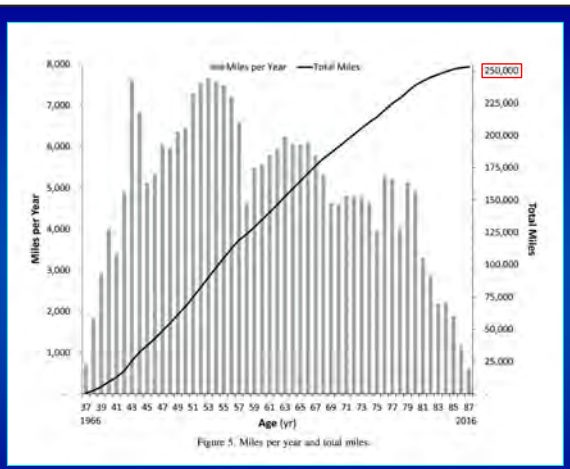
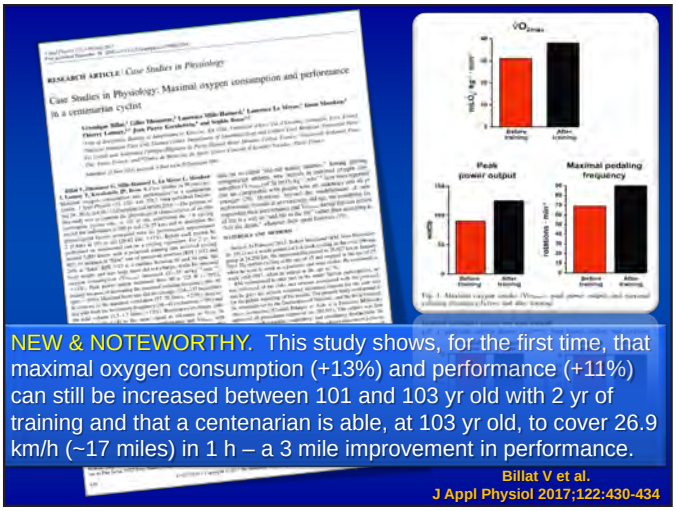
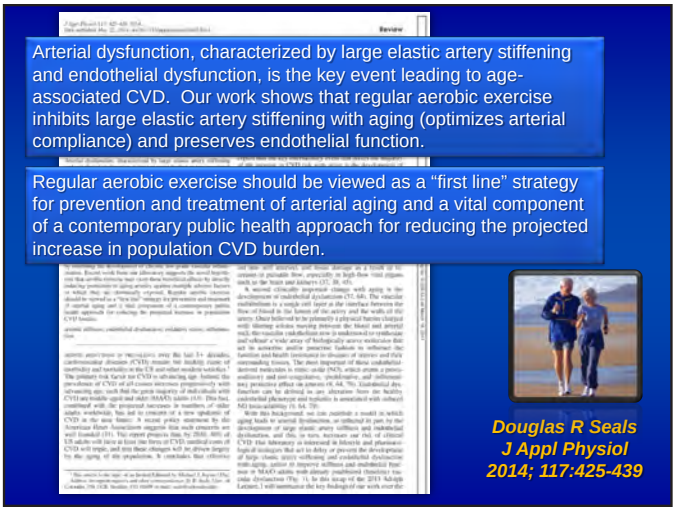


Figure 5. Miles per year and total miles.

Fred HL. Am J Cardiol Feb 2017





SELF EVALUATION

Extreme Exercise and Cardiac Health: Is More Really Better?

1. Poor survival is associated with a low exercise capacity during maximal treadmill testing, specifically ≤ ____ metabolic equivalents (METs).

a. 1
b. 5
c. 7
d. 9
e. None of the above

2. According to a classic report, approximately ___ fatalities occur each year during marathon and half-marathon races in the U.S. The most frequent clinical and autopsy findings were hypertrophic cardiomyopathy and atherosclerotic cardiovascular disease, respectively.

a. 4
b. 8
c. 16
d. 32
e. 59

3. Most sudden cardiac deaths during triathlons occur during the _____period/portion of the endurance event

a. Run
b. Bicycle
c. Swim
d. Post-race
e. Two of the above

4. It has been recently reported that high-volume, high-intensity exercise regimens may, over time, increase the risk of

a. Coronary artery calcification
b. Cardiovascular mortality
c. Vascular disease
d. Atrial fibrillation
e. All of the above

5. T/F - Research has shown that shoveling heavy, wet snow equals or exceeds the cardiac demands of maximal treadmill testing. This finding may account for the large number of non-fatal and fatal cardiac events each year in middle-aged and older snow shovelers with known or occult cardiovascular disease.

6. T/F - When previously sedentary middle-aged and older adults initiate an exercise program, jogging is recommended to safely and rapidly improve cardiorespiratory fitness.

7. In persons with and without heart disease, each 1 metabolic equivalent (MET) increase in cardiorespiratory fitness is associated with a ____% reduced risk of dying from an acute cardiac event.

a. 6
b. 10
c. 15
d. 25
e. 50

Answer Key: 1. B, 2. A, 3. C, 4. E, 5. T, 6. F, 7. 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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CARMEL, INDIANA 46032
(312) 859-2430

The DEA, Opioids and the Healthcare Provider

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.

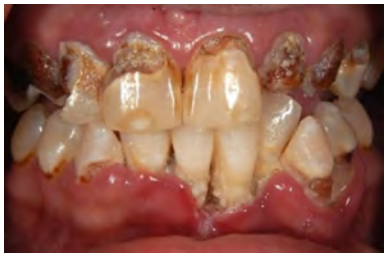
Disclosure Statement

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

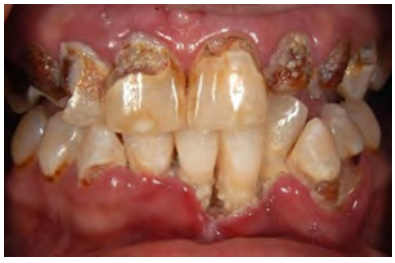
Presentation Outline

- DEA Authority
- Opioid Case Studies & Red Flags
- Emerging Issues
- DEA Resources
- Practice Safeguards

What Drug Causes This?



Methamphetamine Use "Meth Mouth"



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

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

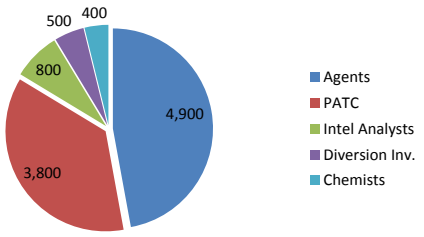
DEA's statutory responsibility under the Controlled Substance Act (CSA) is twofold:

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.

DEA Personnel

(approximately 10,169)



* PATC-Professional, Administrative, Technical, and Clerical

DEA Focus

Primarily on Cartels, Gangs, and Criminal Organizations Trafficking, Heroin, Fentanyl, Cocaine and Methamphetamine

Not Against Medical Providers & Pharmacists

Controlled Substances Act of 1970
21 USC

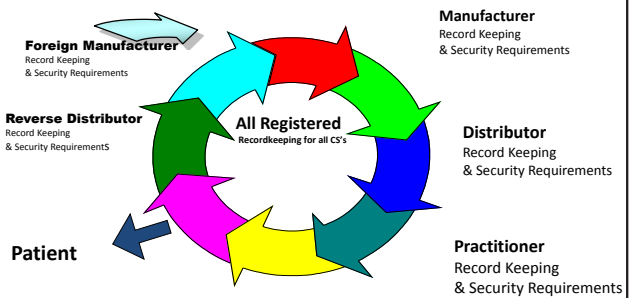
Legal foundation of federal government's authority for controlled substances and listed chemicals.

Under the CSA, Congress established a "closed system" of distribution to prevent the diversion of controlled substances.

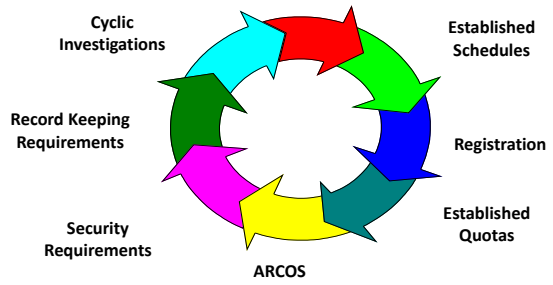
All persons who lawfully handle controlled substances must be registered with DEA or exempt from registration.

Ultimate users (patients) are not required to register with DEA to possess controlled substances.

THE CSA'S CLOSED SYSTEM
EVERYONE IS REGISTERED
RECORDKEEPING FOR ALL CONTROLLED SUBSTANCES



DEA DIVERSION CONTROL PROGRAM
Includes



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

The Latest Numbers

DEA Registrants – 2021

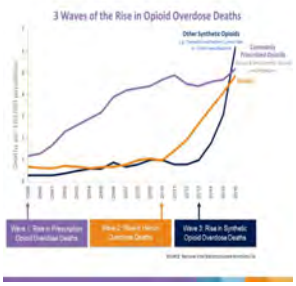
- Approximately 1.10 million MD's & DO's
  - 200,000 Dentists
  - 73,000 Vets
  - 453,000 NP's & PA's
- 18,764 hospitals/clinics
- 70,681 Pharmacies
- Approximately 330,000 pharmacists
- Approximately 400,000 pharmacy techs

Required Records – Controlled Substances

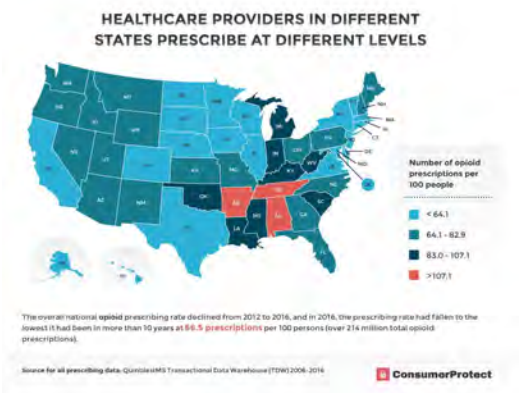
CFR Part 1304

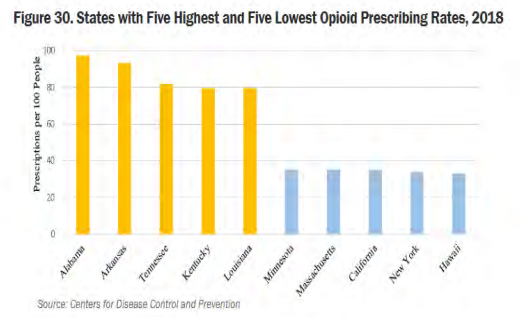
- POA's for II's
- Initial Inventory
- Biennial Inventory
- Closing Inventory
- Receiving Records, 222's or invoices – 2 year federal retention
- Distribution Records
- Theft and Loss – DEA Form 106 Report to LE
- Drug Destruction – DEA Form 41 – Reverse Distributors – Return to Manufacturer
- Prescriptions vs Dispensing (Must keep dispensing records)

The Latest from the CDC



https://www.cdc.gov/drugoverdose/epidemic/index.html



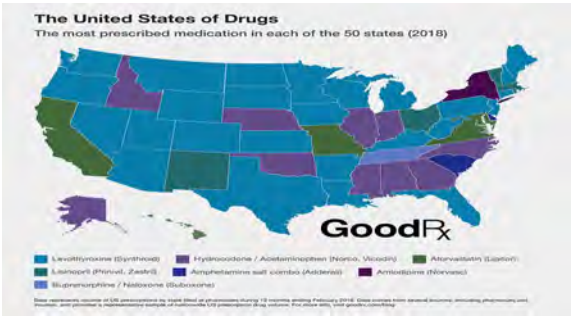


https://www.dea.gov/sites/default/files/2021-02/DIR-008-21%202020%20National%20Drug%20Threat%20Assessment_WEB.pdf

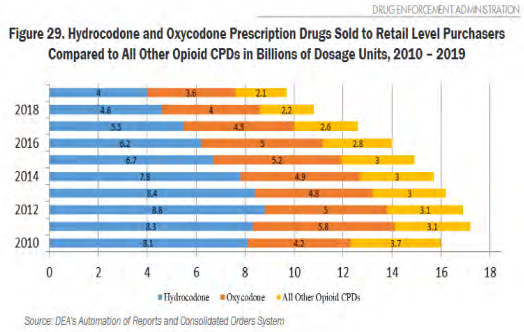
https://www.cdc.gov/media/releases/2017/p0706-opioid-infographic.html

Prescribed Drugs Are All Over the Map

2018

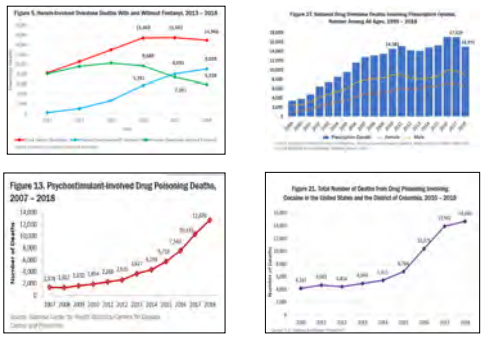


Opioid Prescriptions Have Been Decreasing



https://www.dea.gov/sites/default/files/2021-02/DIR-008-21%202020%20National%20Drug%20Threat%20Assessment_WEB.pdf

All Drug Overdose Deaths are Rising



https://www.dea.gov/sites/default/files/2021-02/DIR-008-21%202020%20National%20Drug%20Threat%20Assessment_WEB.pdf

Give Me an Example of a Typical DEA Investigation

Medical Office?

Medical Office?

Medical Office?

Pain Clinic

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

What are the Red Flags?

- Complaints from LE, pharmacists & family members.
- Overdose deaths.
- Lines outside the office.
- Irregular hours.
- Cash only.
- And others.
- Usually not one thing but a combination of several.

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

What's Going on Here?

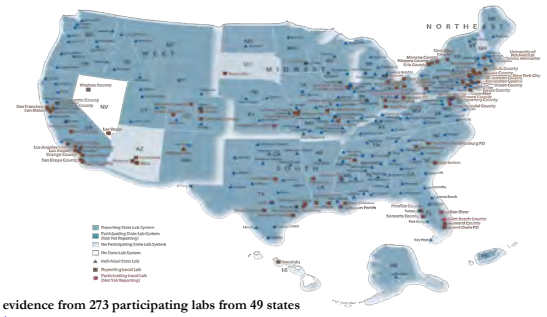
What's Going on Here?

Indiana Pill Mill

Chicago Heroin Line

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

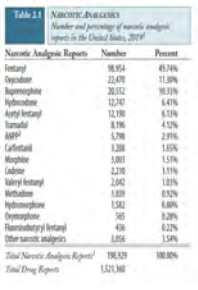
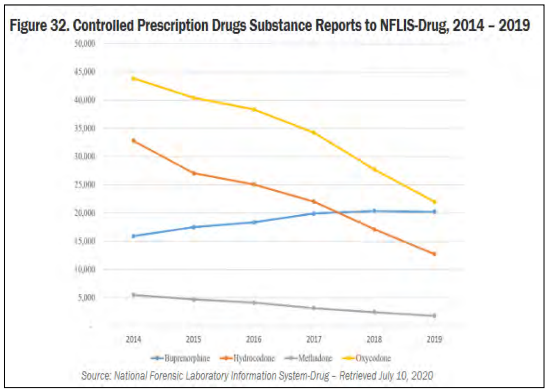


Table 2.1 Narcotic Analgesics
Number and percentage of narcotic analgesic reports in the United States, 2019[a]

Narcotic Analgesic Reports	Number	Percent
Fentanyl	98,954	49.74%
Oxycodone	22,679	11.39%
Buprenorphine	20,552	10.33%
Hydrocodone	12,747	6.41%
Acetyl fentanyl	12,190	6.13%
Tramadol	8,196	4.12%
6APP[c]	5,796	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%
Fluorobutyryl fentanyl	436	0.22%
Other narcotic analgesics	3,056	1.54%
Total Narcotic Analgesic Reports[b]	198,929	100.00%
Total Drug Reports	1,521,360	

https://www.nflis.deadiversion.usdoj.gov/DesktopModules/ReportDownloads/Reports/NFLIS-Drug-AR2019.pdf



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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

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The Holy Trinity

Prescription Drug Combination that Gives Heroin - Like - High

- Hydrocodone – Vicodon/Lortab/Norco
- Alprazolam - Xanax
- Soma - Carisprodol

- No legitimate medical purpose

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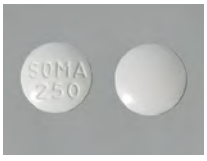
Other Common Drug Cocktails

- Soma + codeine = "Soma coma"
- Always changing

- Gabapentin abuse



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Drug Blogs

(Research Tool)

- Erowid.org
- Bluelight.org
- Drugs-Forum.com
- Opiophile.org

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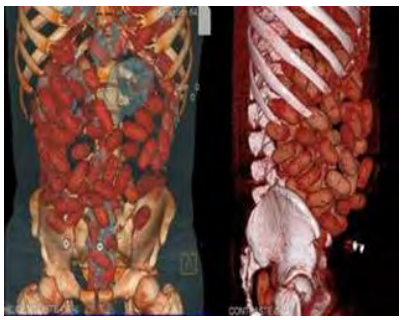
What Does This X-ray Show?



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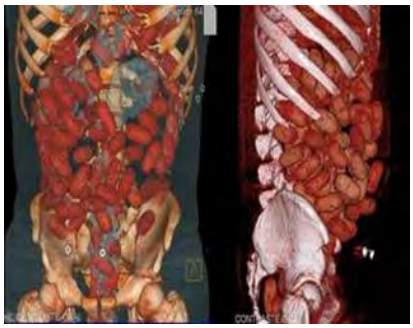
X-Ray of Cocaine Pellet Body Carrier



What are Possible Patient Red Flags?

- Patient has history of seeing multiple providers.
- Patient's providers are located at significant differences from patients residence.
- Patient has opioid and benzo history.
- Patient has higher than normal ER visits.

Walk me through some opioid prescribing case studies

Appalachian Regional Prescription Opioid (ARPO) Strike Force Takedown Results in Charges Against 60 Individuals, Including 53 Medical Professionals
April 17, 2019

- In the Western District of Kentucky, a doctor was charged with controlled substance and health care fraud counts in connection with providing pre-signed, blank prescriptions to office staff who then used them to prescribe controlled substances when he was out of the office, and for directing staff at the clinic, including individuals not licensed to practice medicine, to perform medical services on patients.

https://www.justice.gov/opa/pr/appalachian-regional-prescription-opioid-arpo-strike-force-takedown-results-charges-against

Source: Miami Herald
http://media.miamiherald.com/static/media/projects/2014/innocents-lost/stories/pill-mills/

Appalachian Regional Prescription Opioid (ARPO) Strike Force Takedown Results in Charges Against 60 Individuals, Including 53 Medical Professionals
April 17, 2019

In the Eastern District of Kentucky, a total of five people were charged, including three doctors, a dentist and an office assistant who were charged in connection with several health care fraud and/or controlled substance schemes. In one case a doctor operating a clinic that focused on pain management allegedly provided pre-signed, blank prescriptions to office staff who then used them to prescribe controlled substances when he was out of the office.

https://www.justice.gov/opa/pr/appalachian-regional-prescription-opioid-arpo-strike-force-takedown-results-charges-against

https://heroin.palmbeachpost.com/how-florida-spread-oxycodone-across-america/
http://nymag.com/intelligencer/2014/02/rise-and-fall-of-nycs-biggest-pill-mill.html
https://wsvn.com/news/inside-a-pill-mill/
https://www.orangeobserver.com/article/pill-mill-pain-clinic-busted-winter-park

Doctor sentenced to prison for prescribing narcotics to non-patients
June 13, 2019

SAVANNAH, Ga: Dr. Johnny Di Blasi, 46, of Braselton, Ga., was sentenced to 33 months in prison after pleading guilty.

As described in court filings and proceedings, Di Blasi, known as "Dr. Johnny," admitted writing prescriptions for narcotics, including opioids and amphetamines, to non-patients – many of whom he never met. Di Blasi wrote the prescriptions through clinics he operated in Pooler, Ga., and Braselton, Ga., to individuals traveling from at least 11 states. In addition, Di Blasi also provided and sold prescriptions for opioid pain medications and amphetamines to non-patients he met in restaurants and bars. One of those receiving prescriptions was an individual who was in prison at the time the prescription was written.

https://www.justice.gov/usao-sdga/pr/doctor-sentenced-prison-prescribing-narcotics-non-patients

What Did You Experience?

- Male
- Solo & small practices
- Over 50 years of age
- More rural than urban
- GP & FP
- Cash linked
- Small percentage

Appalachian Regional Prescription Opioid (ARPO) Strike Force Takedown Results in Charges Against 60 Individuals, Including 53 Medical Professionals
April 17, 2019

In yet another case, a Kentucky doctor was charged for allegedly prescribing opioids to Facebook friends who would come to his home to pick up prescriptions, and for signing prescriptions for other persons based on messenger requests to his office manager, who then allegedly delivered the signed prescriptions in exchange for cash.

https://www.justice.gov/opa/pr/appalachian-regional-prescription-opioid-arpo-strike-force-takedown-results-charges-against

Dr. Ranochak Indictment

https://www.justice.gov/file/984456/download

- Doctor's office inside pharmacy
- Pharmacists decided who saw Dr.
- Patient files kept in pharmacy area
- Pharmacists took cash for UDS's
- Pharmacists counseled patients how to pass UDSs
- Pharmacists signed scrips for doctor
- Patients who failed UDSs paid cash fines
- Doctor charged more for early refills
- All prescriptions had to filled at pharmacy
- No exams by doctor
- 90% of business relied on patients tied to doctor
- And more

What else should I know?

Urine Drug Screens

What About Urine Drug Screens?
(No federal law on UDSs)

Do You have a policy or contract in place?

Positive Screens

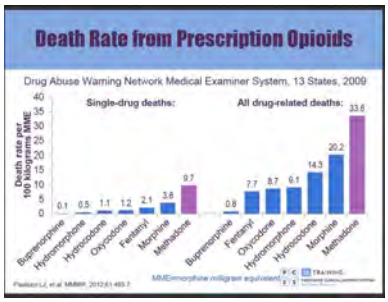
- Using for pain – good thing
- Using other drugs – for how long?
- Terminate?
- How often and how many?
- Methadone in screen?
  - VA
  - NTP/OTP
  - Importance of PMP use
- Other?
- Importance of following guidelines

Negative Screens

- Not good
- Indicates diversion?
- Terminate patient?

Methadone for Pain

Methadone Risk



https://www.cdc.gov/vitalsigns/methadoneoverdoses/infographic.html

Patient Drug Disposal Options

- Pharmacies
- Long-term Care Facilities
- Hospitals/clinics
- Opioid Treatment Programs
- Police Departments

Drug Disposal Links

National Drug Take Back Day - every April and September

NABP https://safe.pharmacy/drug-disposal/

DEA
https://www.deadiversion.usdoj.gov/drug_disposal/takeback/index.html

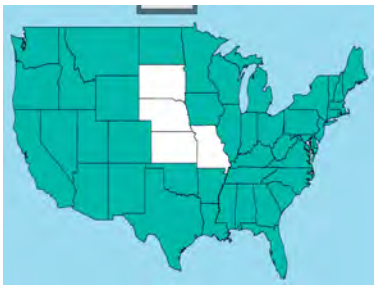
Walgreens (multiple locations)
https://www.walgreens.com/storelocator/find.jsp?RxDisposal=true

CVS (multiple locations)
https://www.cvs.com/content/safer-communities-locate

Prescription Drug Monitoring Programs

Prescription Drug Monitoring Programs

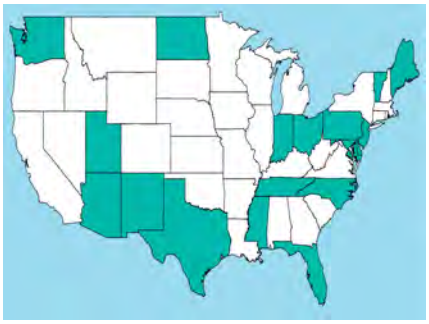
Mandatory Query by Prescribers -2020



https://www.pdmpassist.org/Policies/Maps/PDMPPolicies

Prescription Drug Monitoring Programs

Mandatory Query by Dispensers -2020

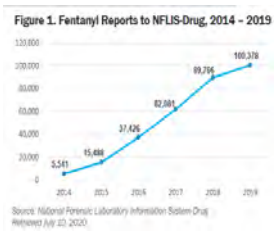


https://www.pdmpassist.org/Policies/Maps/PDMPPolicies

Fentanyl Drug Update

- China as a source country
  - Fentanyl's
  - W-18
  - U-47700 aka Pink
  - Carfentanil
  - Other drugs like Xanax, oxycodone, etc.

Chinese Fentanyl Movement & Statistics



What is My Government Doing on Opioid Epidemic?

- China partnerships
- Expanded treatment, NTP's & MAT
- New Fentanyl laws
- Prevention
  - Discovery Channel

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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Figure 40. Average THC and CBD Potency of Traditional and Concentrated Marijuana, 1995 – 2019

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Figure 39. Current State-Approved Marijuana Status – July 2020

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Online DEA Resources

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

Other Online DEA Resources

https://www.deadiversion.usdoj.gov/

https://www.deadiversion.usdoj.gov/disaster_relief.htm

https://www.deadiversion.usdoj.gov/drug_disposal/takeback/index.html

https://apps.deadiversion.usdoj.gov/rxaor/spring/main?execution=e1s1

I Want to Know More

https://www.deadiversion.usdoj.gov/pubs/manuals/(DEA-DC-046)(EO-DEA154)_Pharmacist_Manual.pdf
https://www.in.gov/dhs/files/DEA_Practicioner_Manual.pdf

DEA FAQ's

Why is Marijuana Still a Schedule I Drug?

The federal Controlled Substance Act (CSA) was implemented in 1970 and has changed little over the years.

The FDA pursuant to federal law makes determinations as to what is medicine and has for over 50 years. Its scientific assessment team determines the safety and efficacy of drugs intended for human consumption.

The FDA has not approved marijuana as a medicine. (Marinol & Epidolex approved)

DEA places drugs into a Schedule (I through V) according to its accepted medical use and potential for abuse in consultation with the FDA pursuant to CSA .

Research: Over 350 researchers have been approved to study marijuana and DEA has never turned a researcher approved by the HHS (first step). DEA oversees security requirements.

https://www.dea.gov/divisions/hq/2016/Letter081116.pdf

My DEA Number has Been Stolen/Being Misused What Should I Do?

- Notify your area's pharmacies of the fraud and follow-up with email.
- Notify your local law enforcement agency of the fraud and follow-up with an email documenting.
- Notify your local DEA office and follow-up with email.
- Assign one or two employees in your office as poc's to aid in pharmacist inquiries.
- Review your PDMP profile periodically.
- Prosecution?
- Electronic prescribing should prevent.
- DEA will issue a new number.

Locus Tenens

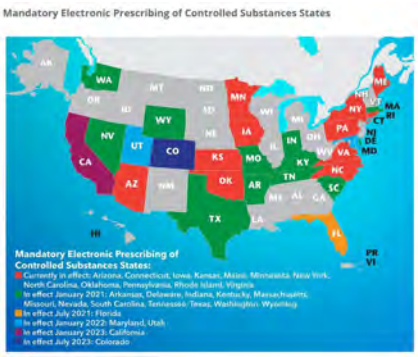
- Coordinate with DEA for license transfer.
- DEA number always contingent upon state license(s).
- Call (800) 882-9539 (8:30 am-5:50 pm EST) or DEA.Registration.Help@usdoj.gov to coordinate.
- Can get 2nd license also but…..

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-12)%20What%20is%20DEA's%20policy%20concerning%20Locum%20Tenens.pdf

E Prescribing

ELECTRONIC PRESCRIBING HISTORY

2010 – DEA's Interim Rule
2011 – Minnesota 1st to mandate/w no penalties
2016 – New York 1st to mandate w/penalties
2016 – Maine was 3rd
2016 – 2021 – multiple states
2020 – DEA's Interim Rule Reopened
2021 – CMS Rule for Medicare Part D (1/2022)



https://www.agd.org/publications-and-news/newsroom/newsroom-list/2020/08/10/don-t-panic-over-mandated-e-prescribing-of-controlled-substances-laws

THE SUPPORT ACT REQUIRES E-PRESCRIBING

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, enacted in 2018, requires Medicare Part D prescriptions of opioids and other controlled drugs be prescribed electronically beginning January 1, 2021.

U.S. Department of Justice ★ Drug Enforcement Administration
DIVERSION CONTROL DIVISION
Use of Mobile Devices in the Issuance of EPCS - August 16, 2018

At this time, the DEA does not preclude the use of a mobile device, for the issuance of an electronic prescription for a controlled substance, if the encryption used on the device meets the latest security requirements set out in Federal Information Processing Standards (FIPS 140-2).
https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-8)%20Use%20of%20Mobile%20Devices%20In%20the%20Issuance%20of%20EPCS.pdf

The value of E-Prescribing

(Similar to E-Banking?)

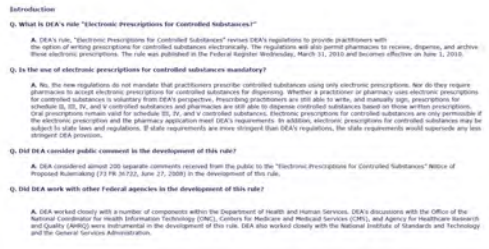
- Streamlined prescriber workflow/faster
- Improved medication safety
- Reduced drug diversion/fraud
- Prescriber identification both assured and easier
- Single workflow for prescribing both controlled and non-controlled drugs
- Instant connectivity between Providers, Pharmacy, health plans, medical records…
- Access by all authorized clinicians

Disadvantages of E-Prescribing

- System Failures and incompatibilities
- Power Outages
- Authentication Errors
- Improper patient selection from electronic lists
- Improper or difficult product selection
- Interfacing challenges between prescribers and pharmacies

DEA EPCS FAQ's

51 Total Q & A's
12/29/2019



Introduction

Q. What is DEA's rule "Electronic Prescriptions for Controlled Substances?"

A. DEA's rule, "Electronic Prescriptions for Controlled Substances" revises DEA's regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations will also permit pharmacies to receive, dispense, and archive these electronic prescriptions. The rule was published in the Federal Register Wednesday, March 31, 2010 and becomes effective on June 1, 2010.

Q. Is the use of electronic prescriptions for controlled substances mandatory?

A. No. The new regulations do not mandate that practitioners prescribe controlled substances using only electronic prescriptions. Nor do they require pharmacies to accept electronic prescriptions for controlled substances for dispensing. Whether a practitioner or pharmacy uses electronic prescriptions for controlled substances is voluntary from DEA's perspective. Prescribing practitioners are still able to write, and manually sign, prescriptions for schedule II, III, IV, and V controlled substances and pharmacies are still able to dispense controlled substances based on those written prescriptions. Oral prescriptions remain valid for schedule III, IV, and V controlled substances. Electronic prescriptions for controlled substances are only permissible if the electronic prescription and the pharmacy application meet DEA's requirements. In addition, electronic prescriptions for controlled substances may be subject to state laws and regulations. If state requirements are more stringent than DEA's regulations, the state requirements would supersede any less stringent DEA provision.

Q. Did DEA consider public comment in the development of this rule?

A. DEA considered almost 200 separate comments received from the public to the "Electronic Prescriptions for Controlled Substances" Notice of Proposed Rulemaking (73 FR 36722, June 27, 2008) in the development of this rule.

Q. Did DEA work with other Federal agencies in the development of this rule?

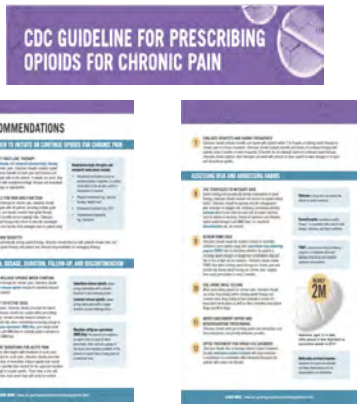
A. DEA worked closely with a number of components within the Department of Health and Human Services. DEA's discussions with the Office of the National Coordinator for Health Information Technology (ONC), Centers for Medicare and Medicaid Services (CMS), and Agency for Healthcare Research and Quality (AHRQ) were instrumental in the development of this rule. DEA also worked closely with the National Institute of Standards and Technology and the General Services Administration.

https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-9)%20Questions%20and%20Answers%20for%20Prescribing%20Practitioners%20(EPCS).pdf
https://www.deadiversion.usdoj.gov/ecomm/e_rx/thirdparty.htm

Final Thoughts on E-prescribing

- It's coming
- Consult with various state Boards for requirements & vendors - Medical Board, Pharmacy Board, Hospital Association, etc.
- Select experienced vendor that can link to your EMR/EHR
- Know the exceptions just in case
- Conduct training
- Audit system at regular intervals

CDC Opioid Guidelines



https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf

CDC Advises Against Misapplication of the Guideline for Prescribing Opioids for Chronic Pain

April 24, 2019

- Misapplication of recommendations to populations outside of the Guideline's scope.
- Misapplication of the Guideline's dosage recommendation that results in hard limits or "cutting off" opioids.
- The Guideline does not support abrupt tapering or sudden discontinuation of opioids.
- Misapplication of the Guideline's dosage recommendation to patients receiving or starting medication-assisted treatment for opioid use disorder.

https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html

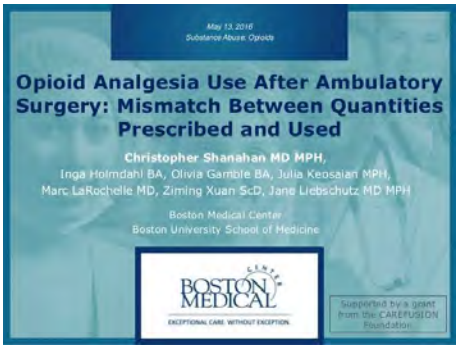
AMA Letter to CDC

June 16, 2020

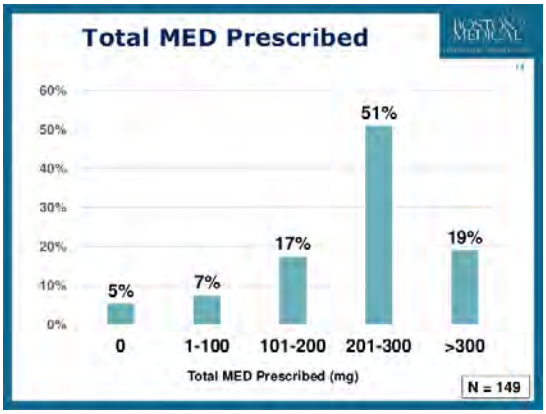
On behalf of the American Medical Association (AMA) and our physician and medical student members, the AMA appreciates the opportunity to review and comment on the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain (CDC Guideline), originally published in 2016. We commend CDC's decision to open a public comment period to allow a broader group of important stakeholders the opportunity to provide their unique perspectives on the public health challenges faced by patients with pain, the unintended consequences of the CDC Guideline, and to provide constructive suggestions on how to revise and update the CDC Guideline to help it more effectively address the intersection of pain management, prescription opioid use, and opioid diversion, misuse, and unintentional overdose.

https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2020-6-16-Letter-to-Dowell-re-Opioid-Rx-Guideline.pdf

Opioid Surgery Study



https://www.slideshare.net/cshanaha/opioid-analgesia-use-after-ambulatory-surgery-mismatch-between-quantities-prescribed-and-used



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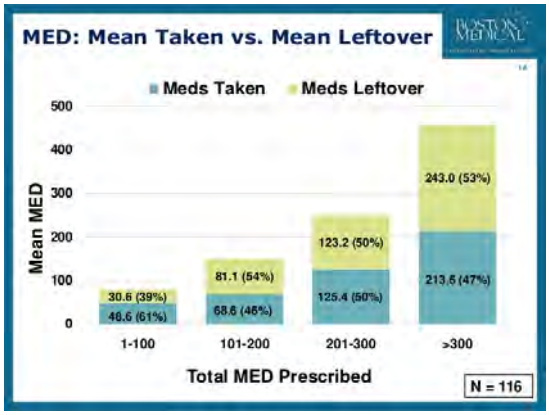

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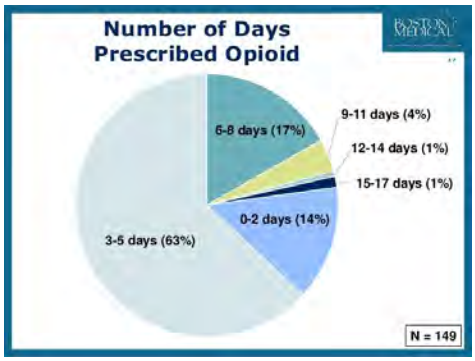

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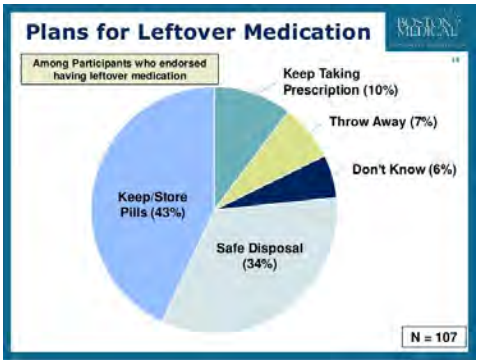
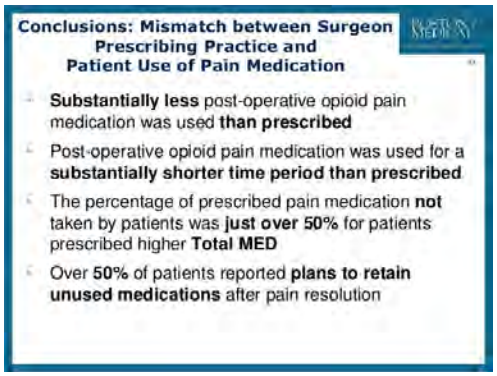


Prescription Drug Consulting LLC — Protecting Healthcare Organizations and Providers Nationwide

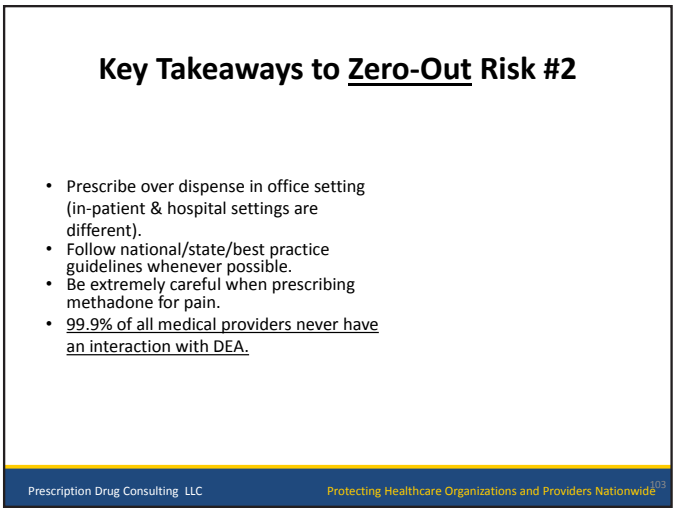


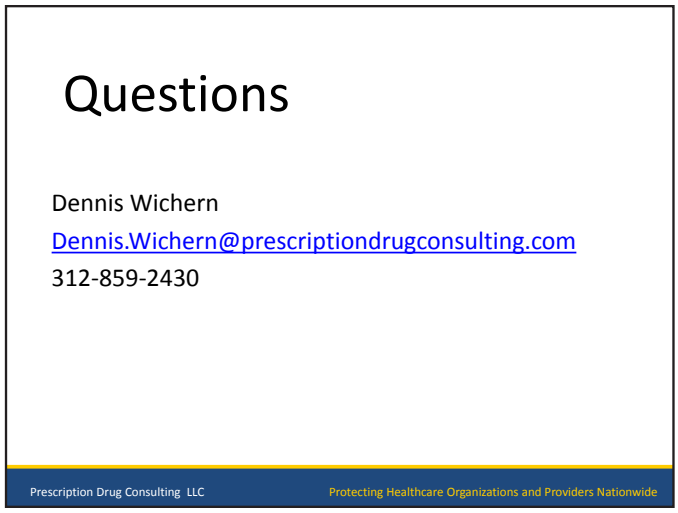
Prescription Drug Consulting LLC — Protecting Healthcare Organizations and Providers Nationwide

Key Takeaways to Zero-Out Risk #1

- Treat your prescription pad like your checkbook & secure other pads.
- Never sign prescription blanks in advance.
- Use the PDMP more - than less.
- Practice due diligence and stay current.
- Practice the way you were taught in medical school.

Prescription Drug Consulting LLC — Protecting Healthcare Organizations and Providers Nationwide 102





SELF EVALUATION

The DEA, Opioids and the Healthcare Provider

True/False

1.___ All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued.

2.___ Methadone can be prescribed for pain treatment but providers should be knowledgeable about its unique pharmacology.

3.___ The CDC opioid guidelines recommend that opioids and benzodiazepines should be prescribed together if at all possible.

4.___ The combination of an opioid, a benzodiazepine and SOMA is known as the Holy Trinity and gives one a synthetic heroin like high.

5.___ The federal definition of a valid prescription is: 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.

6.___ 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.

7.___ DEA's authority is limited to controlled substances only.

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

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Type 2 Diabetes: New Approaches to Reducing Macrovascular Risk

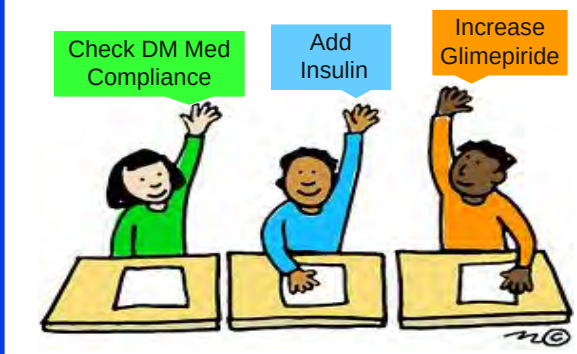
An Abbreviated Case Study

64 y.o. aSx Obese ♀(BMI 33.5), T2DM X 15 yrs

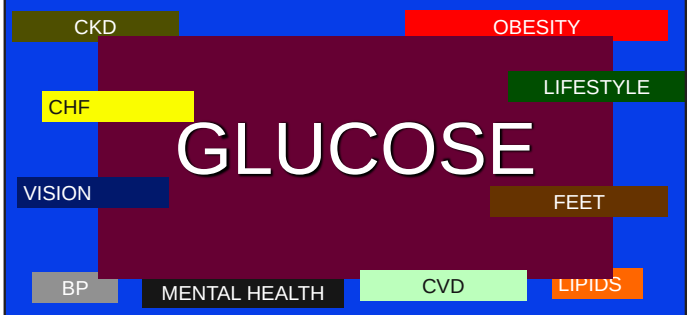
- PMH: MI 2 years ago
  - Metformin 1g b.i.d. + Glimepiride 4mg qd
  - ASA 81 mg qd
  - Atorvastatin 40 mg qd
- Glucose
  - FBS: 160-200 mg/dL
  - Lunch postprandial: 220-300 mg/dL
- HbA1c = 9.8

WHAT SHOULD WE DO NEXT?

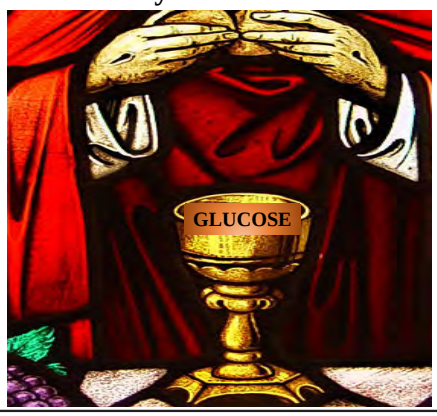
WHAT SHOULD WE DO NEXT?



WHAT's THE PROBLEM?



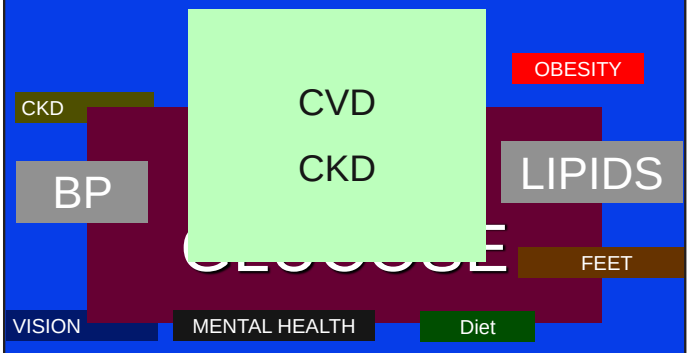
The "Holy Grail' of Diabetes



WHAT's THE PROBLEM?

CKD
OBESITY
LIPIDS
GLUCOSE
VISION
LIFESTYLE
FEET
MENTAL HEALTH
BP

What's THE Problem?



The "Holy Grail' of Diabetes

Why CVD Reduction?

"ASCVD — defined as CHD, CVD disease, or PAD presumed to be of atherosclerotic origin — is the leading cause of morbidity and mortality for individuals with diabetes…."

ADA Standards of Medical Care in Diabetes 2019
Diabetes Care 2019;42(Suppl 1):S103-S123

Mortal Consequences of Diabetes

"The average life expectancy of a 50-year old individual with DM is 6 years shorter than it would be without the disease."

Boena-Diez J et al *Diabetes Care* 2016;39:1987-1995

Mortal Consequences of Diabetes: Why?

" DM not only doubles or quadruples CV risk, compared with the general population, but also leads to an increased risk of cancer…."

Boena-Diez J et al *Diabetes Care* 2016;39:1987-1995

DM and Women: CV Mortality
Nurses Health Study 1976-1996

Baseline Status **n = 121,700 RNs age 30-55**	**CV Mortality RR**
Control	1
DM no CHD	4.86
CHD no DM	7.46
CHD & DM	20.1

Hu FB, et al *Arch Intern Med* 2001;161:1717-1723

Diabetes & Heart Failure

"Recent studies have found that rates of incident heart failure hospitalization….were twofold higher in patients with diabetes compared with those without….As many as 50% of patients with T2DM may develop heart failure."

ADA Standards of Medical Care in Diabetes 2019
Diabetes Care 2019;42(Suppl 1):S103-S123

If CVD is KING, then…… (2019)

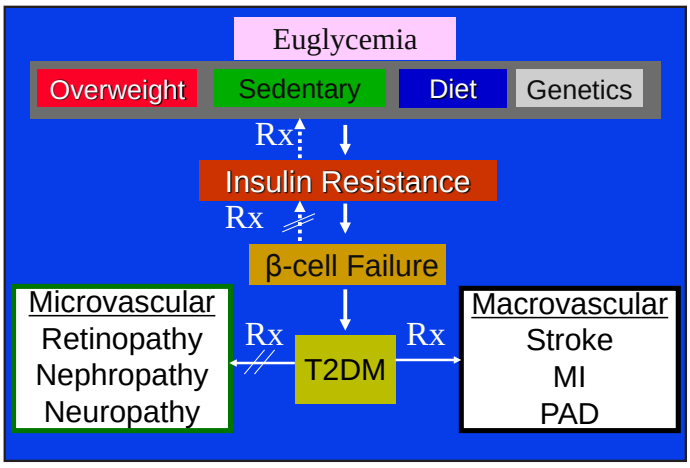
"Among patients with T2DM who have established ASCVD, SGLT2i or GLP1-RA with demonstrated CVD benefit are recommended as part of the antihyperglycemic regimen." **A**

ADA Standards of Medical Care in Diabetes 2019
Diabetes Care 2019;42(Suppl 1):S103-S123

If CVD is KING, then…… (2020)

"For patients with established ASCVD or indications of high ASCVD risk (such as patients ≥55 …with coronary, carotid, or lower extremity artery stenosis >50% or LVH), an SGLT-2-i or GLP-1RA with demonstrated CVD benefit is recommended as part of the glucose lowering regimen independent of A1c…."

ADA Standards of Medical Care in Diabetes 2020
Diabetes Care 2020;43(Suppl 1):S98-S110



GLUCOTROL XL®
(glipizide)
Extended Release Tablets
For Oral Use

Prescribing Information

Glucotrol XL Prescribing Information (2016)
(glipizide)

PRECAUTIONS

General

Macrovascular outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with GLUCOTROL or any other anti-diabetic drug

Glucotrol XL Prescribing Information (2016)
(glipizide)

WARNINGS

SPECIAL WARNING ON INCREASED RISK OF CV MORTALITY:

The administration of oral hypoglycemic drugs has been reported to be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin.

(Emphasis added)

Glucotrol XL Prescribing Information (2016)
(glipizide)

WARNINGS
SPECIAL WARNING ON INCREASED RISK OF CV MORTALITY:

This warning is based on the study conducted by the UGDP, a long-term PCT trial designed to evaluate the effectiveness of glucose-lowering drugs in preventing or delaying vascular complications in patients with non-insulin-dependent diabetes.

UGDP (University Group Diabetes Program)

- Study: T2DM (n=823)
- Rx (X9 years): Diet +
  - Fixed dose insulin (weight based12-16 u/d)
  - Variable dose insulin (to normalize glucose)
  - SFU (Tolbutamide)
  - Placebo
- Outcome: Cardiovascular Events

Meinert CL "The Trials & Tribulations of the UGDP" 2015 Kelmscott Bookshop, Baltimore

UGDP (University Group Diabetes Program)
Diabetes 1970;19:(Suppl 2):747-830

Results: CV mortality
- SFU (Tolbutamide) vs diet: RR = 2.5*
- Insulin vs diet: RR = ±1**

*Glucotrol PI. **Meinert CL "The Trials and Tribulations of the UGDP" 2015 Kelmscott Bookshop, Baltimore

2014


Effect of Aleglitazar on Cardiovascular Outcomes After Acute Coronary Syndrome in Patients With Type 2 Diabetes Mellitus
The AleCardio Randomized Clinical Trial

IMPORTANCE No therapy directed against diabetes has been shown to unequivocally reduce the excess risk of cardiovascular complications. Aleglitazar is a dual agonist of peroxisome proliferator-activated receptors with insulin-sensitizing and glucose-lowering actions and favorable effects on lipid profiles.

Balanced Prioritization of CVD

- BP
- Lipids
- Antiplatelet
- Glucose: CVD-favorable agents*
- Diet
- Exercise

* For Patients with Established ASCVD

BP Targets

10-yr CV Risk	Goal BP mm Hg	Evidence Level
<15%	<140/90	A
>15%	<130/80*	C

* "…if it can be safely attained."

ADA Standards of Medical Care
Diabetes Care 2021;44(Suppl 1):S125-S150

Lipid Rx
Primary Prevention

Age	CV Risk	Statin Intensity	Evidence
<40-75	--	Moderate	A
50-70	High	High	B
All Adults	10 yr CVD>20%	High May add ezetimibe	C
20-39	RF+	Yes	C

ADA Standards of Medical Care
Diabetes Care 2021;44(Suppl 1):S125-S150

Lipid Rx
Secondary Prevention

Categorey	Statin Intensity	Evidence
ALL*	High	A
	If high intensity not tolerated, use max tolerated lower intensity	E
Very High Risk LDL ≥70	May add PCSK9 or ezetimibe	A
Age >75	If already on statin: continue	B
	Maybe start after R:B discussion	C

*Statin contraindicated in pregnancy

ADA Standards of Medical Care
Diabetes Care 2021;44(Suppl 1):S125-S150

Antiplatelet Rx

Category	Agent	Evidence Level
2^0 Prevention	ASA 75-162 mg/d Clopidogrel if ASA Allergy	A
1^0 Prevention	*ASA 75-162 mg/d	A

*After Comprehensive Risk Benefit Discussion

ADA Standards of Medical Care
Diabetes Care 2021;44(Suppl 1):S125-S150

ADA 2021 Recommended A1C/CGM Goals
"Many Non-Pregnant Adults"

A1c:
<7% with Hypoglycemia
(Evidence A)

CGM:
TIR >70% and TBR <4%
(Evidence B)

American Diabetes Association. *Diabetes Care.* 2021;44(Suppl 1):S73-S84

ADA 2021 Recommended A1C/CGM Goals
When A1c << 7% Might Be Appropriate

"On the basis of provider judgment and patient preference…lower A1c levels than the goal of 7% may be acceptable, and even beneficial, if it can be achieved safely without significant hypoglycemia or other adverse effects of Rx" (Evidence Level C)

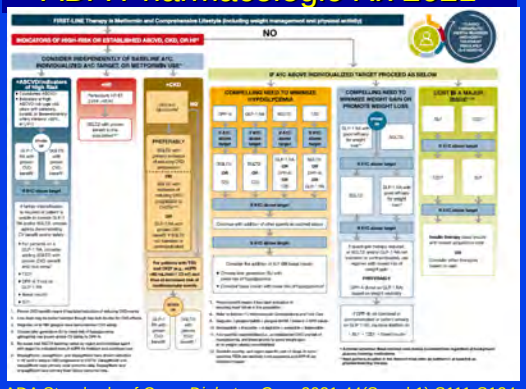
American Diabetes Association. *Diabetes Care.* 2021;44(Suppl 1):S73-S84

ADA 2021 Recommended A1C/CGM Goals
When A1c <8% Might Be Appropriate

"Less stringent A1c goals (such as 8%) may be appropriate for patients with limited life expectancy, or where the harms of Rx are greater than the benefits." (Evidence Level B)

American Diabetes Association. *Diabetes Care.* 2021;44(Suppl 1):S73-S84

ADA Pharmacologic Rx 2021



ADA Standards of Care *Diabetes Care* 2021;44(Suppl 1):S111-S124

ASCVD or ASCVD High Risk

Consider Independent of Baseline A1c/Individualized A1c Target

FDA label for CVD Benefit	Established ASCVD	High ASCVD Risk***
GLP-1-RA*	#1	#1
SGLT2i**	#2	#2

* GLPs: dulaglutide, liraglutide, semaglutide SQ

**SGLT2: canagliflozin, dapagliflozin, empagliflozin

***ASCVD High Risk: >55 with CAD, Carotid or PAD >50% stenosis or LVH

ADA Standards of Care *Diabetes Care* 2021;44(Suppl 1):S111-S124

HF or CKD

Consider Independent of Baseline A1c/Individualized A1c Target

FDA labeled CHF/CKD	HF	CKD UACR>30	CKD UACR WNL GFR <60
SGLT2*	#1	#1	#1 or #2
GLP1**	#2	#2	#1 or #2

* SGLT2: canagliflozin, dapagliflozin, empagliflozin

**GLP (CVDR labeled): dulaglutide, liraglutide, semaglutide SQ

ADA Standards of Care *Diabetes Care* 2021;44(Suppl 1):S111-S124

Guidance for Industry

Diabetes Mellitus — Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

December 2008
Clinical/Medical

FDA 2008 Guidance for Industry

"Specifically, this guidance makes recommendations about how to demonstrate that a new antidiabetic therapy to treat T2DM is not associated with an unacceptable increase in CV risk."

Emphasis added

https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm071627.pdf accessed January 6, 2019

How Does Industry Respond to the FDA 2008 Guidance for Industry?

Performing Non-inferiority Trials

- New Drug A vs Placebo added to existing Rx

https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm071627.pdf accessed January 6, 2019

What Does a Non-Inferiority Trial Demonstrate?

"New Drug A has been found to be 'non-inferior' to Old Drug B" means:

NO
- Drugs A and B are equally effective

YES
- New Drug A is not more than a specific amount less effective than Old Drug B

or

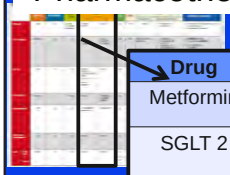
YES
- New Drug A (given, usually, similar efficacy), is not more than a specific amount more toxic than Old Drug B

What Does "Non-Inferiority" Mean In Terms of CV Outcomes for New T2DM Drugs?

- New Drug A incurs <30% increase in CV risk

https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm071627.pdf accessed January 6, 2019

Pharmacotherapy: Clinical Characteristics



Drug	ASCVD	CHF
Metformin	Potential benefit	Neutral
SGLT 2	Benefit: Cana-, empagliflozin	Benefit Cana-, Empagliflozin
GLP1-RA	Benefit: liraglutide	Neutral
DPP4	Neutral	Potential risk Alogliptin, saxagliptin
TZD	Potential benefit	Increased risk
SFU	Neutral	Neutral
Insulin	Neutral	Neutral

ADA Standards of Medical Care 2018 Diabetes Care 2018;41(Suppl 1):S55-S64

DM2 CV Safety Outcome Trials (Thru Jan 2018)

DPP-4i		GLP-1RA		SGLT-2i	
Alogliptin	EXAMINE	Albiglutide	HARMONY	Canagliflozin	CANVAS
Linagliptin	CARMELINA	Dulaglutide	REWIND		CANVAS-R
	CAROLINA	Exenatide QW	EXSCEL		CREDENCE
Saxagliptin	SAVOR-TIMI53	Exenatide ITCA 650	FREEDOM 3	Dapagliflozin	DECLARE-TIMI 58
Sitagliptin	TECOS	Liraglutide	LEADER	Empagliflozin	EMPA-REG OUTCOME
		Lixisenatide	ELIXA	Ertugliflozin	VERTIS CV
		Semaglutide	SUSTAIN 6		

CV Safety Trial Showing CV Risk REDUCTION Canagliflozin

Endpoint [a] = primary endpoint * = all p < 0.05	Rate/100 pt-years		Hazard Ratio* (95% CI)
	Cana	Pbo	
CV death, nonfatal MI & stroke	2.69	3.15	0.86 (0.75-0.97)
HF hospitalization	0.55	0.87	0.67 (0.52-0.87)
CV death or HF hospitalization	1.63	2.08	0.78 (0.67-0.91)
Progression of albuminuria	8.94	12.87	0.73 (0.67-0.79)
40% ↓ eGFR, renal dialysis or transplantation, renal death	0.55	0.90	0.60 (0.47-0.77)

Neal B, et al. *N Engl J Med*. 2017;doi:10.1056/NEJMoa1611925.

CV Safety Trial Showing CV Risk REDUCTION Empagliflozin

Endpoint [a] = primary endpoint * = all p < 0.05	Rate/100 pt-years		Hazard Ratio * (95% CI)
	Empa	Pbo	
CV death, nonfatal MI & stroke	3.74	4.39	0.86 (0.74-0.99)
All cause mortality	1.94	2.86	0.68 (0.57-0.82)
CV death	1.24	2.02	0.62 (0.49-0.77)
HF hospitalization	0.94	1.45	0.65 (0.50-0.85)
HF hospitalization of CV death (excluding fatal stroke)	1.97	3.01	0.66 (0.55-0.79)

Zinman B et al *N Engl J Med*. 2015;373(22):2117-2128

CV Safety Trial Showing CV Risk REDUCTION Liraglutide

Endpoint [a] = primary endpoint * = all p < 0.05	Rate/100 pt-years		Hazard Ratio (95% CI) *
	Lira	Pbo	
CV death, nonfatal MI & stroke[a]	3.4	3.9	0.87 (0.78-0.97)
1^0 + revascularization, unstable angina, or HF hospitalization	5.3	6.0	0.88 (0.81-0.96)
All cause mortality	2.1	2.5	0.85 (0.74-0.97)
CV death	1.2	1.6	0.78 (0.66-0.93)
Microvascular event	2.0	2.3	0.84 (0.73-0.97)
Nephropathy	1.86	3.06	0.78 (0.67-0.92)

Marso SP, et al. *N Engl J Med*. 2016;375(4):311-322.

CV Safety Trial Showing CV Risk REDUCTION Semaglutide

Endpoint [a] = primary endpoint * p < 0.05	Rate/100 pt-years		Hazard Ratio (95% CI)
	Sema	Pbo	
CV death, nonfatal MI & stroke[a]	3.24	4.44	0.74 (0.58-0.95)*
1^0 + revascularization, unstable angina, or HF hospitalization	6.17	8.36	0.74 (0.62-0.89)*
All cause mortality	1.82	1.76	1.05 (0.74-1.50)
CV mortality	1.29	1.35	0.98 (0.65-1.48)
Nonfatal stroke	0.80	1.31	0.61 (0.38-0.99)*
New or worsening nephropathy	1.86	3.06	0.64 (0.46-0.88)*

Marso SP, et al. *N Engl J Med*. 2016;375(19):1834-1844.

The CVD Stars

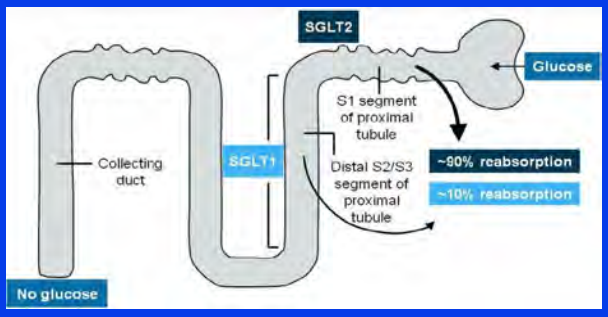
SGLT2-i

GLP1-a

SGLT2 Inhibitors

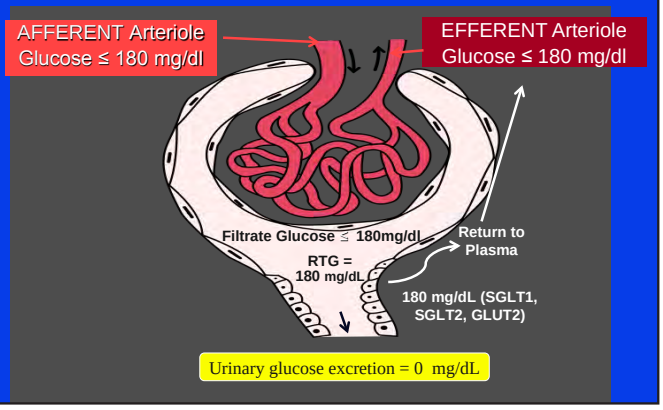
Canagliflozin (Invokana)
Dapagliflozin (Farxiga)
Empagliflozin (Jardiance)

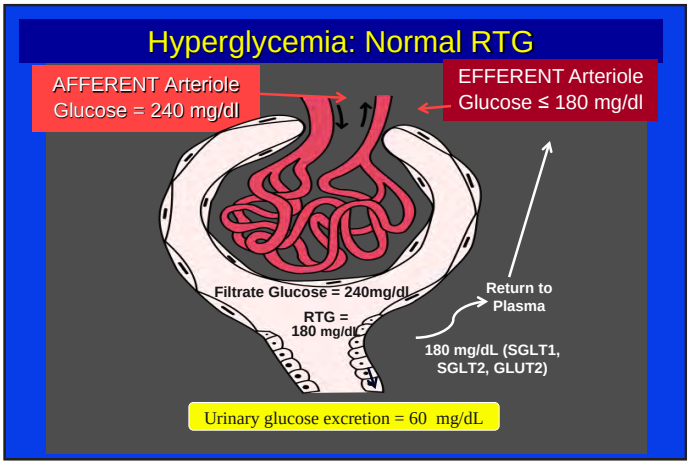
Targeting the Kidney:SGLT2 Inhibition (Cana-, Dapa-,Empa-, Etrugliflozin)

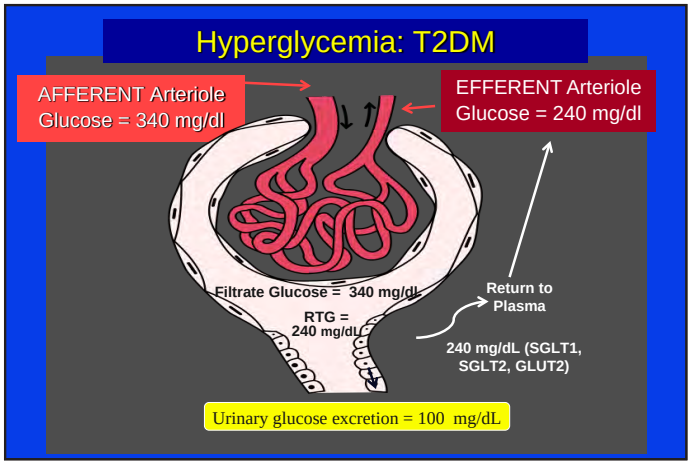


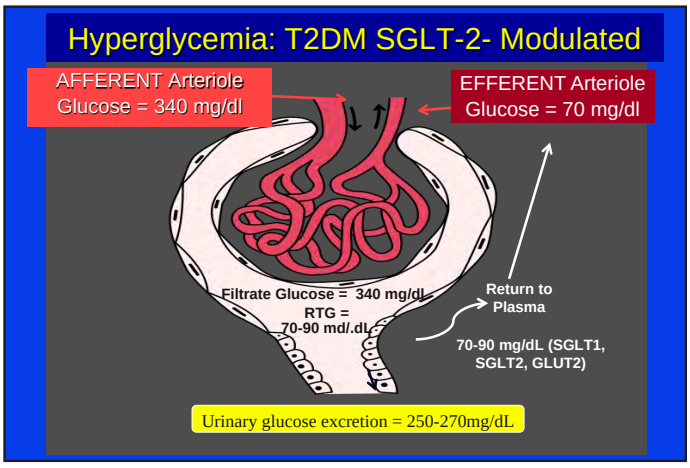
Adapted from Chao EC, et al. *Nat Rev Drug Discovery*. 2010;9:551-559.

Normal Glucose: Normal RTG





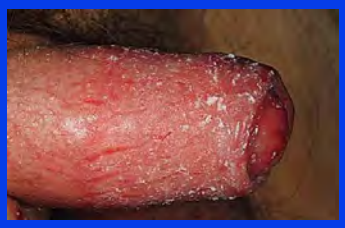




Safe Use of SGLT2i
Selected PI Warnings October 2018

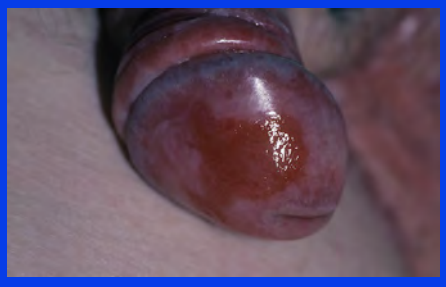
AE	Canagliflozin (Invokana)	Empagliflozin (Jardiance)
Hypotension	√	√
Ketoacidosis	√	√
AKI	√	√
UTI/Urosepsis	√	√
Hypoglycemia	√	√
Fournier's Gangrene	√	√
Amputations	√	
Genital Mycotic Infections	√	√

Candida Balanoposthitis



Dermnet.com accessed 2014 June

Candidal Balanitis



Dermnet.com accessed 2014 June

Balanitis Rx

- Clotrimazole 1% cream b.i.d. X 1-3 weeks
- Miconazole 2% cream b.i.d. X 1-3 weeks
- Nystatin 100,000 u/g b.i.d. X 1-3 weeks
- Fluconazole 150 mg PO X 1

+

- Hydrocortisone cream if inflammation problematic

GLP1 Agonists

Exenatide (Byetta, Bydureon)
Liraglutide (Victoza, Saxenda)
Dulaglutide (Trulicity)
Lixisenatide (Adlyxin)
Semaglutide (Ozempic)

The 'Magic' of GLP-1-RA
Physiologic Effects of GLP-1

- Blunted glucose-dependent glucagon secretion
- Augmented glucose-dependent insulin secretion
- Enhanced satiety
- Modulation of gastric emptying

Gallwitz B Int J Clin Pract 2006;60(12):1654-1661

GLP1 Benefit #1
Blunted Glucagon Secretion

- Alpha cell function is impaired in T2DM
  - Glucagon should only be elevated when glucose is low
  - In T2DM, FASTING glucagon levels are elevated[1]
  - In T2DM, glucagon levels RISE after a meal (→ worsening hyperglycemia)[1]

Del Prato S et al *Horm Metab Res* 2004;36:775–781

GLP1 Benefit #2
Enhances Glucose Dependent Insulin Secretion

- Insulin secretagogues (eg, sulfonylurea)
  - Stimulate insulin secretion irrespective of ambient glucose levels
  - Continue to stimulate insulin secretion in the face of hypoglycemia
  - Long-acting agents can → protracted episodes of hypoglycemia
- GLP1→ insulin secretion ONLY when glucose elevated: minimizes hypoglycemia

Drucker DJ Diabetes Care 2003;26:2929-2940

GLP1 Benefit #3
Improved Satiety

- Believed to be a CNS effect
- Associated with WEIGHT LOSS
- Weight loss NOT attributable to nausea
- Similar weight loss NOT seen with DPP4

Meier JJ, Nauck MA Best Pract Res Clin Endocrinol Metab 2004;18:587-606

GLP1 Benefit #4
Modulation of Gastric Emptying

- 1st-Phase insulin (preformed) absent in T2DM[1]
- Dietary CHO ingestion → exaggerated plasma glucose from to sluggish insulin response due to absent preformed insulin
- Delay in delivery of gastric contents to intestine allows sluggish β-cell better provision of insulin
- Alpha glucosidase inhibitors have favorable glucose effects simply by slowing glucose absorption

[1]Marchetti P et al *J Clin Endocrinol Metab* 2004;89:5535–5541

GLP1-RA vs DPP4i

Property	GLP-1RA	DPP-4i
MOA	GLP-1RA	GLP/GIP degradation inhibitor
Route	SQ	PO
A1C Δ	Up to 2%	Up to 1%
Gastric emptying	Slowed	No Δ
Promotes satiety	Yes	No
Weight	Decreased	Neutral

Drucker DJ. *Cell Metab*. 2006 Mar;3(3):153-165; Lund A, et al. *Eur J Intern Med*. 2014;25(5):407-414; Neumiller JJ. *Clin Ther*. 2011;33(5):528-576.

Diabetes & Heart Failure

"Recent studies have found that rates of incident heart failure hospitalization….were twofold higher in patients with diabetes compared with those without….As many as 50% of patients with T2DM may develop heart failure."

ADA Standards of Medical Care in Diabetes 2019
Diabetes Care 2019;42(Suppl 1):S103-S123

Diabetes & Heart Failure Risk

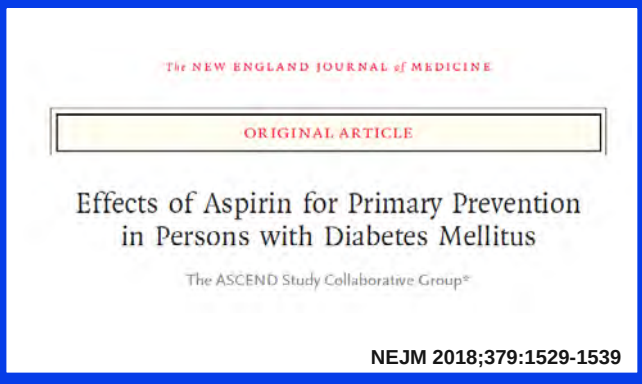
Class	Agent	Trial	RR vs placebo
DPP4i	Saxagliptin	SAVOR-TIMI	1.27 (1.07-1.51)*
	Alogliptin	EXAMINE	1.19 (0.90-1.58)
	Sitagliptin	TECOS	1.00 (0.83-1.20)
GLP1 RA	Lixisenatide	ELIXA	0.96 (0.75-1.23)
	Semaglutide	SUSTAIN	1.11 (0.77-1.61)
	Liraglutide	LEADER	0.87 (0.73-1.05)
	Exenatide QW	EXSCEL	0.94 (0.78-1.13)
SGLT2i	Empagliflozin	EMPA-REG	0.65 (0.50-0.85)*
	Canagliflozin	CANVAS	0.77 (0.55-1.08)
	Canagliflozin	CANVAS-R	0.56 (0.38-0.83)*

ADA Standards of Medical Care in Diabetes 2019
Diabetes Care 2019;42(Suppl 1):S103-S123

ASPIRIN in Diabetes

	n	f/u yrs	ASA mg/d	CV RR	p
Primary Prevention Project	1,031	3.7	100	0.9	NS
Early Rx DM Retinopathy	3,711	3-8	650	0.83	NS
POPADAD	1,276	6.7	100	0.98	NS
Japanese PPP	±5/14K	5	100	0.89	NS

McCulloch DK Overview of medical care in adults with DM UpToDate Updated 3/9/16


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Effects of Aspirin for Primary Prevention in Persons with Diabetes Mellitus

The ASCEND Study Collaborative Group*

NEJM 2018;379:1529-1539

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Effects of Aspirin for Primary Prevention in Persons with Diabetes Mellitus

The ASCEND Study Collaborative Group*

BACKGROUND

"DM is associated with an increased risk of CV events. ASA use reduces the risk….but increases the risk of bleeding; the balance of benefits and hazards for the prevention of 1st CV events in patients with DM is unclear."

NEJM 2018;379:1529-1539

DM: ASA for 1^0 Prevention The ASCEND Trial

- DBRPCT Adult DM (n=15,480)
- Rx ASA 100 mg/d vs placebo X 7.4 yrs
- Inclusion:
  - Age >40 (mean = 63)
  - No known CVD
- Outcomes: CV events, major bleeding

ASCEND Study Collaborative Group NEJM 2018;379:1529-1539

DM: ASA for 1^0 Prevention The ASCEND Trial

	ASA	PBO	RR	p
CV Events	8.5%	9.6%	0.88	0.01
Major Bleed	4.1%	3.2%	1.29	0.003
GI CA	2.0%	2.0%	1	NS
All CA	11.6%	11.5%	1	NS

ASCEND Study Collaborative Group NEJM 2018;379:1529-1539

DM: ASA for 1^0 Prevention The ASCEND Trial

CONCLUSIONS

"ASA use prevented serious vascular events….but it also caused major bleeding…The absolute benefits were largely counterbalanced by the bleeding hazard."

ASCEND Study Collaborative Group NEJM 2018;379:1529-1539

Conclusions

- The most important T2DM 'end-game' has always been CVD, however….
- Only recently has focus shifted to magnify the role of Rx that is favorable for CVD and CKD as top priority
- For ASA, the balance is delicate

SELF EVALUATION

Type 2 Diabetes: New Approaches to Reducing Macrovascular Risk

1. Until the year 2016, which pharmacotherapies for T2DM had shown mortality benefit?

a. Sulfonylurea
b. Metformin
c. Thiazolidinedione
d. None of the above

2. The first hypoglycemic agent to demonstrate CV risk reduction in type 2 diabetes was

a. An SGLT2 inhibitor (empagliflozin)
b. An alpha-glucosidase inhibitor (miglitol)
c. A sulfonylurea (glimepiride)

3. In a non-inferiority trial, New Drug “B” was found to be non-inferior to Old Drug “A”. This means:

a. New Drug B and Old Drug A are equivalent
b. New Drug B should replace Old Drug A
c. New Drug B is not more than a small margin less effective or safe than Old Drug A

4. CV safety trials with GLP agents in type 2 diabetes have shown

a. All GLP-RA drugs improve CV outcomes
b. Only liraglutide improves CV outcomes
c. Only exenatide improves CV outcomes
d. Liraglutide, parenteral semaglutide, and dulaglutide are the only GLP1-RA proven to reduce CV enpoints

5. A patient with T2DM and CKD would likely achieve the most CKD benefit most from

a. An SGLT2 agent (e.g., canagliflozin, dapagliflozin, empagliflozin)
b. A GLP-1-RA (eg., dulaglutide, exenatide, liraglutide)
c. A sulfonylurea (e.g., glimepiride, glipizide, glibenclamide)
d. A basal insulin (e.g., glargine, detemir, degludec)

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

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.

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Medical Director of Liver Transplantation

Non-Alcoholic Fatty Liver Disease & Alcoholic Hepatitis

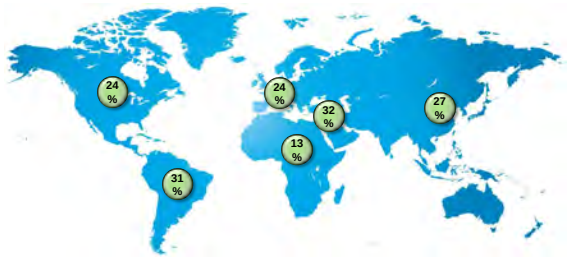
FAT AND THE LIVER

IT'S BAD FOR PEOPLE TOO

NON-ALCOHOLIC FATTY LIVER DISEASE (NAFLD)

- NAFLD is a burgeoning problem in the US and the world because of an increase in metabolic syndrome
- In evaluating patients with NAFLD, the critical distinction is between simple steatosis and non-alcoholic steatohepatitis
- The emphasis in evaluating and staging NAFLD is on non-invasive modalities
- Medical therapy for NAFLD is evolving

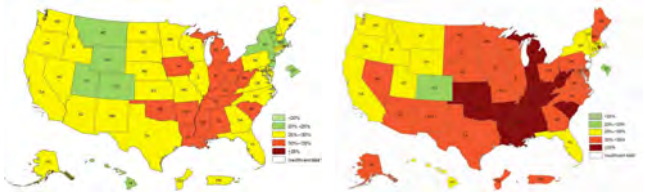
NAFLD: ESTIMATED GLOBAL PREVALENCE: 25%



- Meta-analysis: NAFLD by imaging (US, CT, MRI/SPECT: n=45 studies).
- Of patients with NAFLD, 6-29% will have NASH

Younossi ZM, et al. Hepatology 2016

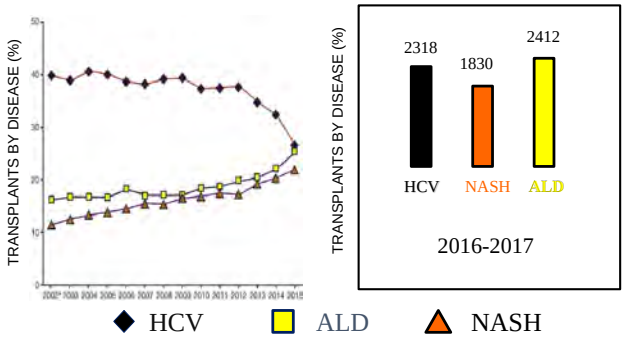
CDC: U.S. OBESITY TRENDS (BMI > 30)



2011 2019

www.cdc.gov/obesity/data/prevalence-maps.html

LIVER TRANSPLANT: SHIFTING INDICATIONS



Goldberg D, et al. Gastroenterology 2017

Nagai S, et al. Clin Gastroenterol Hepatol 2019

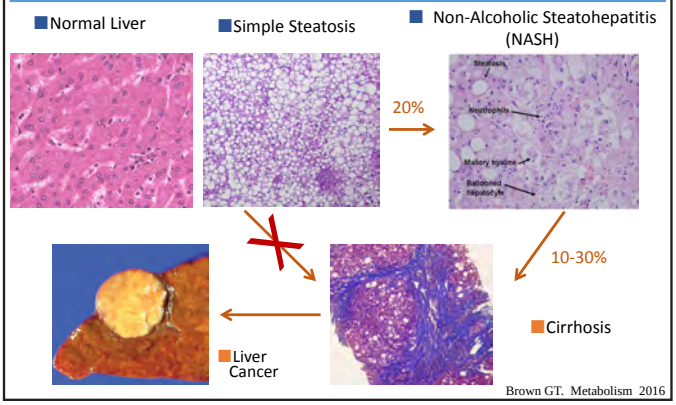
NON-ALCOHOLIC FATTY LIVER DISEASE (NAFLD): DEFINITION

- Evidence of fat in the liver (hepatic steatosis) on imaging or histology
  - Usually asymptomatic
  - Evaluation prompted by abnormal liver transaminases or incidental finding on imaging ordered for another reason
- Lack of other cause of hepatic steatosis or liver disease
- Diagnosis is not excluded by a normal AST or ALT
  - 25-50% of patients with NAFLD will not have ALT elevations
  - Current normal ranges for ALT are probably too high

NAFLD: ETIOLOGY

- Obesity
  - Most common and best documented risk factor for NAFLD
  - > 95% undergoing bariatric surgery have NAFLD
- Type 2 Diabetes (T2DM)
  - 33-66% will have NAFLD
  - Bidirectional association
- Hypertension
- Dyslipidemia
  - High triglycerides
  - High cholesterol to HDL ratio
  - 50% of patients in lipid clinics
- Ethnicity
  - Hispanics ↑
  - African-Americans ↓
  - Patatin-like phospholipase domain-containing protein 3 (PNPLA-3)
    - rs738409 C>G variant

NON-ALCOHOLIC FATTY LIVER DISEASE (NAFLD)



Brown GT. Metabolism 2016

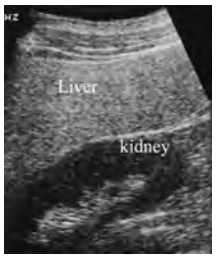
NAFLD: DIAGNOSIS

- AASLD: Does not advise the routine screening for NAFLD in high risk groups, including those with diabetes or an elevated BMI.
  - Uncertainties around diagnostic testing
  - Lack of linkage of screening to long-term benefits
  - Lack of medication based treatments

Chalasani N. AASLD Guidelines Hepatology 2018

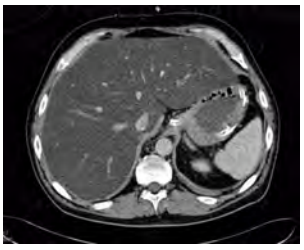
NAFLD DIAGNOSIS: IMAGING

ULTRASOUND



- Non-invasive, widely available and inexpensive
- Increase liver brightness and hepatorenal contrast with vascular blurring
- Limitations: operator dependent, poor sensitivity for mild steatosis and no fat or fibrosis quantitation

COMPUTED TOMOGRAPHY (CT)



- More specific than ultrasound
- Reduced attenuation correlated with degree of hepatic steatosis
- Can identify some signs of portal hypertension

Hashimoto E. J Gastro Hep 2013

NAFLD: DIAGNOSIS

- Critical to rule out other causes of hepatic steatosis or liver disease
  - Alcoholic Liver Disease
  - Viral Hepatitis (Hepatitis C Antibody and Hepatitis B surface Antigen)
  - Autoimmune liver disease (ANA, ASMA and AMA)
  - Wilson's, Hemochromatosis and alpha-1 antitrypsin deficiency
- Medications that can cause steatosis
  - Corticosteroids
  - Antiretrovirals (HAART), Amiodarone, Methotrexate, Parenteral Nutrition, Tamoxifen, valproic acid
- Serum ferritin is frequently elevated in NAFLD
- Up to 20% of NAFLD patients can have positive autoimmune markers

PHOSPHATIDLYETHANOL (PETH) TEST

- Phospholipid formed only in presence of alcohol
- Alcohol consumption in the last 28 days
- Sensitivity of 90% for two or more drinks a day
- Specificity of 100% with threshold of 20 ng/dl
- Validated as a quantitative test
- Negative with unintentional, low-level ETOH use
- Not affected by age, sex, anemia or renal function
- Validated in liver disease
- Send out lab with turn around of two weeks: $75
- Positive in 23.8% of ALD transplant patients who deny ETOH

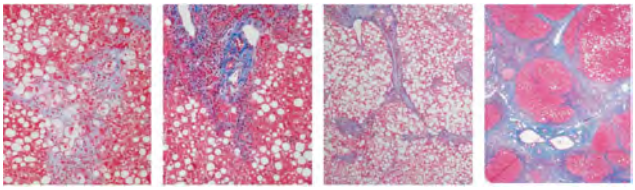
Fleming MF, et al. Alcohol Clin Exp Res 2017 41: 857

NAFLD: EVALUATION

- Rule out other causes of liver disease
- Assess disease severity
- Identify modifiable causes of NAFLD: metabolic syndrome

Chalasani N. AASLD Guidelines Hepatology 2018

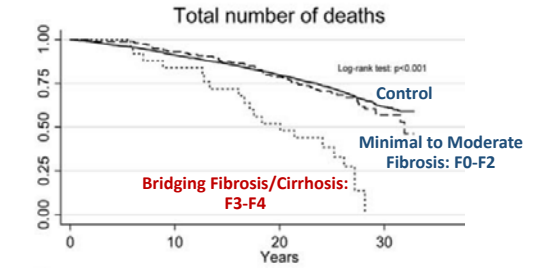
STAGES OF FIBROSIS FROM NASH



- Stage 1: Perisinusoidal Fibrosis
- Stage 2: Periportal Fibrosis
- Stage 3: Bridging Fibrosis
- Stage 4: Cirrhosis

Albhaisi S. Pharmac Med 2019

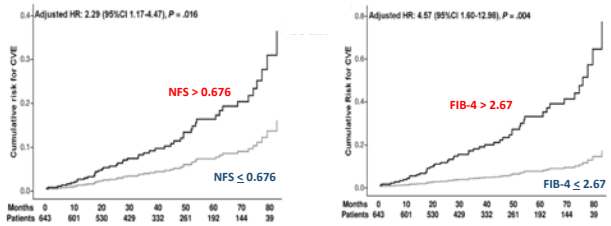
NAFLD AND FIBROSIS: MORTALITY



- Fibrosis stage is the strongest indicator of death in NAFLD
- Fibrosis progression rate of NASH is 1 stage every 7 years
- Causes of Death in NAFLD: CV, liver failure and death

Ekstedt M. Hepatology 2015: Chalasani N Hepatology 2018

NAFLD AND FIBROSIS: CARDIOVASCULAR MORBIDITY



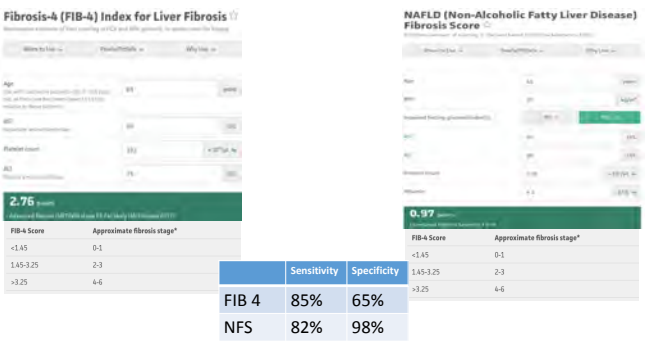
Bratta et al. Clin Gastro Hepatol 2020

NON-INVASIVE TESTS TO DETERMINE THE PRESENCE OF FIBROSIS

Test	Diagnostic Ability (AUROC)	Comments
Enhanced liver fibrosis panel	0.87	Detects markers of matrix turnover, which includes tissue inhibitor metalloproteinase 1, N-terminal propeptide of type III procollagen, and hyaluronic acid
Fibrometer	0.82	Includes ALT, AST, GGT, platelets, prothrombin time index, α_2-macroglobulin, hyaluronic acid, ferritin, glucose, and urea
FibroTest	0.81	Components include age, sex, bilirubin, GGT, haptoglobin, α_2-macroglobulin, and apolipoprotein A1
BARD score	0.81	Components include BMI, AST/ALT ratio, and diabetes
NFS	0.84	Validated scoring system; components include age, diabetes, BMI, AST, ALT, platelets, and albumin
FIB-4 index	0.84	Reliably excludes advanced fibrosis because of high NPV. Components include age, AST, and platelets
APRI	0.67	Initially developed for use in hepatitis C virus. Not specific for NAFLD
VCTE	0.83-0.95	Results may be invalid in obese patients (BMI >35 kg/m^2); hence a FibroScan XL probe is developed to overcome this problem
MRE	0.92	Widespread clinical adoption is limited because of its high cost and low availability

Tariq T. Clin Liver Dis 2020

NAFLD FIBROSIS: MARKERS



	Sensitivity	Specificity
FIB 4	85%	65%
NFS	82%	98%

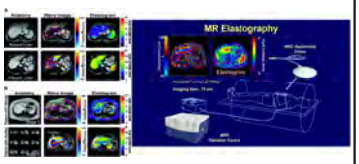
McPherson Gut 2010: Tsai Clin Liver Dis 2018: Angulo Hepatology 2007

NAFLD FIBROSIS: FibroScan and MRE

Transient Elastography: FibroScan

- Non-invasive
- Measures fibrosis and steatosis
- High sensitivity and specificity for advanced fibrosis

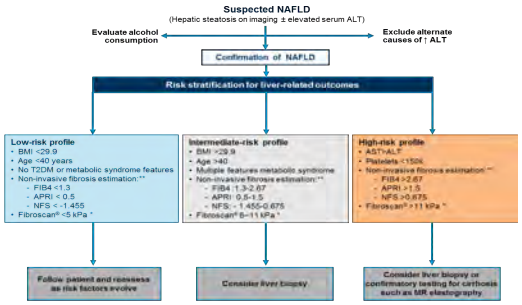
MR-Elastography (MRE)



- Evaluates anatomy, steatosis and fibrosis
- Highest accuracy for fibrosis
- Issues of availability and cost

https://pbc-society.ca/mre-magnetic-resonance-elastography

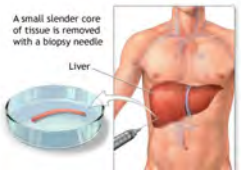
NAFLD EVALUATION: RISK STRATIFICATION



Rinella M. Nat Rev Gastro Hep 2016

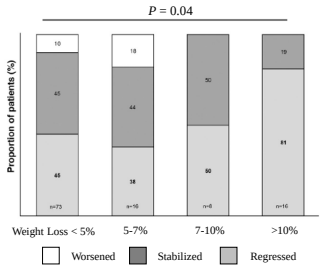
NAFLD FIBROSIS: LIVER BIOPSY

- Gold Standard
- Pitfalls
  - Invasive with risks
  - Expensive
  - Sampling error
- Role of liver biopsy
  - Clarify competing diagnoses
  - Accurate staging when non-invasive testing is indeterminate or conflicting
  - Establish urgency for therapy



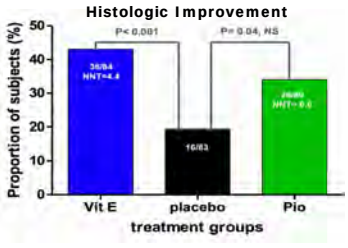
NAFLD THERAPY: WEIGHT LOSS

- Cuban study of 261 patients with biopsy proven NASH
  - Paired liver biopsy after 1 year
- Hypocaloric, low-fat diet
- Sustained weight loss has significant effect on fibrosis
- Weight loss of 7-10% necessary for effect
- Fewer than 10% of patients achieved this weight loss at 1 year



Vilar-Gomez et al. Gastroenterol 2015

NAFLD THERAPY: VITAMIN E

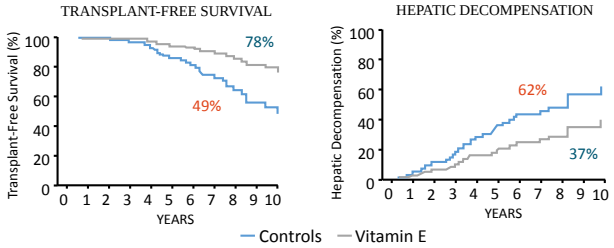


- Vitamin E at 800 IU improves histology but not fibrosis
- AASLD: It may be considered in non-diabetic, non-cirrhotic patients
- Increased risk of prostate cancer

Sanyal et al. NEJM 2010

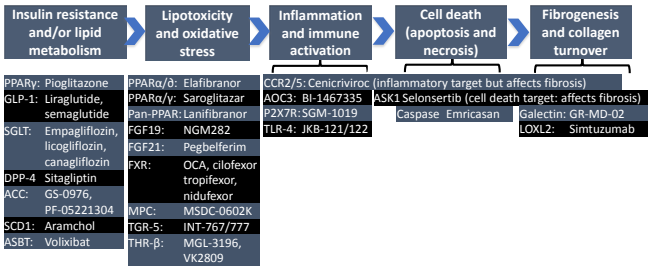
VITAMIN E IMPROVES TRANSPLANT-FREE SURVIVAL AND HEPATIC DECOMPENSATION IN PATIENTS WITH NASH AND ADVANCED FIBROSIS

- Single-center, cohort-controlled study of patients with biopsy-proven NASH and bridging fibrosis or cirrhosis (N = 236) followed for median of 5.62 years



Vilar-Gomez Hepatology 2019

NAFLD : MEDICAL THERAPY
PHASE II/III CLINICAL TRIALS



- There are no FDA approved drugs for NAFLD

clinicaloptions.com

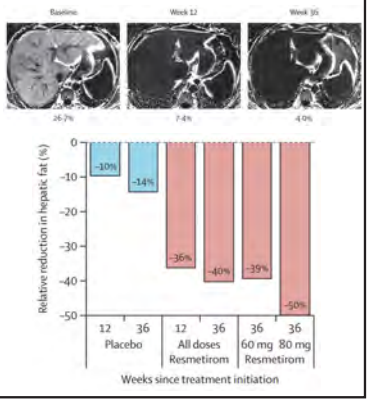
NAFLD : MEDICAL THERAPY
PHASE III CLINICAL TRIALS

Agent	Target	Trial	N	Primary Endpoint(s)	Time Point
~~Cenicriviroc~~	CCR2/5 antagonist	AURORA[1]	2000	≥ 1 stage fibrosis improvement with no NASH worsening	12 mos
~~Elafibranor~~	PPARα/σ agonist	RESOLVE-IT[2]	2000	Resolution of NASH with no fibrosis worsening	72 wks
Obeticholic acid	FXR agonist	REGENERATE[3]	931	≥ 1 stage fibrosis improvement with no NASH worsening; resolution of NASH with no fibrosis worsening	18 mos
		REVERSE[4]	900	≥ 1 stage fibrosis improvement with no NASH worsening	18 mos
Resmetirom	THR-β agonist	MAESTRO-NASH[5]	2000	Resolution of NASH	52 wks
Aramchol	SCD1 inhibitor	ARMOR[6]	2000	≥ 1 stage fibrosis improvement with no NASH worsening; resolution of NASH with no fibrosis worsening	52 wks
Belapectin	Galectin-3 inhibitor	NASH-RX	500	NASH resolution without worsening of fibrosis	52 wks

1. NCT03028740. 2. NCT02704403. 3. Younossi. Lancet. 2019;394:2184. 4. NCT03439254. 5. NCT03900429. 6. NCT04104321.

RESMETIROM (MGL-3196)
THR-β AGONIST

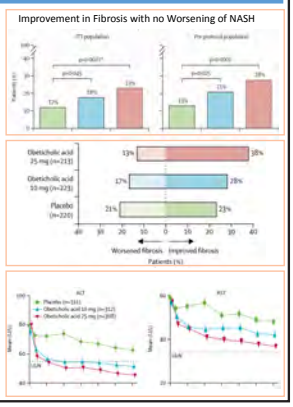
- 36 Week, Phase II trial
  - 84 Patients Resmetirom: 42 placebo
  - Randomized, blinded, placebo controlled
  - Biopsy proven NASH with hepatic fat fraction ≥ 10% (Fibrosis Stage 1-3)
  - 18 Centers in US
- Resmetirom was associated with significant relative reductions in hepatic steatosis at 12 and 36 weeks
- Well tolerated: Mild diarrhea and nausea



Harrison Lancet 2019

NAFLD : MEDICAL THERAPY
OBETICHOLIC ACID (OCA)

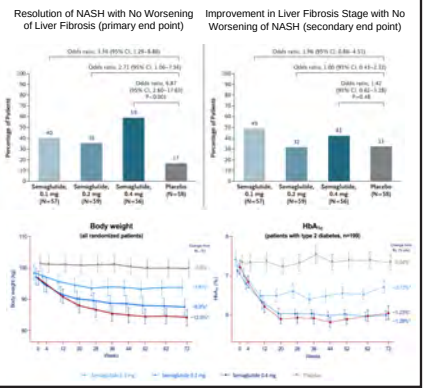
- OCA: FXR receptor antagonist: approved for primary biliary cholangitis
- Regenerate Trial
- Randomized, double-blind, placebo controlled
- 931 Patients: Placebo vs. OCA 10 mg vs. OCA 25 mg
- 18 months of therapy: Interim analysis
- Primary endpoint: improvement in fibrosis with no worsening of NASH
- Adverse reaction: pruritus (51% in 25 mg dose)



Younossi et al. Lancet 2019

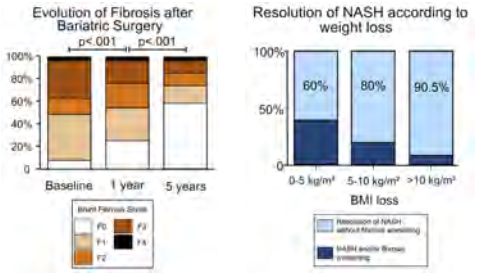
NAFLD : GLUCAGON-LIKE PEPTIDE-1 (GLP-1) AGONIST: SEMAGLUTIDE

- Semaglutide: GLP-1 receptor agonist
- Randomized, double-blind, placebo controlled
- 320 Patients: Placebo vs. Semaglutide 0.1, 0.2, 0.4 mg
- 72 weeks with daily SQ injections
- Primary endpoint: resolution of NASH with no worsening of fibrosis
- No change in fibrosis
- AE: nausea (42% vs. 11%), vomiting, constipation



Newsome et al. NEJM 2020

NAFLD : WEIGHT LOSS (BARIATRIC) SURGERY

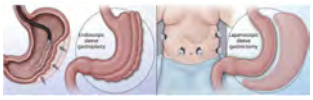


- French, single center study of 180 patients: 125 at 1 year: 64 at 5 years
- Different bariatric procedures performed over the time of the study
- 5 years: 84.4% of patients had resolution of NASH with no worsening of fibrosis

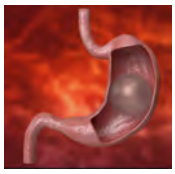
Lassailly G. Gastroenterol 2020

NAFLD : ENDOSCOPIC BARIATRIC THERAPY (EBT)

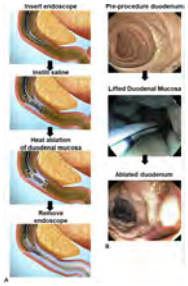
- Endoscopic Sleeve Gastroplasty



- Space Occupying Devices



- Duodenal Mucosal Resurfacing



Haidry R. Gastrointest Endo 2019

NAFLD: CONCLUSIONS

- NAFLD and NASH are common and increasing causes of disease morbidity and mortality
- In evaluating patients with NAFLD, the critical distinction is between simple steatosis and NASH
- Fibrosis is a surrogate marker for NASH and has prognostic value in its own right
- A variety of non-invasive instruments are available for evaluating fibrosis in NASH
- Medical therapy is evolving but there is no current FDA approved, medical therapy for NASH
- Bariatric surgery and bariatric endoscopic therapy are options.

ALCOHOLIC HEPATITIS

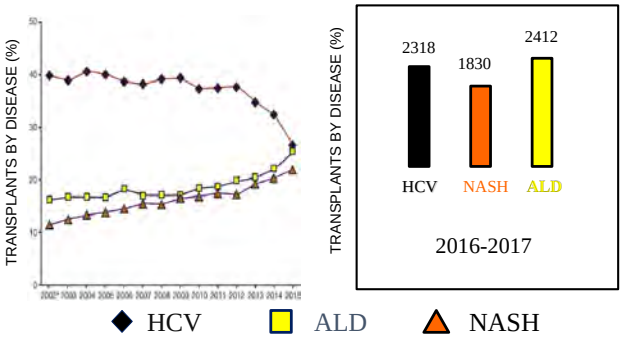
- Acute process in the setting of heavy, sustained and recent ETOH use
- Characterized by an acute and progressive rise in the bilirubin
- Typically a clinical diagnosis
  - Liver biopsy not necessary unless suspicion of other etiology
- 25-50% of patients will have underlying cirrhosis

ALCOHOL USE IN UNITED STATES

- 5% of all deaths attributed to alcohol: directly or indirectly
  - 88,000 deaths a year
- 10% average more than two drinks a day
  - Men 18%
  - Women 3%
- 5% of US population classified as heavy drinkers (30-60 g/day)
  - Steatosis 90%
  - Alcoholic hepatitis 10-35%
  - 8-20% alcoholic cirrhosis

Singal AK, et al. ACG Guidelines. Am J Gastroenterol 2018

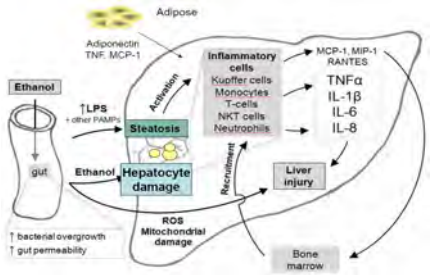
LIVER TRANSPLANT: SHIFTING INDICATIONS



Goldberg D, et al. Gastroenterology 2017

Nagai S, et al. Clin Gastroenterol Hepatol 2019

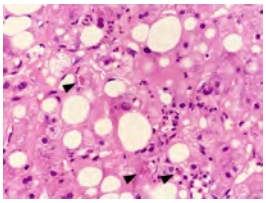
ALCOHOLIC HEPATITIS: PATHOPHYSIOLOGY



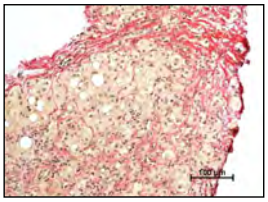
Szabo G. DASH: Defeat Alcoholic Steatohepatitis NIAA consortium

ALCOHOLIC HEPATITIS (AH)

HISTOPATHOLOGY



STEATOSIS, MALLORY'S HYALINE, BALLOONING DEGENERATION, NEUTROPHILIC INFILTRATE



PERICELLULAR FIBROSIS, CIRRHOSIS

Theise ND. Clin Liver Dis 2013 2: 64

EASL CPG ALD. J Hepatol 2018 69:154

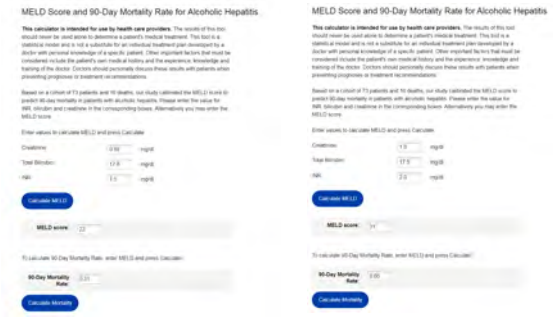
PHOSPHATIDLYETHANOL (PETH) TEST

- Phospholipid formed only in presence of alcohol
- Alcohol consumption in the last 28 days
- Sensitivity of 90% for two or more drinks a day
- Specificity of 100% with threshold of 8 ng/dl
- Validated as a quantitative test
- Negative with unintentional, low-level ETOH use
- Not affected by age, sex, anemia or renal function
- Validated in liver disease
- Send out lab with turn around of two weeks: $75
- Positive in 23.8% of ALD transplant patients who deny ETOH

Fleming MF, et al. Alcohol Clin Exp Res 2017 41: 857

ALCOHOLIC HEPATITIS

MELD CALCULATOR

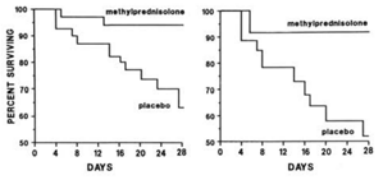


https://www.mayoclinic.org/medical-professionals/transplant-medicine/calculators/meld-score-and-90-day-mortality-rate-for-alcoholic-hepatitis/itt-20434719

ALCOHOLIC HEPATITIS: THERAPY

- Abstinence
- Hydration
- Nutrition
- Treatment of kidney injury
- Identification and treatment of infection

PREDNISOLONE IN ALCOHOLIC HEPATITIS



No Encephalopathy Encephalopathy

Discriminant Function = 4.6 (protime - control time) + serum bilirubin
MDF > 32 (mean 46.5) or Hepatic Encephalopathy

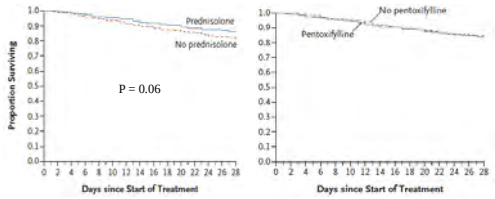
Carithers RL-Maddrey W. Ann Intern Med 1989

STEROIDS AND PENTOXIFYLLINE IN ALCOHOLIC HEPATITIS: STOPAH TRIAL

- Double-blind: randomized
- 4 groups: 260 patients in each group
- MDF Mean 62.6: MELD Mean 21.2
  - Placebo
  - Pentoxifylline
  - Prednisolone
  - Pentoxifylline and Prednisolone
- Endpoints
  - 28 day survival
  - 90 day and one year transplant free survival

Thursz MR, et al. N Engl J Med 2015 372: 1619

STEROIDS AND PENTOXIFYLLINE IN ALCOHOLIC HEPATITIS: STOPAH TRIAL



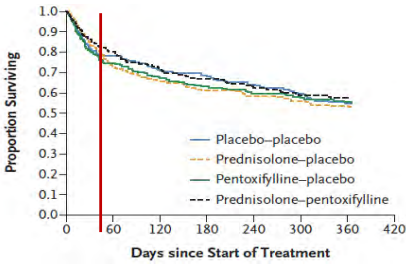
MDF Mean 62.6 MELD Mean 21.2

Thursz MR, et al. N Engl J Med 2015 372: 1619

STEROIDS AND PENTOXIFYLLINE IN ALCOHOLIC HEPATITIS: STOPAH TRIAL

- Infection
  - Prednisone 13%
  - No prednisone 7%

P = 0.02



Thursz MR, et al. N Engl J Med 2015 372: 1619

STEROIDS IN ALCOHOLIC HEPATITIS: Lille Model

- Six readily available variables
- Bilirubin is calculated on Day 1-7
- Lille score > 0.56 means poor response to prednisolone
- Steroids should be avoided
  - MDF < 32
  - Infection
  - Active gastrointestinal hemorrhage
  - Acute kidney injury

Mathurin P, et al Gut 2011

AH: LIVER TRANSPLANTATION

NIH CONSENSUS CONFERENCE: 1983

- "Patients who are judged likely to abstain from alcohol and who have established clinical indicators of fatal outcomes may be candidates for transplantation"
- "Only a small proportion of alcoholic patients with liver disease would be expected to meet these rigorous criteria."

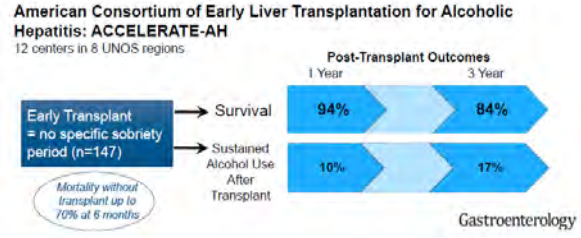
NIH Consensus Conference Statement: Liver Transplantation Hepatology 1984 4: 107S

USA TODAY

Young life hangs in balance as tighter rules restrict path to transplants

AH: LIVER TRANSPLANTATION

ACCELERATE-AH: American Consortium of Early Liver Transplant for Alcoholic Hepatitis: Outcomes



1 and 3 year survival: No ETOH: 97% and 97%: Any ETOH: 100% and 75%: P = 0.03

Lee BL, et al. Gastroenterol 2018

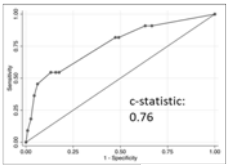
AH: LIVER TRANSPLANTATION

ACCELERATE-AH: American Consortium of Early Liver Transplant for Alcoholic Hepatitis: Recidivism

- 129 patients
- Sustained use > 100 days and drinking at time of last visit (vs. Slip)
- 7 of 12 centers used laboratory testing?
- 1 and 3 year ETOH use: 26% and 33%
- 1 and 3 year sustained use: 10% and 16%

SALT Variable	Points
>10 Drinks/Day at Presentation	+4
≥2 Prior Failed Rehabilitation Attempt	+4
Any History of Prior Alcohol-Related Legal Issues	+2
History of Non-THC Illicit Substance Abuse	+1

- SALT Score ≥ 5
  - Positive predictive value 25%
  - Negative predictive value 95%
  - Positive predictive value of SALT score of 11 is 50%



Lee BL, et al. Hepatology 2019

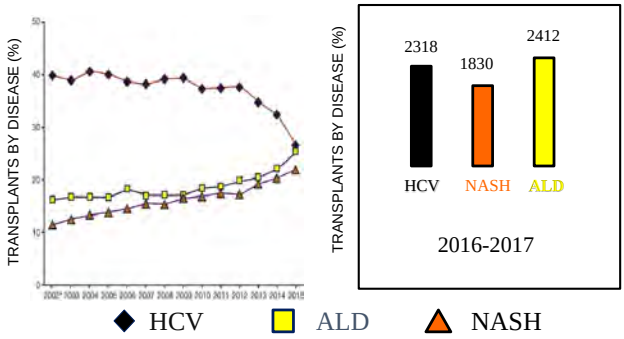
DALLAS CONSENSUS CONFERENCE ON LIVER TRANSPLANT FOR ALCOHOL ASSOCIATED HEPATITIS

"DALLAS CRITERIA"

- Lack of repeated unsuccessful attempts at addiction rehabilitation
- Lack of other current substance abuse or dependency
- Acceptance of ALD diagnosis with insight
- Commitment of patient to lifelong sobriety with support of sober caregivers to assist patient with abstinent goals
- Presence of close, supportive family members or caregivers
- Patient should be assessed while fully coherent (not intubated or floridly encephalopathic)

Asrani Dallas Criteria 2020 Liver Transplantation

LIVER TRANSPLANT: SHIFTING INDICATIONS

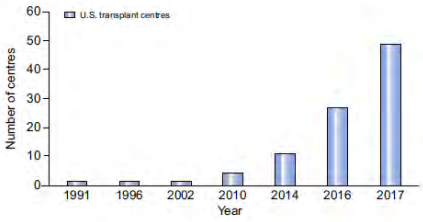


Goldberg D, et al. Gastroenterology 2017

Nagai S, et al. Clin Gastroenterol Hepatol 2019

AH: LIVER TRANSPLANTATION

NUMBER OF CENTERS IN US PERFORMING TRANSPLANT FOR ALCOHOLIC HEPATITIS



Im GY, Cameron AM, Lucey MR. J Hepatology 2019 70: 328

ALCOHOLIC HEPATITIS: CONCLUSIONS

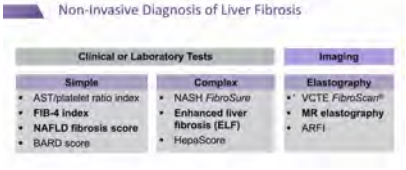
- AH is a major cause of morbidity and mortality in the United States and the World
- Primary management is abstinence and supportive care
- Corticosteroids can be considered in appropriate patients using stopping rules based on the Lille Model
- Liver Transplant can be considered in select patients with on-going alcohol use with low rates of relapse

NON-INVASIVE TESTS TO DETERMINE THE PRESENCE OF FIBROSIS

CLINICAL OR LABORATORY TESTS

ELASTOGRAPHY

ELASTOGRAPHY



SELF EVALUATION

Non-Alcoholic Fatty Liver Disease & Alcoholic Hepatitis

1. Which is true of NAFLD?

a. NAFLD is a growing problem and is now the leading indication for liver transplant in the US.
b. NAFLD is primarily a medical problem in Europe and North America.
c. NAFLD will lead to significant liver damage in a majority of affected individuals.
d. A majority of individuals with NAFLD will not have non-alcoholic steatohepatitis (NASH).
e. Rates of obesity in the US were increasing but have been stable since 2015.

2. In evaluating patients with NAFLD, which is true?

a. Typically a normal ALT rules out NAFLD.
b. Non-invasive modalities can reliably distinguish simple steatosis from NASH.
c. NAFLD is associated with metabolic syndrome and ethnicity does not play a significant role.
d. On ultrasonography, fat in the liver is echogenic and a “fatty liver” will appear dark.
e. The phosphatidylethanol (PETH) test is a reliable test to rule out significant alcohol use.

3. Which of the following are have been shown to slow or reduce fibrosis in NAFLD?

a. Bariatric surgery
b. Weight loss
c. Obeticholic acid
d. All of the above
e. None of the above

4. Which is true of medical therapy for NAFLD?

a. For medical therapy to work, it must be given when patients have simple steatosis and before they develop NASH.
b. Vitamin E did showed improvements in fibrosis in patients with NASH but has been linked to prostate cancer.
c. There are no approved medical therapies for NAFLD.
d. GLP-1 agonists are effective, result in weight loss and are well tolerated.
e. All are true.

5. Which of the following is false about alcoholic hepatitis?

a. Alcoholic hepatitis can reliably distinguished from NASH on liver biopsy.
b. 25-40% of at patients with alcoholic hepatitis will also have alcoholic cirrhosis.
c. Pentoxifylline has no efficacy in the treatment of alcoholic hepatitis
d. Corticosteroids have not been shown to be of long term benefit in alcoholic hepatitis.
e. The phosphatidylethanol test can measure significant alcohol use as far back as two to four weeks.

6. Which of the following statements is true about alcoholic hepatitis and liver transplant?

a. Alcoholic liver disease is a potential indication for liver transplant only after a defined period of abstinence proven with phosphatidylethanol testing.
b. Alcoholic liver disease is now the leading indication for liver transplant in the US
c. Liver transplant for alcoholic hepatitis is performed by a small but growing number of transplant centers.
d. Patients with alcoholic hepatitis are candidates for liver transplant per the “Dallas” criteria if they have had no more than three prior attempts at alcohol treatment
e. Patients undergoing liver transplant for alcoholic hepatitis have worse survival because the inflammation set off by the alcohol attacks the new liver

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

Michael S. Byrd, Esq.

Michael S. Byrd, Esq., of Dallas, Texas, is partner of ByrdAdatto, a business and health care boutique law firm with offices in Dallas and Chicago. As the son of a doctor and entrepreneur he comes to his specialty naturally and has become a leading advocate for doctors and dentists throughout the United States lecturing routinely at academic institutions, hospitals, and professional gatherings. Mr. Byrd has been named to Texas Rising Stars and Texas Super Lawyers for multiple years (2009-2019), Top Rated Lawyer by the Dallas Morning News (2016) and recognized as a Best Lawyer in Dallas in health care by D Magazine (2013, 2016-2019).

You may contact Mr. Byrd with your questions or comments at 214-291-3202, or by email at MByrd@ByrdAdatto.com.

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The Big Five: What You Must Know About Professional Employment Agreements

The Big 5

1. **Written Contract**
2. Compensation
3. Covenants
4. Patients
5. Termination

5

Written Contract

- Most states allow oral contracts
- Problem: Unmet Expectations
- Four Corners Test

The Big 5

1. Written Contract
2. **Compensation**
3. Covenants
4. Patients
5. Disability Insurance

5

Compensation

- Compensation Structure
  - Base Salary
  - Bonus /Incentive Compensation
  - Percentage-Based Compensation
  - RVUs
- Get Examples
  - Must clearly define collections credited
  - **Not paid based upon billed charges**

Compensation - Benefits

1. Continuing Education Reimbursement
2. Licensing Fees, Societal Dues, Subscriptions
3. Benefits – Health Care, 401k, etc.
4. Malpractice Insurance

Compensation Models

- **Hospital and Academic Models**
  - Kaiser Model
- **Flex Model**
  - Income Guarantee
- **Private Practice Models**
  - Percentage Model
  - Base Employment Model
  - Partnership Models

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Kaiser Model

- Risk to Practice: High
- Risk to Employed Physician: Low
- Annualized base salary (typically closer to hospital contracts)
- Possible fixed or discretionary bonus (typically low)

KAISER PERMANENTE®

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Compensation Models

- **Hospital and Academic Models**
  - Kaiser Model
- **Flex Model**
  - Income Guarantee
- **Private Practice Models**
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  - Partnership Models

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Basic Terms

- Hospital Obligation
  - Guarantee and Payment of Income
  - Moving Expenses
  - Signing Bonus
  - Student Loans
  - Benefits
  - Forgiveness
- Physician Obligation
  - Medical Service
  - Remain active and good standing with the hospital's medical staff
  - Stay in Service Area
  - Repayment of Guarantee
  - Repayment of Excess Receipts
  - Cap on Total Guarantee

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Income Guarantee Model

- **Pros**
  - Funding To Start Practice
  - Forgivable Loan If Stay
  - Hospital Help (locate office space, vendors, etc.)
  - Patient Flow
- **Cons**
  - Limitations on Earnings
  - Limitations on Timing and Purpose of Draws
  - Onerous Reporting Requirements
  - Note Forgiveness is a Taxable Event

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Compensation Models

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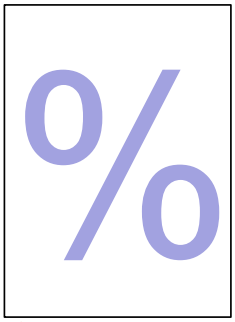
Percentage Model

- Compensation based on percentage of collections
- Risk to Practice: Low
- Risk to Employed Physician: High



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Compensation Models

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  - Partnership Models

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Base Employment Model

- Risk: Shared though risk shifts depending on guarantee amount.
- Annualized base salary
- Additional opportunity to earn incentive compensation based on productivity formula and thresholds

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Compensation Models

- **Hospital and Academic Models**
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Partnership Models

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Compensation Model

Three Basic Partnership Compensation Models:

1. Eat What You Kill
2. Enterprise Model
3. Communist Model

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Ancillary Compensation

- Medical Spas
- ASCs
- Medical Office Buildings
- Anesthesia Services
- Device Companies
- Lab
- Imaging Centers
- Physical Therapy
- Neuromonitoring
- Stem Cell Therapy
- Pain Management Centers

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The Big 5

1. Written Contract
2. Compensation
3. **Covenants**
4. Patients
5. Termination

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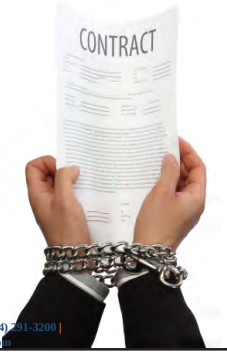
Restrictive Covenants

- Non-Compete
- Non-Solicitation
  - Patients
  - Employees
- Non-Disclosure
- Confidentiality Section



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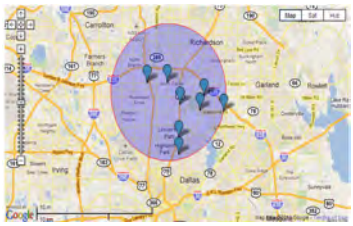
Why Have Covenants

- ***Reasonable***
  Restraint of Trade
  - Time
  - Geographic Scope
  - Activity



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The Big 5

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Termination

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Notice

- Typical – 60-90 days

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Definition of Cause

- Bad actor list
- Look for subjective provisions
- Right to cure?

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Tail Insurance

- Occurrence v. Claims Made
- Who pays?
- General Cost = 2x annual premium

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Compensation

- Final paycheck
- Incentive Compensation
- Account receivable

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Hospital Privileges

- Could trigger data bank reporting obligation

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Takeaways

- Conduct Your Due Diligence.
- Don't go to FedEx Office
- Evaluate the opportunity both inside and outside the contract.

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Supplemental Material

To receive a copy of our supplemental material, visit our website:

https://www.byrdadatto.com/landing/aeiwebinar/

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SELF EVALUATION

The Big Five: What You Must Know About Professional Employment Agreements

True or False

1.___ The first step to evaluate your employment opportunity is to determine your plan A and plan B.

2.___ The biggest problem with handshake agreements is the risk of unmet expectations.

3.___ Oral contracts are not enforceable in most states.

4.___ The key to understanding your compensation provisions is to understand how productivity will be measured.

5.___ Physician non-competes are unenforceable.

6.___ Understanding how you are expected to be busy with patients is an important example of an issue outside the employment agreement that should be discussed prior to employment.

7.___ Absent language saying otherwise, upon termination of an employment agreement, the account receivable for the leaving physician will likely remain as property of the practice.

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

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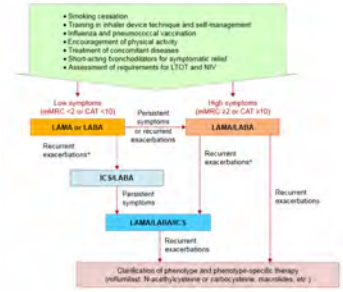
COPD: Diagnosis, Therapies and Management

COPD Rx Algorithm: Russian Guidelines



Aisanov Z et al *Int J COPD* 2018;13:183-187

COPD Rx Algorithm: Russian Guidelines

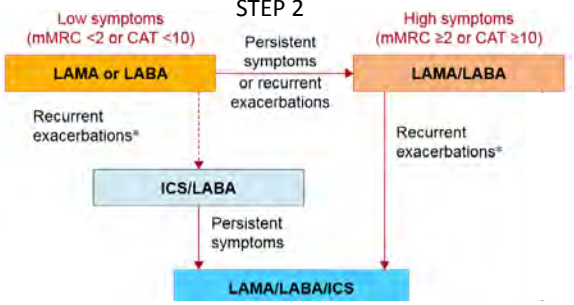
STEP 1

- Smoking cessation
- Training in inhaler device technique and self-management
- Influenza and pneumococcal vaccination
- Encouragement of physical activity
- Treatment of concomitant diseases
- Short-acting bronchodilators for symptomatic relief
- Assessment of requirements for LTOT and NIV

Aisanov Z et al *Int J COPD* 2018;13:183-187

COPD Rx Algorithm: Russian Guidelines

STEP 2



Aisanov Z et al *Int J COPD* 2018;13:183-187

COPD Rx Algorithm: Russian Guidelines

STEP 3

Recurrent Exacerbations

Clarification of phenotype and phenotype-specific therapy
(roflumilast, N-acethylcysteine or carbocysteine, macrolides, etc.)

Aisanov Z et al *Int J COPD* 2018;13:183-187

COPD: Why Bother?

"COPD is currently the 4th leading cause of death in the world but is projected to be the 3rd leading cause of death by 2020."

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COPD

How Did We Get Into This Mess?

Cigarettes for Sale In the Hospital
1950's

Who Was the Voice of "The Turtle"

COPD: Why *NOT* Bother?

With the exception of smoking cessation and oxygen in late-stage COPD, no pharmacologic interventions have been shown to be disease modifying or reduce overall mortality.

COPD: GOLD Guidelines

- **Definition and Overview**
- **Dx and Assessment**
- **Therapeutic Options**
- **Manage Stable COPD**
- **Manage Exacerbations**
- **Manage Comorbidities**
- **Asthma COPD Overlap Syndrome**

GOLD: Diagnosis and Assessment: Key Points

- Consider clinical Dx: dyspnea, chronic cough or sputum production, and risk factors
- Spirometry is *required* to make the Dx
  - Post-bronchodilator $FEV_1/FVC < 0.70$ confirms persistent airflow limitation (COPD)
  - To avoid over-Dx in elderly, check age-related norms

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COPD: *Other* Risk Factors

"Other types of tobacco,(e.g., pipe, cigar, water pipe) and marijuana are also risk factors for COPD, as well as environmental tobacco smoke."

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COPD: Marijuana

RESEARCH CMAJ

Marijuana and chronic obstructive lung disease: a population-based study

Wan C. Tan MB, Christine Lo BSc, Aimee Jong BSc, Li Xing MSc, Mark J. FitzGerald MB, William M. Vollmer PhD, Sonia A. Buist MD PhD, Don D. Sin MD MPH, for the Vancouver Burden of Obstructive Lung Disease (BOLD) Research Group

Tan WC et al CMAJ 2009;180(8):814-820

COPD: Marijuana

RESEARCH Tan WC et al CMAJ 2009;180(8):814-820 CMAJ

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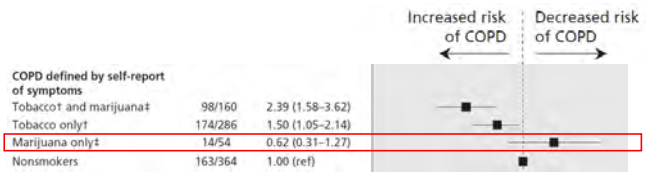
"Compared with nonsmokers, participants who reported smoking only tobacco, but not those who reported smoking only marijuana, experienced more frequent respiratory Sx…and were more likely to have COPD…."

*Reference cited in GOLD 2020 Guideline to Assert Marijuana as a COPD Risk Factor (emphasis added)

COPD: Marijuana NOT



Tan WC et al *CMAJ* 2009;180(8):814-820

Alpha-1-antitrypsin Deficiency: Maybe

"The WHO recommends that all patients with a Dx of COPD should be screened…."

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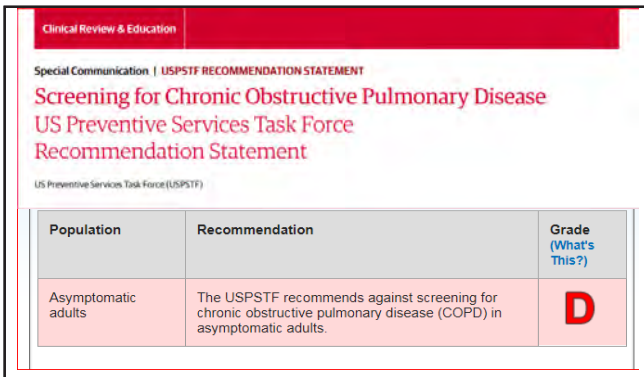
NICE
(UK National Institute for Health and Care Excellence)

"With the exception of smoking cessation and the avoidance of other environmental risk factors, current Rxs for emphysema caused by AATD aim to alleviate Sx and do not slow down the progression of the disease….NICE clinical guideline 101 does not recommend replacement therapy for people with AATD and COPD."

NICE Final Scope Report on Human Alpha-1-proteinase Inhibitor for Maintenance Rx of Emphysema March 2018



USPSTF Recommendation Grading

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

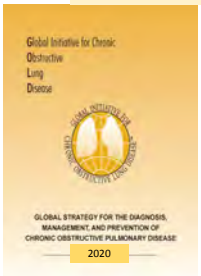
USPSTF: COPD Screening NOT

"Similar to 2008, the USPSTF did not find evidence that screening for COPD in a Sx persons improves health-related QOL, morbidity, or mortality. The USPSTF determined that early detection of COPD before the development of Sx, does not alter the course of the disease or improve patient outcomes. The USPSTF concludes with moderate certainty that screening for COPD in aSx persons has no net benefit."

*emphasis added

Siu AS *JAMA* 2016;315(13):1372-1377

COPD: GOLD Guidelines



- **Definition and Overview**
- **Dx and Assessment**
- **Therapeutic Options**
- **Manage Stable COPD**
- **Manage Exacerbations**
- **Manage Comorbidities**
- **Asthma COPD Overlap Syndrome**

Global Strategy for Diagnosis, Management and Prevention of COPD

Diagnosis and Assessment: Key Points

- Goals of COPD assessment: determine
  - severity of the disease
  - severity of airflow limitation
  - impact on the patient's health status
  - risk of future events

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GOLD: Chest X-ray? NOT

"A chest X-ray is not useful to establish a Dx in COPD, but it is valuable in excluding alternative Dxs and establishing the presence of significant comorbidities…."

*emphasis added

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GOLD: COPD-Asthma Overlap? Rx Like Asthma

"A major differential Dx is asthma. In some patients with chronic asthma, a clear distinction from COPD is not possible using current imaging and physiological testing techniques. In these patients, current management is similar to that of asthma."

*emphasis added

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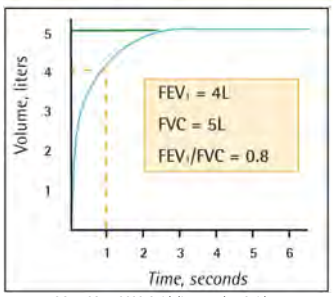
Differentiating Asthma from COPD

	Asthma	COPD
Age of Onset	Usually < 30	Usually > 40
History of Atopy	Often	Uncommon
Family Hx	Usually+	Usually -
Intercritical Lung Fx	WNL/Nearly WNL	Impaired
Lung Fx Under Rx	WNL/Nearly WNL	Impaired
Bronchodilator Response	Strong (>15% FEV1↑)	Modest (<12% FEV1)
ICS Response	Strong	Modest
LKTR Response	Strong	None
Smoking Hx	Variable	Prominent

Adapted from Kuritzky L "COPD Testing as a Vital Sign" Primary Care Special Edition 1999(3):2

Spirometry

Figure 2.2A. Spirometry – Normal Trace



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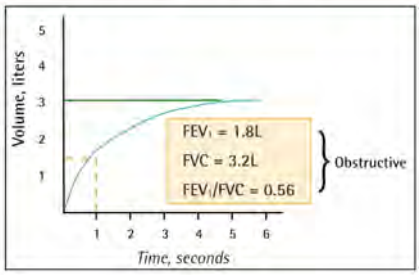
Spirometry: Post-bronchodilator

Figure 2.2B. Spirometry – Obstructive Disease



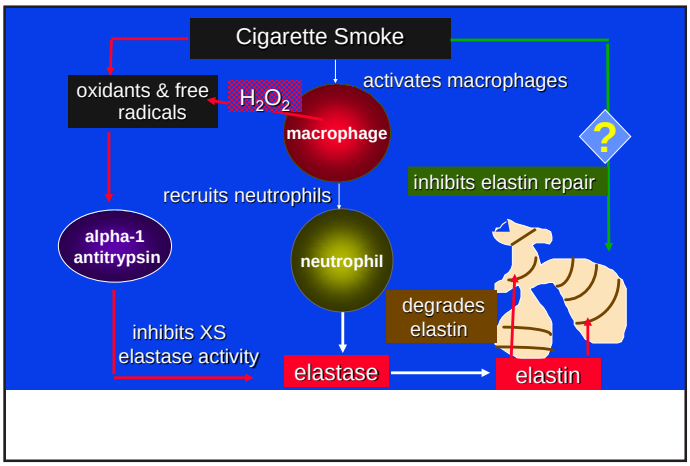
COPD

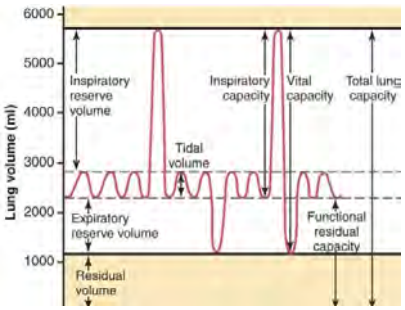
Physiology/Pathophysiology

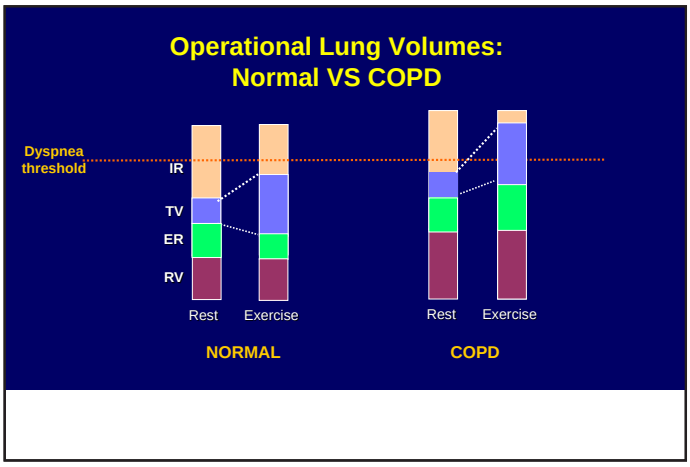
Aging and the Lung

- Normal Δ , From age 25 to 75:
  - 20% ↓ Vital Capacity
  - 25% ↓ FEV_1 (30ml/yr)
- > 65 : ↑ Elastin fiber degradation → ↓ elastic recoil
- Some Smokers : 80 - 150 ml/yr ↓FEV_1

Barker L Principles of Ambulatory Medicine Williams & Wilkins (Baltimore) 1999







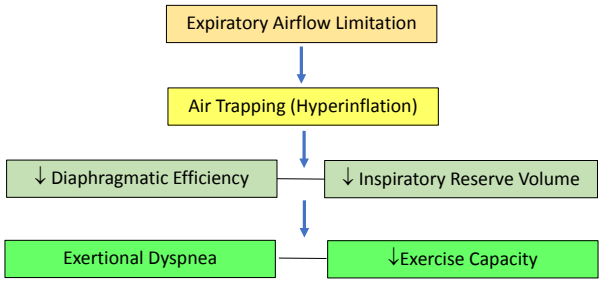
Dynamic Hyperinflation: MOA

Effect of Fluticasone Propionate/Salmeterol on Lung Hyperinflation and Exercise Endurance in COPD*

Denis E. O'Donnell, MD; Frank Sciurba, MD; Bartolome Celli, MD; Donald A. Mahler, MD; Katherine A. Webb; Chris J. Kalberg, PhD; and Katharine Knobil, MD

O'Donnell DE et al CHEST 2006;130:647-656

Dynamic Hyperinflation: MOA



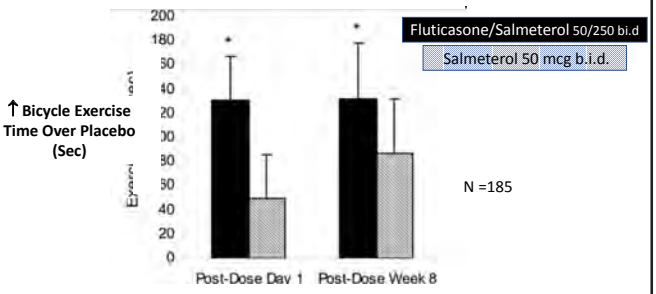
O'Donnell DE et al CHEST 2006;130:647-656

Dynamic Hyperinflation: MOA

"During exercise, as ventilation increases and expiratory time diminishes, further dynamic hyperinflation occurs as reflected by the progressive ↑ in end-expiratory lung volume and a reciprocal ↓ in inspiratory capacity. Dynamic hyperinflation is a primary mechanism for the exertional dyspnea and reduced exercise capacity associated with COPD."

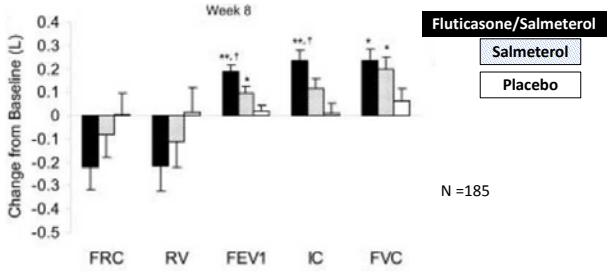
O'Donnell DE et al CHEST 2006;130:647-656

Fluticasone/Salmeterol vs Salmeterol vs Placebo: Bicycle Exercise Time



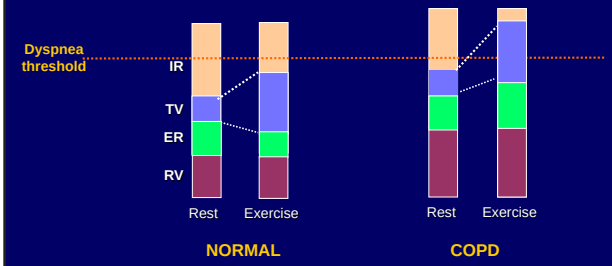
O'Donnell DE et al CHEST 2006;130:647-656

Fluticasone/Salmeterol vs Salmeterol Vs Placebo



O'Donnell DE et al CHEST 2006;130:647-656

Operational Lung Volumes: Normal VS COPD

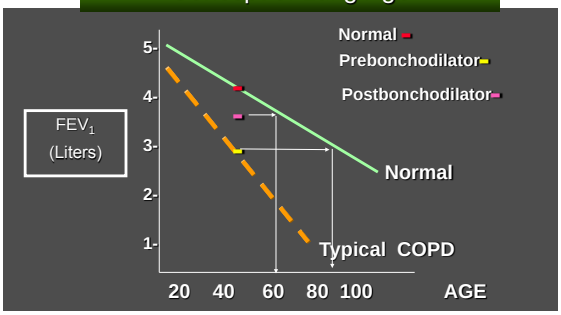


Differentiating Asthma from COPD

	Asthma	COPD
Hypoxemia	Extremis Only	Common
Polycythemia	Rare	Common
Carboxyhemoglobin	WNL	Elevated
Progressive Decline	Uncommon	Typical
Cough Prominence	Nocturnal, Exercise	Early AM
Purulent sputum	Uncommon	Typical
Bronchodilator Response	B agonist > Anticholinergic	Anticholinergic = B agonist
IgE Elevation	Common	Uncommon
Exacerbation: Antibiotics	Ineffective	Usually Effective

Adapted from Kuritzky L "COPD Testing as a Vital Sign" Primary Care Special Edition 1999(3):2

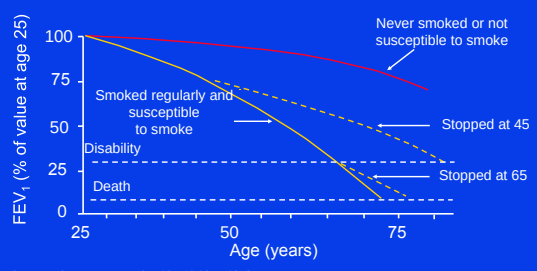
Concept of Lung Age



Petty TL *Hospital Practice* 1990; October: p 90

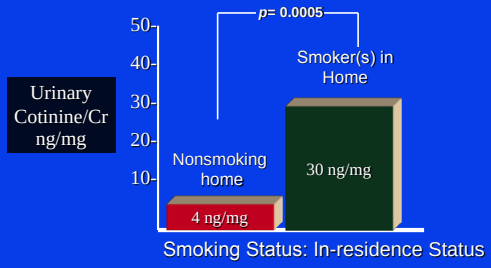
What about the guy who says "Well, Doc after all these years of smoking, there's no sense in stopping now, is there….?

Decline of FEV_1 with Age and Smoking Hx



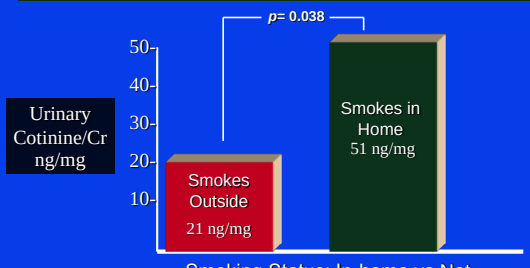
Fletcher C and Peto R. Br Med J. 1977;1:1645-1648

Urinary Cotinine in Children Effect of at-home Smokers



Winkelstein ML, Tarzian A, Wood RA "Parental Smoking Behavior and Passive Smoke Exposure in Children with Asthma" Ann Allergy Asthma Immunol 1997;78(4):419-423

Don't Worry, Doc, We Only Smoke Outside!



Winkelstein ML, Tarzian A, Wood RA "Parental Smoking Behavior and Passive Smoke Exposure in Children with Asthma" Ann Allergy Asthma Immunol 1997;78(4):419-423

Are Cigars Safer?

- Tobacco content = >20 cigarettes
- 1 cigar vs 1 cigarette:
  - 7 X tar
  - 11X carbon monoxide
  - 4 X nicotine
- ↑Alkaline cigar smoke → enhanced entry to bloodstream through oral vasculature

Cowley G. "Are stogies safer than cigarettes?" *Newsweek* 1997;(July21): 57

Smoking Cessation & Stroke Prevention: Does it help?

- Smokers vs non-smokers RR = 1.5
- Former smokers vs nonsmokers RR = 1.2
- Most recent studies (1993): Former smokers begin to approach risk of nonsmokers at 2-5 years cessation

Bronner, Leslie "Primary Prevention of Stroke " NEJM 1995;333:21

Reducing Smoking: How Much Benefit?

You are speaking to a new patient about smoking cessation. Taken aback, he says "But doc, I've cut down by more than 50% in the last two years and kept it up….isn't that good enough?" Your evidence based response should be

a) Yes, risk of CVD is correspondingly ±50% lower

b) Yes, but CVD risk reduction is only ± 25%

c) No, cutting down has been shown NOT to help

RESEARCH PAPER

Health consequences of reduced daily cigarette consumption

Aage Tverdal, Kjell Bjartveit

Tobacco Control 2006;15:472-480. doi: 10.1136/tc.2006.016246

Cutting Down Smoking: Benefits?

- Study: Prospective study (Norway) heavy smokers (n=51,210) who cut down by >50%
- Inclusion
  - Age at enrollment 20-49 years
  - Smoked >15 cigs/d at baseline
  - ♀ (n=24,959)
  - ♂ (n=26,251)
- Exclusion: Known CHD; pipe smokers
- Followup 1974-1978 thru 2003 (mean 21.2 yrs)

Tverdal A, Bjartveit K *Tobacco Control* 2006;15:472-480

Cutting Down Smoking: Benefits?

Mortality	Reducers vs Sustained Heavy Smokers RR	p
All-cause	1.02 (0.84-1.22)	NS
CVD	1.02 (0.75-1.39)	NS
IHD	0.96 (0.65-1.41)	NS
Lung Ca	0.66 (0.36-1.21)	NS
Smoking-related CA	0.86 (0.57-1.29)	NS

Tverdal A, Bjartveit K *Tobacco Control* 2006;15:472-480

Cutting Down Smoking: Benefits? Conclusions

"Long-term follow-up provides no evidence that heavy smokers who cut down their daily cigarette consumption by >50% reduce their risk of premature death significantly."

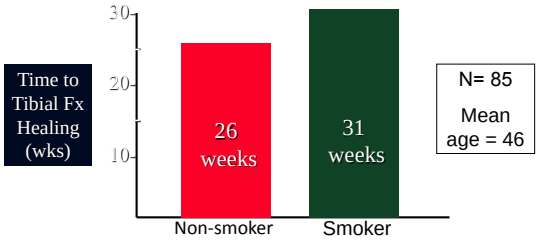
Tverdal A, Bjartveit K *Tobacco Control* 2006;15:472-480

Cutting Down Smoking: Benefits? Conclusions

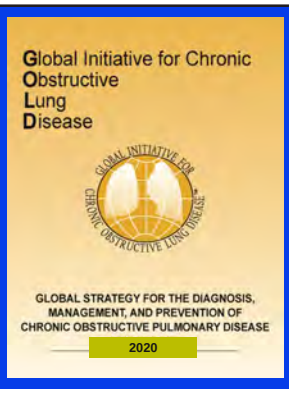
"…it may give people false expectations to advise that reduction in consumption is associated with reduction in harm."

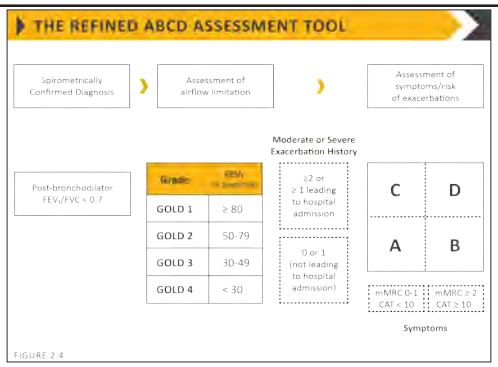
Tverdal A, Bjartveit K *Tobacco Control* 2006;15:472-480

Smoking Goes Clear to the BONE …and it's NOT just Osteoporosis



Moghaddam A, et al "Cigarette smoking influences the clinical and occupational outcome of patients with tibial shaft fractures" Injury 2011;42(12):1435-42





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COPD: Severity of Airflow Limitation

Post-Bronchodilator FEV1	
GOLD 1: Mild	$FEV_1 \geq 80\%$ predicted
GOLD 2: Moderate	$50\% \leq FEV_1 < 80\%$ predicted
GOLD 3: Severe	$30\% \leq FEV_1 < 50\%$ predicted
GOLD 4: Very Severe	$FEV_1 < 30\%$ predicted

GOLD COPD 2020 Guidelines Pocket Guide

Global Strategy for Diagnosis, Management and Prevention of COPD

Assessment of COPD Sx

COPD Assessment Test (CAT)

or

Clinical COPD Questionnaire (CCQ)

or

mMRC Breathlessness scale

GOLD COPD 2020 Guidelines Pocket Guide

Global Strategy for Diagnosis, Management and Prevention of COPD

Modified MRC (mMRC)Questionnaire

PLEASE TICK IN THE BOX THAT APPLIES TO YOU
(ONE BOX ONLY)

mMRC Grade 0. I only get breathless with strenuous exercise. ☐

mMRC Grade 1. I get short of breath when hurrying on the level or walking up a slight hill. ☐

mMRC Grade 2. I walk slower than people of the same age on the level because of breathlessness, or I have to stop for breath when walking on my own pace on the level. ☐

mMRC Grade 3. I stop for breath after walking about 100 meters or after a few minutes on the level. ☐

mMRC Grade 4. I am too breathless to leave the house or I am breathless when dressing or undressing. ☐

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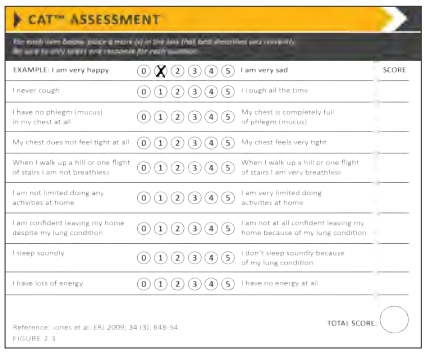


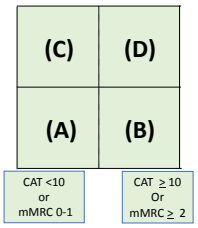
CAT Distilled: 8 Questions Scored 0-5

- Cough: never—often
- Mucus: none—my chest is full of mucus
- Chest tightness: none—very tight
- Breathless with 1 flight of stairs: none--very
- ADL at home: no limitations—very limited
- Confidence when leaving home: confident—not at all confident
- Sleep: soundly—not at all soundly because of COPD
- Energy: lots—none at all

Jones PW et al *Eur Respir J* 2009;34(3):648-654

Assess Sx First

If CAT < 10 *or* mMRC 0-1: LESS Sx/breathlessness (A or C)



If CAT ≥ 10 *or* mMRC ≥ 2: MORE Sx/breathlessness (B or D)

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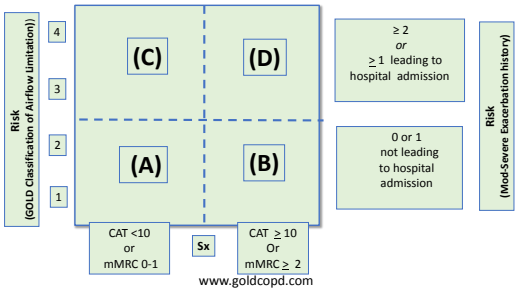
Global Strategy for Diagnosis, Management and Prevention of COPD

Combined Assessment of COPD



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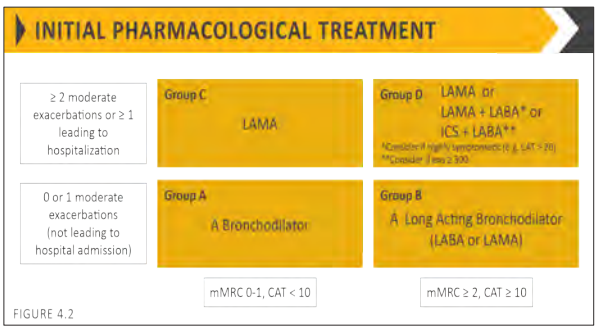

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COPD Pharmacologic Rx: 10 General Principles

- All patients: SABA for rescue
- Initial Rx:
  - LAMA > LABA (fewer exacerbations)
  - LAMA/LABA > LABA
  - LAMA/LABA > LAMA (±)
- ICS/LABA:
  - When LABD insufficient + exacerbations
  - When ↑ eosinophils (>300 /µl) or comorbid asthma

GOLD COPD 2020 Guidelines Pocket Guide

COPD Pharmacologic Rx: 10 General Principles

- ≥GOLD 3 + exacerbations: add PDE4-i (roflumilast) to LABD regimen
- *Consider* macrolides (eg, azithromycin): continued exacerbations despite GDMT
- Long-term ICS monotherapy: NOT recommended
- Theophylline: Last resort

GOLD COPD 2020 Guidelines Pocket Guide

The ATBC (α–tocopherol β–carotene) Study

- STUDY: Lung Cancer Prevention Trial (1985-1993)
- 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 ↑

Alpha-Tocopherol, Beta-Carotene Cancer Prevention Study Group "The Effect of vitamin E and beta-carotene on the incidence of lung cancer and other cancers in male smokers." N Engl J Med 1994;330:1029-1035

"β-Carotene and Vit A Halted in Lung CA Prevention Trial"

- STUDY: 18, 314 male & female high-risk subjects: current or former smokers, 4,060 asbestos exposed
- Rx : 30 mg b-carotene + 25,000 IU Vit A daily
- OUTCOME: 4 Yrs Rx
  - 28%↑ lung CA
  - 17% ↑ deaths → study terminated 21months early

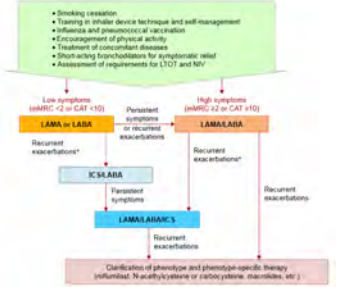
Primary Care & Cancer p21 January 1996

Vitamin Supplementation?

"Smokers should avoid beta carotene supplementation."

The ATBC Study Group "Incidence of Cancer and Mortality Following alpha-Tocopherol and beta-Carotene Supplementation" JAMA 2004;290(4):476-485

COPD Rx Algorithm: Russian Guidelines



Aisanov Z et al *Int J COPD* 2018;13:183-187

COPD Rx Algorithm: Russian Guidelines

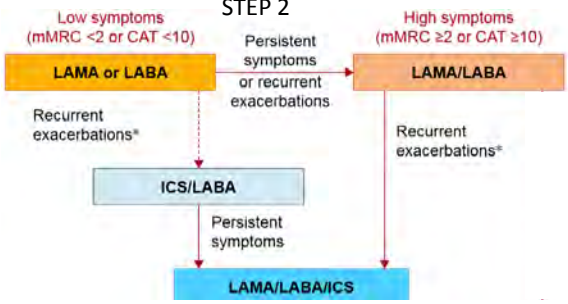
STEP 1

- Smoking cessation
- Training in inhaler device technique and self-management
- Influenza and pneumococcal vaccination
- Encouragement of physical activity
- Treatment of concomitant diseases
- Short-acting bronchodilators for symptomatic relief
- Assessment of requirements for LTOT and NIV

Aisanov Z et al *Int J COPD* 2018;13:183-187

COPD Rx Algorithm: Russian Guidelines

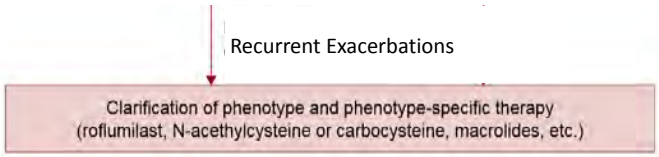
STEP 2



Aisanov Z et al *Int J COPD* 2018;13:183-187

COPD Rx Algorithm: Russian Guidelines

STEP 3



Aisanov Z et al *Int J COPD* 2018;13:183-187

KEY PRACTICE POINTS

- The USA status for adult smoking is the best it's been in >50 years
- Rx reduces exacerbations and improves function
- Talk to parents of children with URI/OME/AOM about smoking
- You only have to give up 1 cigarette: the next one
- Don't test your abstinence
- No pharmacologic Rx has been shown to be disease modifying or reduce mortality. Hence, your choice about Guideline Directed Treatments certainly has room for individualization

SELF EVALUATION

COPD: Diagnosis, Therapies and Management

1. The diagnosis of COPD is best confirmed by

a. A chest xray
b. Carbon dioxide diffusion
c. A post-bronchodilator FEV1/FVC ratio <0.70
d. Resting SaO2 of <93%

2. During exercise, one of the phenomenon that magnifies dyspenea in COPD patients is

a. Dynamic hyperinflation, thereby reducing available inspiratory reserve
b. Small airway bronchospasm
c. Decreased residual volume

3. In regards to the pharmacotherapy of COPD:

a. Anticholinergics reduce total mortality
b. Beta agonists reduce total mortality
c. PDE4 inhibitors reduce total mortality
d. No pharmacologic treatment (except O2 in late stage COPD) has been shown to reduce mortality

4. Your patient has reduced smoking by 50%. What type of long-term benefits might he anticipate?

a. 30% reduction in MI
b. 25% reduction in stroke
c. 15% reduction in overall mortality
d. The largest long-term followup of such patients found no statistically significant endpoint reduction

5. What are the benefits in smokers as far as antioxidant supplements (e.g., beta-carotene, vitamin E) go?

a. Antioxidant vitamins reduce stroke
b. Only cold-processed vitamin E is beneficial for smokers
c. Two randomized trials showed worse outcomes in smokers who supplemented beta carotene
d. For best effects, beta-carotene and vitamin E need to be combined

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

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The Physician as a Witness

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.

At some point in their career, most physicians will be called upon by their patients to testify in a deposition as a treating physician, a defendant in a lawsuit, or as an expert witness.

Automobile Accidents
Criminal Proceedings
Malpractice Lawsuits
Workers Compensation Claims
Divorce/Child Custody Battles
Administrative Hearings
Independent Medical Examinations

The Basics

What is a deposition?

- A deposition is testimony taken under oath by a party or witness taken before a court reporter.
- During a deposition, all parties and their attorneys have the right to attend and ask questions of the witness being deposed.
- A written transcript is produced by the court reporter of all of the questions and answers by the witness.

How do you find out who wants to depose you and when?

Who will be there?

- You
- The attorney requesting the deposition
- Your attorney (if you have one)
- Any party (optional) and the attorney representing it
- Any interested party (insurance claims representatives, etc.)(optional)
- Paralegals/Nurse Consultants (optional)
- Court Reporter
- Videographer

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Where will it take place?

Virtually anywhere:

- Attorney office
- Hotel conference room
- Hospital conference room
- Airport
- Court reporter office
- Your office
- Your home (Zoom or other virtual depositions)

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Why are depositions requested?

1. Party
   - Discover what facts you know and what opinion you hold
   - Custom and practice
   - Admissions against your interest
   - Admissions against the interests of others
   - Establish facts helpful to plaintiff's burden of proof or to undermine your defenses
   - Undermine your credibility and experience

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Why are depositions requested? (continued)

2. Treating physician
   - Discover what facts you know
   - Elicit opinions regarding issues in the case
   - Life expectancy
   - Performance of injury
   - Reasonableness and necessity of your treatment
   - Your customs and practices (if applicable)
   - Pure fact depositions about treatment rarely are used outside of the proceeding its used for

GUST ROSENFELD P.L.C. 10

Why are depositions requested? (continued)

3. Expert Witness
   - Discover what facts you know and what opinion you hold
   - Custom and practice
   - Admissions against the interest of the physician or hospital for who you are hired
   - Admissions against the interests of others
   - Establish facts helpful to plaintiff's burden of proof or to undermine your defenses
   - Undermine your credibility and experience
   - Explore your history as an expert
   - Past expert testimony
   - Fees and expenses
   - Hours spent and money charged, past and future
   - Number of depositions that month, year, career
   - Income derived from expert witness work
   - Expert witness services/advertisements

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What can your deposition be used for?

- At trial
- At depositions of other witnesses
- At licensing hearings
- In other lawsuits
- Expert witness services

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"The Ground Rules"

1. Make sure you understand the question before you answer.
2. If you do not understand the question or are not sure what was asked, ask to have the question repeated or rephrased.
3. Wait until the question is finished before you give your answer.
4. Do not talk over any other person talking while on the record.
5. Answer verbally.
6. If the question asks for a "yes" or "no", do not respond to the question with "uh huh" or "mmm mmm".

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My Rules

1. Tell the truth.
2. Answer the question asked and only the question asked completely.
3. If you don't know, say so.
4. If you don't remember, say so.
5. Take the day off.

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7 Deadly Sins

1. Do not guess or speculate
2. Do not argue with the attorney or become hostile
3. Do not volunteer information beyond what the questions calls for
4. Do not ask for a break when a question is pending
5. Do not give an opinion outside your expertise
6. Do not talk with others outside of your counsel about your deposition testimony or care of the patient
7. Do not discuss your conversations/communications with your counsel.

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Why is everyone objecting so much?

- Why attorneys object to questions
- Why it matters
- What you should do

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The Doctor as Treating Physician

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Treating physicians who are asked for depositions should have certain rights.

1. The right to request the deposition be scheduled at a time and place convenient to the physician.
2. The right to ask for compensation for your time away from your practice.
3. The right to refuse to talk to any lawyer without a proper medical authorization from the patient.
4. The right to refuse a pre-deposition meeting.
5. The right to refuse to give expert or opinion testimony outside of the facts and scope of your care.

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THE DOCTOR AS DEFENDANT DEPONENT

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Why it's important

- Most important deposition in case
- Likeability and bedside manner
- Knowledge of subject matter
- Experience counts

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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

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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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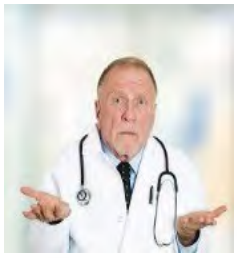
What will be asked?



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Your background

- Personal identification and professional practice;
- Education – both formal and continuing education;
- Licensure;
- Board certification;
- Hospital affiliations;
- Teaching responsibilities;
- Professional associations and affiliations;
- Publications and research;
- Other claims or lawsuits; or
- Experience with medical condition and treatment at issue.

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Every aspect of your care of patient

1. Dates
2. Times
3. Conversations not in record
4. Information available to you
5. Information provided to others
6. Your custom and practice
7. Your diagnosis
8. Your differential diagnose
9. Consultations ordered and why

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Every aspect of your care of patient

(continued)

10. Your treatment plan and alternatives presented
11. Informed consent re: risks/complications
12. Follow up care
13. Patient discharge
14. The standard of care

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Special Considerations for Defendants Deposed in Malpractice Suits

1. Realistic expectations
   a) Your goals
   b) Your attorney's goals
2. You will not "win" your case in your deposition
3. Do not unnecessarily educate your opponent
4. Listen to your attorney
5. Do not be evasive
6. Do not play lawyer

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Tips and Suggestions

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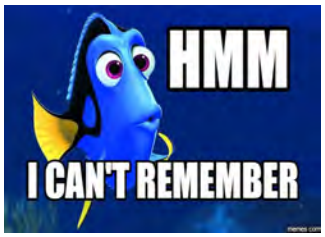
1. Coping with memory loss



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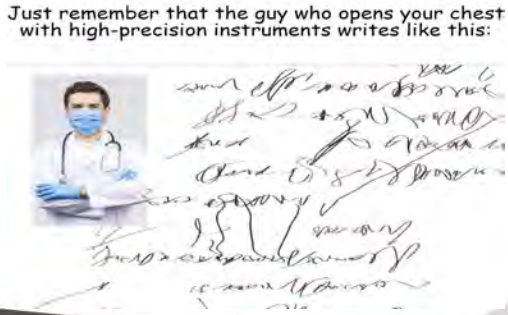
2. Navigating poor documentation (let this be a lesson to you)



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3. Looking before you leap

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4. You got some 'splain'in to do

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5. Don't ever let them see you sweat

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Physician as Expert Witness

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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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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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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.

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Expert Witness Testimony

- Compensated hourly
- Fair market rate
- Separate charges for record review, depositions and trial appearances

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Your deposition as an expert:

- Discover what facts you base your opinions on
- Your own custom and practice
- Admissions against the interest of the physician or hospital for who you are hired
- Admissions against the interests of others
- Establish facts helpful to plaintiff's burden of proof or to undermine your defenses asserted or opinions held
- Undermine your credibility and experience
- Explore your history as an expert
- Review your past expert testimony
- Fees and expenses ask how you calculated
- Hours spent and money charged, past and future
- Number of depositions that month, year, career
- Income derived from expert witness work
- Expert witness services/advertisements

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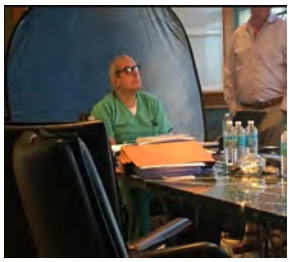
Videotaped Testimony

1. You on camera
2. Formal proceeding
3. Best behavior of witness and counsel



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Zoom Depositions

The New "Normal"

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Zoom Depositions

GUST ROSENFELD P.L.C. 47

Appearance to Audience

- Camera height
- Eye height
- Angle
- Distance (no talking heads, body language)
- Look at camera not your picture
- Sit still
- Background
- Lighting
- Dress (no stripes, checks)

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Zoom Depositions Appearance to Audience (continued)

Your Microphone

- Outside noise
- Slow down
- Same rules as depositions

Technology

- Internet connection speed, computer or tablet RAM

Background Photo

Avitars and Filters

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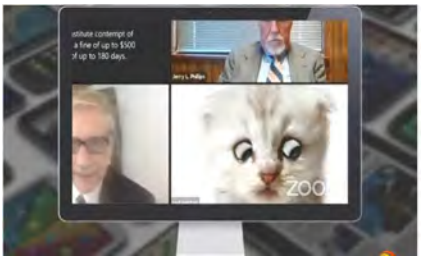

PROS

1. Location
2. Cost savings
3. Health considerations
4. Scheduling

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Cons

1. Your attorney is remote
2. Mechanics of exhibits
3. Chat function
4. Technical difficulties
5. Zoom fatigue
6. HIPPA and privacy

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Special Circumstances

1. Objections
2. Argumentative counsel
3. Extended depositions
4. EMRs
   - Fingerprints
   - Audit trails
5. Exhibits

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Tricks of the Trade

1. The smiling assassin
2. Catch more flies with honey approach
3. The button pusher
4. The ever-changing hypothetical situation
5. The bully

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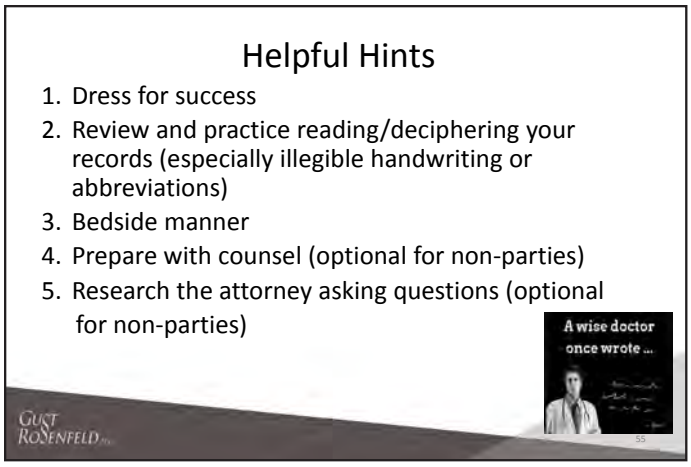

SELF EVALUATION

The Physician as a Witness

1. T/F - When you are subpoenaed to testify about one of your patients, you are placed under oath and asked questions by the patient at his or her house?

2. T/F - If you are a defendant in a lawsuit, the patient's lawyer will want to discover what you recall of the patient?

3. Which of the following is false?
If you are an expert witness in a lawsuit or administrative proceeding at your deposition, you can expect to be asked about:

a. Your income derived from expert witness work.
b. Your history as an expert witness.
c. Your favorite movies.
d. Your education, training and experience to learn whether you are an expert in the subject you are testifying about.

4. T/F - If you are a defendant in a malpractice lawsuit, the best practice is to argue with the patient's attorney when he asks questions you do not like?

5. Which of the following is recommended you do at your deposition?

a. Argue with counsel if asked a ridiculous question.
b. Object to a question you don't like.
c. Project a calm demeanor and professional appearance.
d. Give your best guess if you don't know an answer.

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

Herman P. Houin, MD, FACS

Herman P. Houin, MD, FACS, of Detroit, Michigan, is board-certified in plastic surgery with a Certificate of Added Qualifications in surgery of hand. Dr. Houin practices as a plastic surgeon at Henry Ford Hospital in Detroit and serves on that institution's OR Operations Committee. He is associate clinical professor at Wayne State University's Department of Surgery and sits on Purdue University's Biological Sciences Academic Alumni Council. He has received numerous awards and recognitions, has published numerous articles and is a frequent speaker on his specialty.

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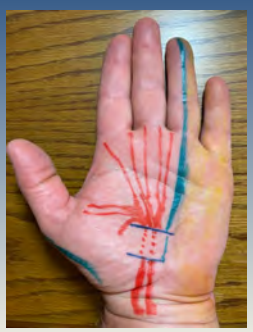
Understanding and Treating Carpal Tunnel Syndrome

Herman P. Houin, MD, FACS

Understanding and Treating Carpal Tunnel Syndrome

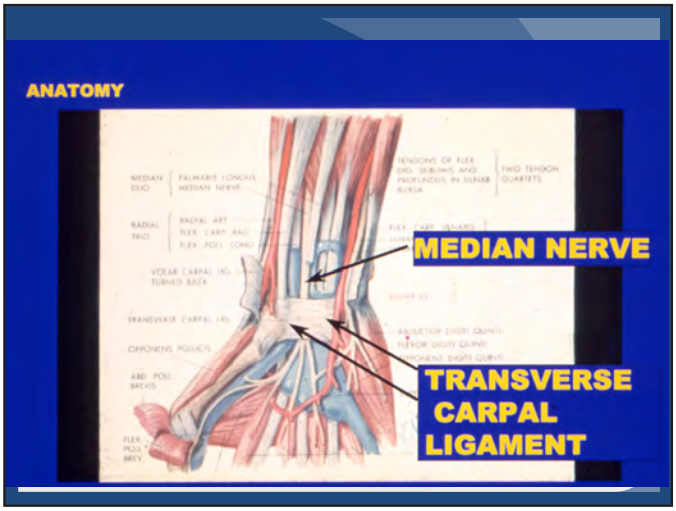
- Compression of Median nerve within Carpal Tunnel

Palmar Innervation



Carpal Tunnel Symptoms

- Numbness and Tingling in Median Fingers
- Pain in wrist, palm, fingers or Forearm
- Usually dynamic symptoms
- Nocturnal
- Loss of Proprioception
- Weakness of pinch or grip strength
- Late- Motor wasting



Pathophysiology

- Median nerve most compressible structure in Carpal Tunnel
- Any condition which elevates pressure in tunnel will compress nerve and cause ischemia

Pressures in the Carpal Tunnel

Wrist Position	Controls	Carpal Tunnel Syndrome
Neutral	2.5 mm Hg	32 mm Hg
Wrist Flexion	31 mm Hg	94 mm Hg
Wrist Extension	30mm Hg	110 mm Hg

Physiologic Changes with Compression

Type	Pathology	Effect on Function
Transient- mild	Venous stasis—anoxia	Nerve recovers when compression relieved
Sustained & Increases	Loss of myelin—conduction delay/block	Motor fibers more susceptible than Sensory fibers
Prolonged/Unrelieved	Wallerian degeneration & Intraneural fibrosis	Slow recovery and possible irreversible loss after release

Causes of Symptoms

- Tenosynovitis
- Lumbrical compression
- Position
- Diabetes
- Vibration
- Systemic disease / ESRD
- Mass effects

Tinel's Sign

TINEL'S SIGN IS PERFORMED BY FIRMLY TAPPING WITH A FINGER TIP OVER THE CARPAL TUNNEL

- A positive TINEL'S SIGN is a tingling sensation radiating to the median nerve finger tips.

Phalen's Sign

PHALEN'S TEST IS PERFORMED BY ACTIVELY SHARPLY FLEXING THE WRIST

- A positive PHALEN'S TEST is numbness developing in the median nerve fingers within 60 seconds.

DURKAN'S PRESSURE PROVOCATIVE TEST: PLACE THE PRESSURE PAD DIRECTLY OVER THE CARPAL TUNNEL .

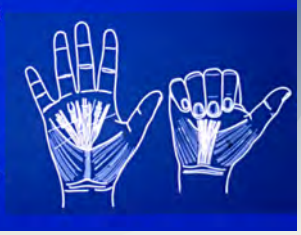
PRESS THE INSTRUMENT INTO THE PALM UNTIL THE NEEDLE IS IN THE GREEN .

- A positive result is numbness in the median nerve fingers within 60 seconds

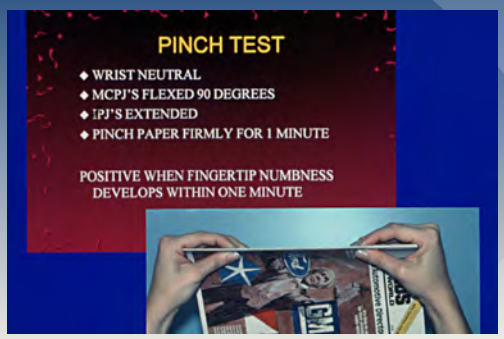
Lumbrical's The Dynamic Culprits

PATTERN: *LUMBRICALS*

THE LUMBRICALS WHICH ORIGINATE FROM THE FLEXOR PROFUNDUS TENDONS IN THE MID PALM ..... ARE PULLED INTO THE DISTAL CARPAL TUNNEL WITH FINGER FLEXION



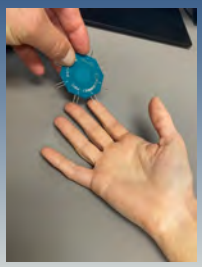
Lumbrical Pinch Test

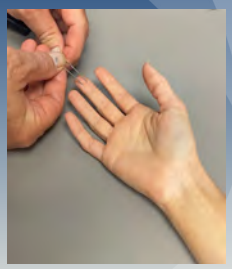


Proprioception

Moving 2 Point discrimination

Clinically ask patient to differentiate coins in pocket

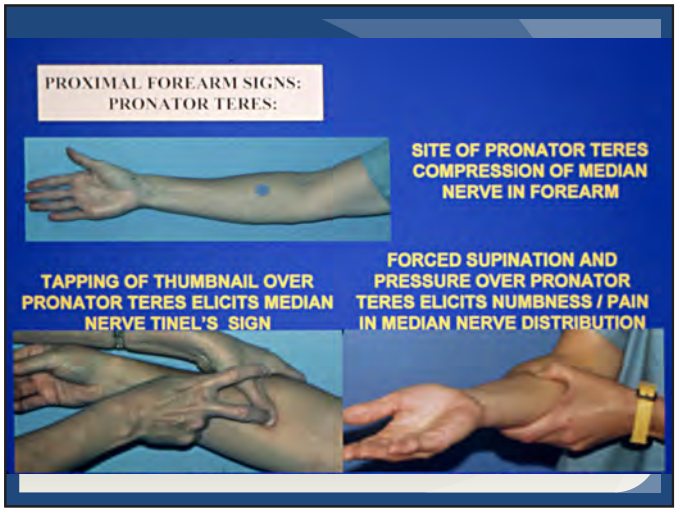


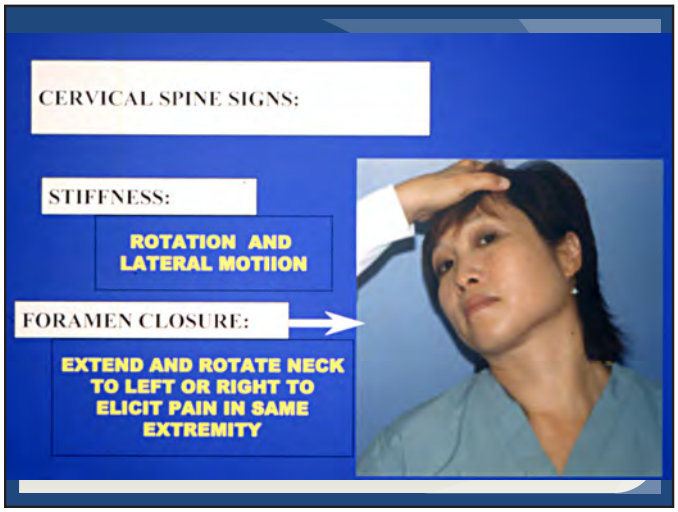


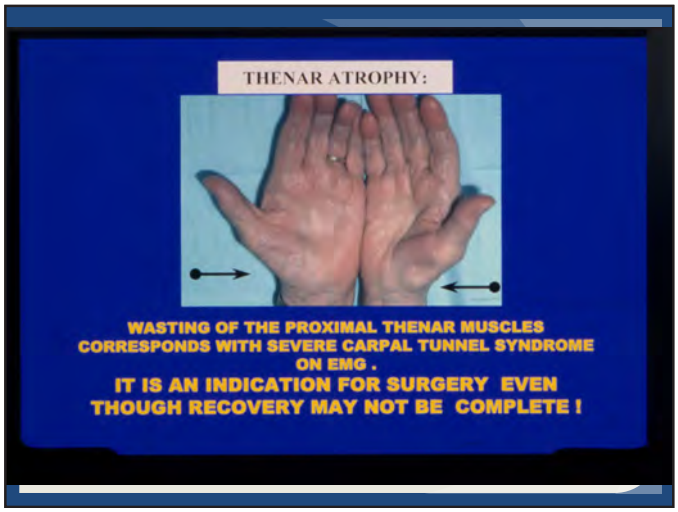
Fine Touch Testing

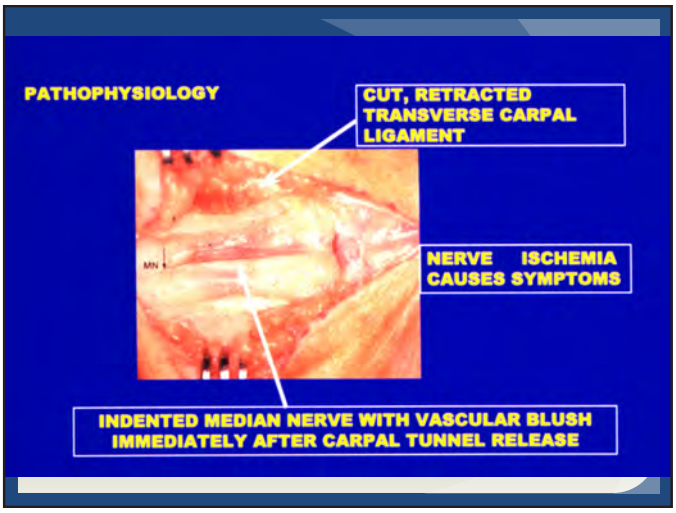
Classic- Semmes-Weinstein Filaments

Practical- Q-Tip and compare to contralateral side or Ulnar Nerve distribution









Nerve Conduction/EMG

Not a fun test for the patient!!!

Used define extent and to localize point of nerve compression

NC can differentiate peripheral neuropathies

EMG documents level of chronic myopathy from compression

Can be used to follow recovery from surgery or non-surgical care

Interpreting NCV/EMG

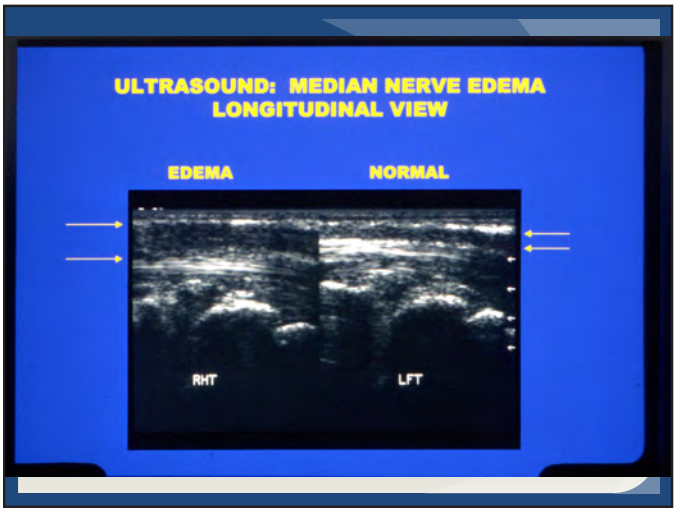
Normal….All values normal
Minimal…Sensory difference <0.5
Mild……..Median nerve sensory >3.5 msec
Moderate...Median nerve motor >4.5 msec
Severe……Median nerve motor >5.5 decreased amplitude and sensory potentials
Very Severe… median motor >6 No response (NR) on amplitude

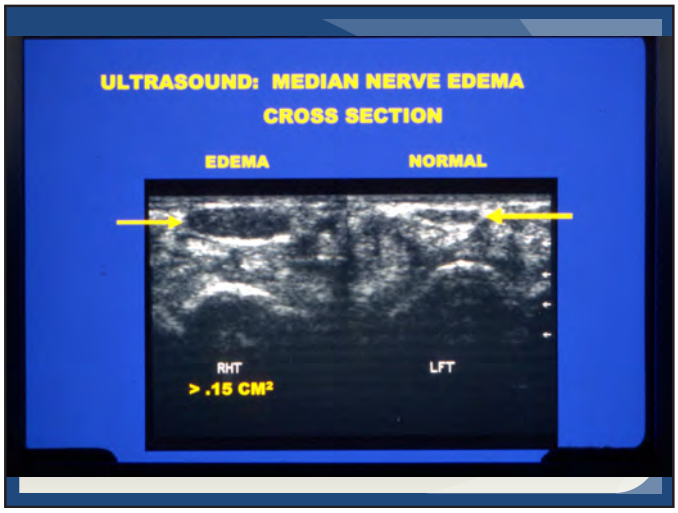
EMG-MUP activity depicts chronicity

Diagnostic Ultrasound

Normal Median Nerve <0.15cm2

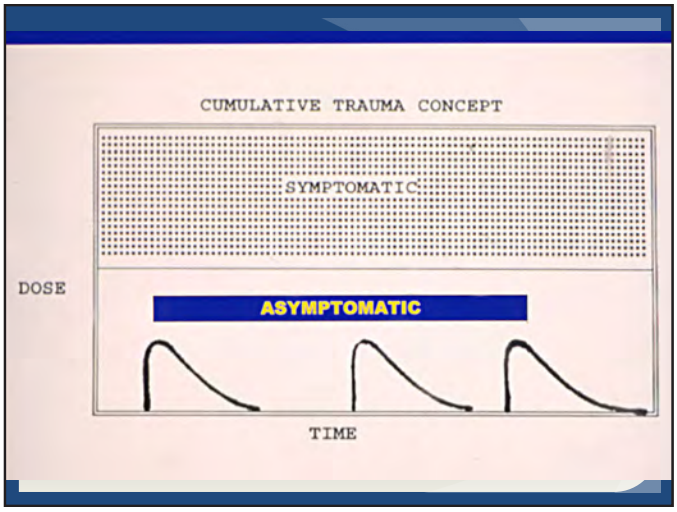
Carpal tunnel compression leads to nerve edema just proximal to wrist crease

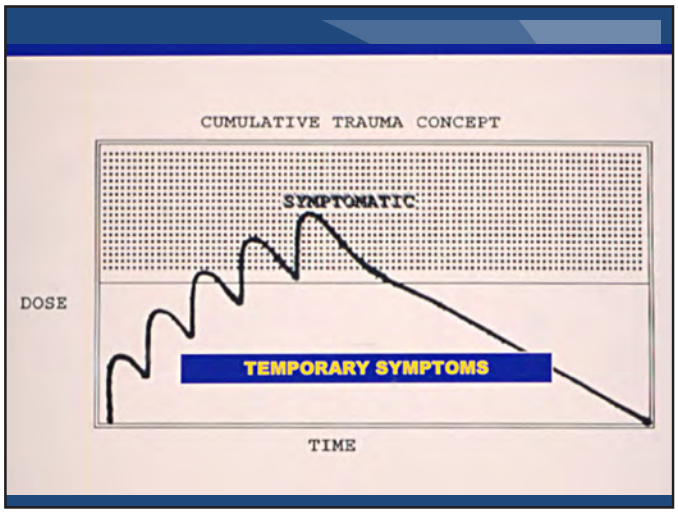


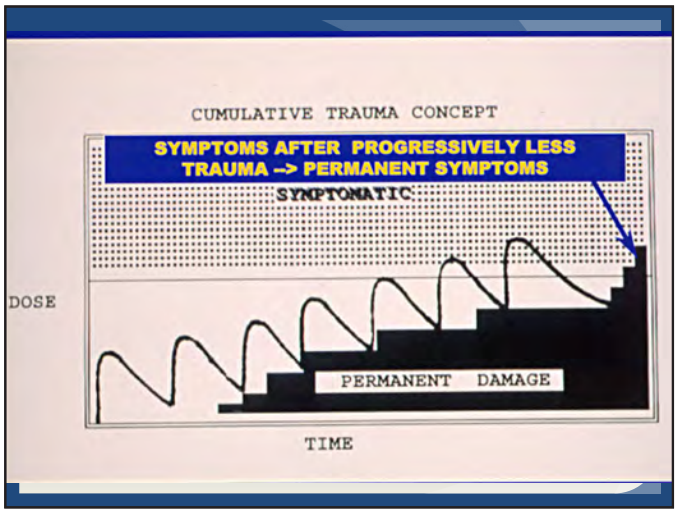


TREATMENT OPTIONS

AVOIDANCE
SPLINTING
STEROID INJECTION
ANTI-INFLAMMATORY DRUGS
SYSTEMIC CONDITION TREATMENT
THERAPY
SURGERY







PATTERN: *LUMBRICALS*

HISTORY

NUMBNESS WITH:

- PINCHING
- DRIVING
- WRITING
- READING

PATTERN: *LUMBRICALS*

EVALUATION:

NERVE CONDUCTIONS MILDLY ABNORMAL

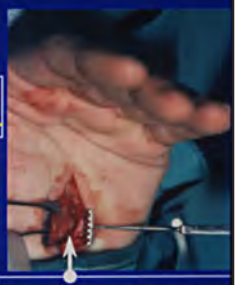
RESULTS:

CARPAL TUNNEL RELEASE GIVES RELIABLY GOOD RESULTS >95%

PATTERN: *LUMBRICALS*

FINGERS EXTENDED: NO LUMBRICALS

FINGERS FLEXED: LUMBRICALS IN CARPAL TUNNEL

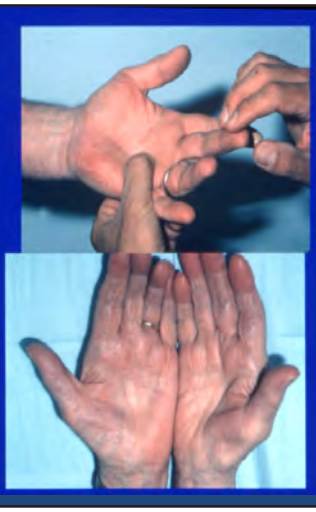


LUMBRICALS CONTRACT WHEN THE INTERPHALANGEAL JOINTS ARE ACTIVELY EXTENDED (LOCAL ANESTHESIA)

PATTERN: *TENOSYNOVITIS*

ASSOCIATED WITH:

- REPETITIVE MOTION
- TRIGGER FINGERS
- TRIGGER THUMB
- GANGLIONS
- THENAR ATROPHY
- SWELLING
- DeQUERVAIN'S
- BURNING PAIN



PATTERN: *TENOSYNOVITIS*

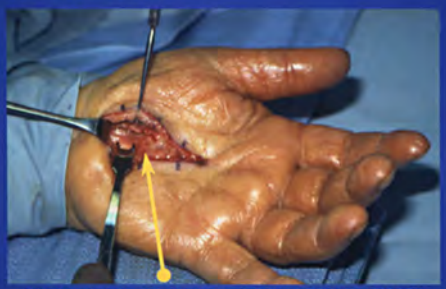
OFFICE TREATMENT:

STEROID INJECTION (2 ml *Celestone Soluspan*) IS BEST PROXIMAL TO THE WRIST TO AVOID INJURY TO MIDPALM STRUCTURES.

BEST USE IS FOR ACUTE CARPAL TUNNEL PAIN FLARE.

AVERAGE EFFECT LASTS FOR ONLY 2 -3 MONTHS.

PATTERN: *TENOSYNOVITIS*



HYPERTROPHIC TENOSYNOVIUM AROUND FLEXOR TENDONS AND MEDIAN NERVE IN CARPAL TUNNEL

PATTERN: *METABOLIC*

RENAL DIALYSIS
- AMYLOID DEPOSITION
- CARPAL TUNNEL RELEASE HELPS

HYPOTHYROIDISM
- THYROID REPLACEMENT
- DOES NOT FIT TRUE CTS DEFINITION

CTS Metabolic Pattern

Renal Dialysis- Amyloid Depositon CTR helps
Gout- medical management
- CTR and debulking if uncontrollable
Hypothyroidism- Thyroid replacement
- CTR if residual symptoms

PATERN: *MASSES*

SUSPECTED MASSES ARE EVALUATED BY ULTRASOUND.

WRIST GANGLIONS CAN HAVE EXTENSIONS INTO THE CARPAL TUNNEL.

PATTERN: VIBRATION

HISTORY IS MOST IMPORTANT

- NUMBNESS DURING AND AFTER WORK
- RECURRENT
- 40 HZ TOOLS
- UNBALANCED TOOLS
- WHITE FINGERS
- NIGHT BURNING PAIN

PATTERN: VIBRATION

VIBRATION LEADS TO:

- EDEMA
- INFLAMMATION
- TENOSYNOVITIS
- VASCULAR DISEASES
- JOINT DISEASES
- SENSITIVITY TO COLD

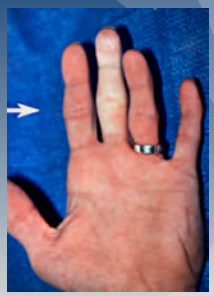
Vibration Exposure

Beauticians, barbers, lumber industry

Any prolonged vibratory tools

Vasospasm with Raynauds

Cold intolerance



PATTERN: *PREGNANCY*

HISTORY

- SWELLING
- NUMBNESS
- ONSET THIRD TRIMESTER

EXAM

- ALL MANEUVERS MILDLY POSITIVE

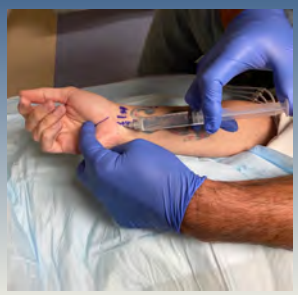
WALANT

Wide
Awake
Local
Anesthesia
No
Tourniquet

Requires good wrist block and
Local anesthesia by surgeon

Wrist Block

Median Nerve – Distal wrist crease behind Palmaris Longus tendon



Inject Ulnar to tendon
Place Index finger distal to Carpal Ligament and feel for fluid wave as you inject

Wrist Block Ulnar Nerve

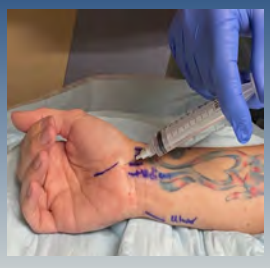
Flex Wrist – Main nerve lies deep to FCU tendon which is most powerful flexor of wrist

Dorsal branch is blocked by directing same needle dorsal as nerve passes 1cm proximal to ulnar styloid

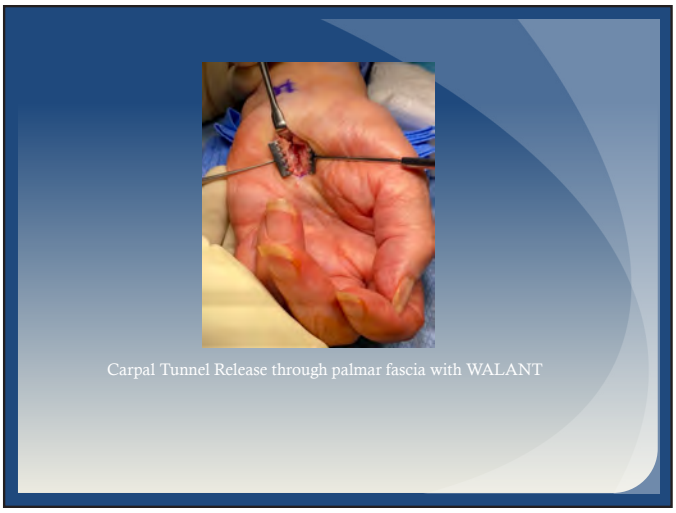
Wrist Block – Superficial Radial Nerve

2 Fingerbreadths proximal to Radial Styloid or just distal to Brachioradialis tendon. Pass injection needle below Cephalic vein and go to middorsum of wrist. Nerve can have multiple branches.

Wrist Block – Palmar cutaneous branch and Incision



After Median nerve block sets infiltrate planned incision line with local containing epinephrine and usually don't need a tourniquet.



SELF EVALUATION

Understanding and Treating Carpal Tunnel Syndrome

True/False

1.___ Median nerve supplies sensation to thumb, Index, Middle and 1/2 ring finger

2.___ Lumbrical muscles can contract into the carpal tunnel in many patients

3.___ WALANT allows dynamic inspection of carpal tunnel during surgery

4.___ Night splints and anti-inflammatory's best initial treatment

5.___ Wrist blocks are simple for any physician to perform

6.___ Nine tendons and the median nerve pass within the carpal tunnel

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

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Practice Process Evaluation and Improvement

By the End

- Understand how to evaluate any process
- Be able to determine the points of inefficiency and ineffectiveness
- Understand the necessary steps to improving any process
- Be well equipped to tackle any process problem

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My Mission and Purpose

To help healthcare professionals obtain the practice they desire by improving their business intelligence.

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Process Improvement

You cannot control what you do not understand

Similar to med school

- Start with basics - anatomy, physiology
- Add in the pathology later
- Learn how to detect problems and treat them

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"An undefined problem has an infinite number of solutions."

- Robert A. Humphrey

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"If I had an hour to solve a problem, I'd spend 55 minutes thinking about the problem and 5 minutes thinking about solutions."

- Albert Einstein

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Processes Can Cost or Make You Money

Processes are critical in service industry

Inefficient processes can cost time and money

Poor processes can lead to low quality outcomes

Proper processes are efficient and improve quality

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Characteristics of Service

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Aspects of Service

Intangibility

Simultaneous production and consumption

Proximity to consumer

Cannot be inventoried

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What is Service?

Materials
Equipment
People
Knowledge
Technology
Facilities

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What is Service?

Materials
Equipment
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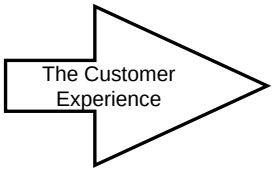
Facilities



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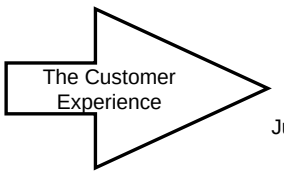
What is Service?

Materials
Equipment
People
Knowledge
Technology
Facilities



Services
Benefits
Feelings
Judgements

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What is Service?

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Equipment
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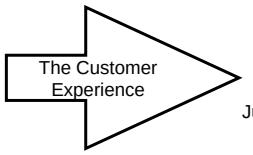

Services
Benefits
Feelings
Judgements

Personal interaction
Ease of use
Courtesy
Interactions with other customers
Responsiveness of company

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Why Manage Your Service?

Better for the company

Better for you

Better for your staff

Better for your customer

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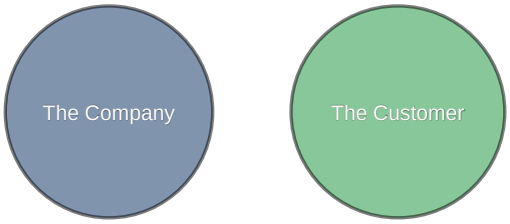
Two Perspectives

Inside-out - what you think is going on

Outside-in - what your customers think is going on



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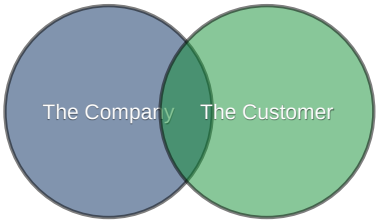
Two Perspectives

Inside-out - what you think is going on

Outside-in - what your customers think is going on



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Two Perspectives

The company perspective
- Inputs
- Processes
- Outputs

The customer perspective
- The experience
- The "products"
- The Benefits

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Two Perspectives

	Input	Process	Output
Company	ER, MDs, RNs, OR, Wards, PT, Equipment	Dx, Tx, Therapy	Hip fixed
	Experience	Service	Benefit
Patient	Empathetic, timely care	Hip fixed	Ambulate again, return home

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Know Your Process

You've got to know every bit of your process

Diagram it

Actually go through it as a provider and as a patient

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What's Your Process

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The Service Concept

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The Service Concept

Know what it is you're doing

Understand the nature of what you're doing so customer and staff understand

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Components

Mission and purpose

What and why

How - the service provided

What - customer experience & outcomes

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Example

Mission and purpose

To help physicians have the practice they desire by raising their business intelligence through business education

How

Online education, books, seminars, consulting

What

Experience

Easy to use and understand concepts in courses and books

Outcome

Physician who has business intelligence and creates the practice they desire

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Connecting with Your Customers

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Who is Your Customer?

Customers can be many things

Patient

Hospital

Other physicians

Health plans

Employers

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Service is a Two-Way Street

Your service is a two-way street

Information flows between you and your customer

Information leads to changes in the service provided

Information leads to changes in the customers expectations

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Managing Your Customer's Expectations

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Customer Satisfaction

Satisfaction is their overall assessment of their perceptions of the service

Process, their experiences, their outcomes

Expectations → Service → Perceptions

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Customer Satisfaction

Expectations → Service → Perceptions

Poor service design
Don't understand their expectations
Inadequate resources

Wrong service provided

Satisfaction is their overall assessment of their perceptions of the service

Process, their experiences, their outcomes

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Influencers of Expectations

Price of your service
Alternatives in marketplace
Marketing of your service
Your reputation (word of mouth)
Their previous experiences
Their attitude/mood
Your confidence

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The Zone of Tolerance

Patients have a zone of tolerance based upon their expectations

As you design a process, consider your patients expectations to develop a zone of tolerance

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Overall Satisfaction Factors

There are points in the process where the customer's satisfaction can be altered

Research shows satisfaction is heavily influenced by

- the peaks (best and worst)
- how they felt at the **end**

Design the experience with the end in mind

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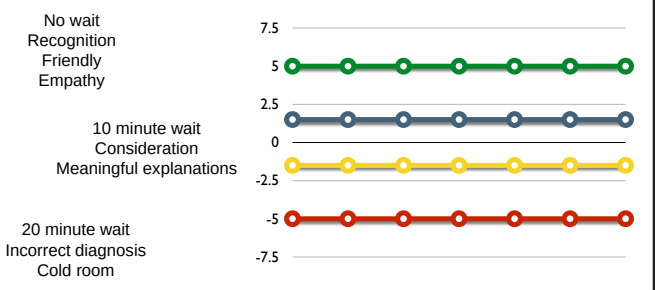

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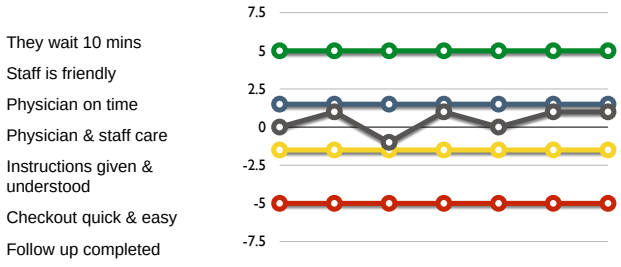

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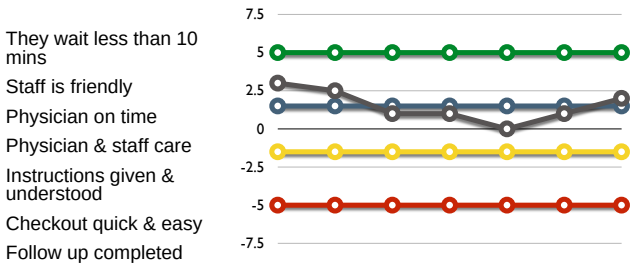

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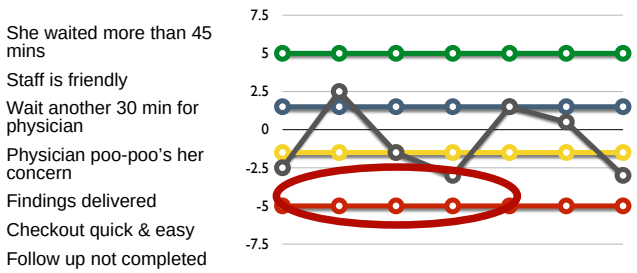
My Wife's Latest Visit



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Factors That Affect Your Quality

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Service Quality Factors

- Access
- Aesthetics
- Helpfulness
- Availability
- Concern and empathy
- Cleanliness
- Comfort
- Communication
- Staff commitment
- Competency
- Flexibility
- Friendliness
- Integrity
- Responsiveness

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Herzberg-ish Model

Dissatisfaction is not the opposite of satisfaction or delight

There are two types of factors

Hygiene factors - these need to be in place to satisfy; if absent they will dissatisfy

Enhancing factors - these can delight if present; if absent likely do not lead to dissatisfaction

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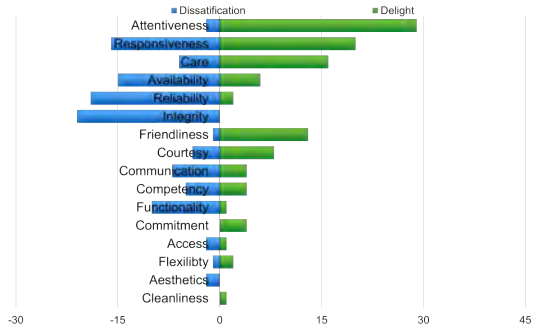
The Data



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Where Should You Focus?

Dissatisfy	**Delight**
Slow to respond	Be attentive to them
Don't be available	Be responsive
Don't be reliable	Care about them
Don't have integrity	Be friendly
Don't communicate	Communicate with them
Don't be competent	Be competent

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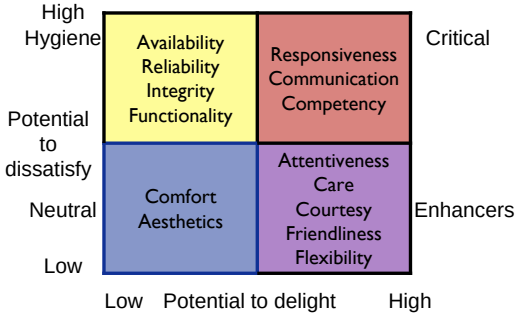
Herzberg-ish Model



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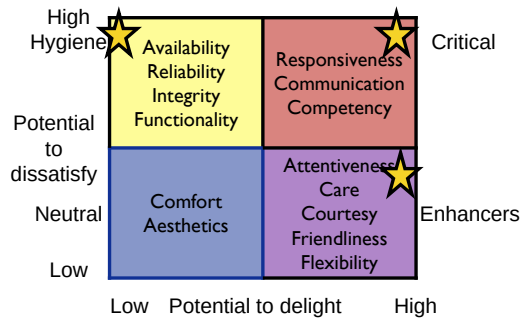
Herzberg-ish Model



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How to Get the Data

Questionnaires & surveys

Customer advisory panels

New & lost customer surveys

Complaint & compliment analysis system

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Design & Deliver

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The Servicescape

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Servicescape

In healthcare, the patient will experience the service we provide in a physical environment

It comprises everything the patient will see, touch, and how those physical aspects impact their experience

They provide clues to the patient as what to expect

Chairs, odors, music

Patients will use all of their senses to build their experience

Using a servicescape can help you design your service

It's a large part of the experience

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Customer Experience Statement

Define the experience you want the patient to have

The experience and outcomes from their point of view

Include the emotions they should feel as a result of the experience and benefits of the service

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The Power of Emotion

Seven primary emotions

Joy

Surprise

Love

Fear

Anger

Shame

Sadness

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The Power of Emotion

Emotions drive decisions

Limbic system overrules any perceived rational decision-making

In fact, emotions drive the decisions and rational brain searches for reasons to justify the emotion

Responses to emotions are swift and powerful and can be permanent

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Front or back?

Front office processes
- Face to face
- Telephone
- Internet services & remote interaction

Back office processes
- Building the chart
- Billing the proper fee

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Design the Experience

Customer journey mapping

Walk-through audits

Emotion mapping

Customer experience analysis

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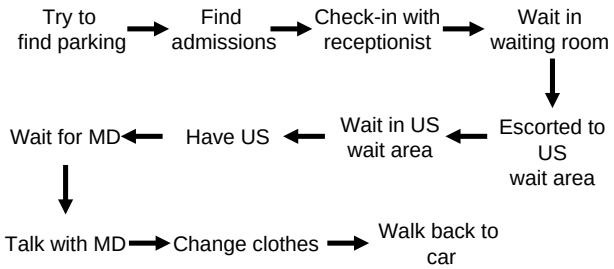
Customer Journey

Map out the touch points between you and the patient



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Walk-through Audit

You, other staff, consultants act as surrogate patient

Develop checklist of questions you want the surrogate to answer as they experience the process

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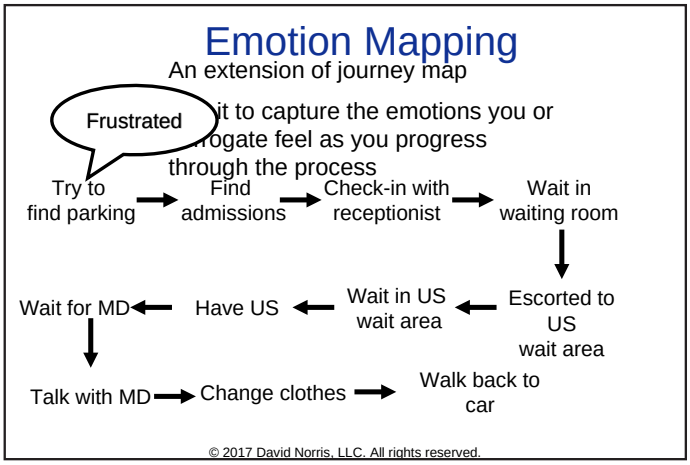
Emotion Mapping
An extension of journey map
Frustrated
Try to find parking
Find admissions
Check-in with receptionist
Wait in waiting room
Escorted to US wait area
Wait in US wait area
Have US
Wait for MD
Talk with MD
Change clothes
Walk back to car
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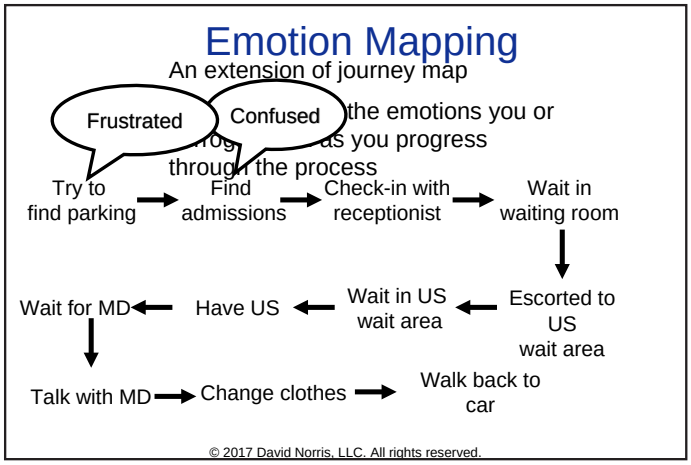
Emotion Mapping
An extension of journey map
Frustrated
Confused
Try to find parking
Find admissions
Check-in with receptionist
Wait in waiting room
Escorted to US wait area
Wait in US wait area
Have US
Wait for MD
Talk with MD
Change clothes
Walk back to car
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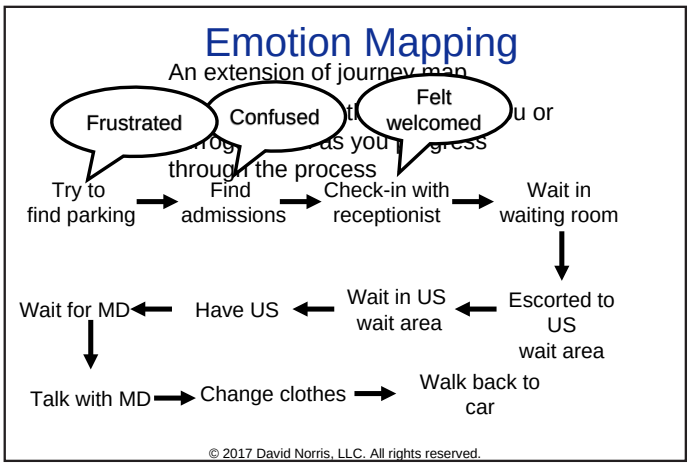
Emotion Mapping
An extension of journey map
Frustrated
Confused
Felt welcomed
Try to find parking
Find admissions
Check-in with receptionist
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Wait in US wait area
Have US
Wait for MD
Talk with MD
Change clothes
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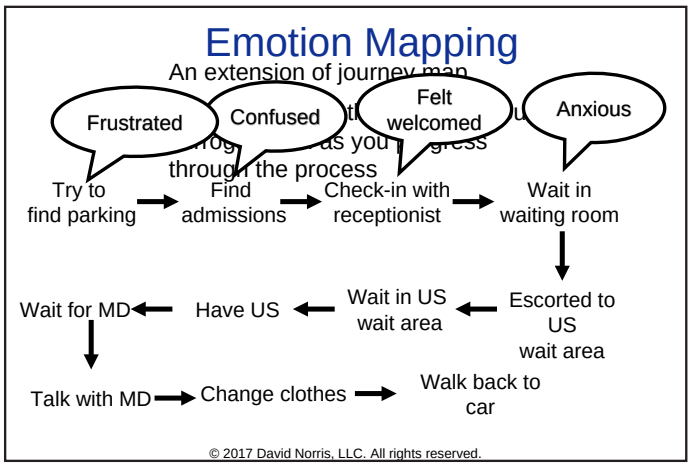
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Wait for MD
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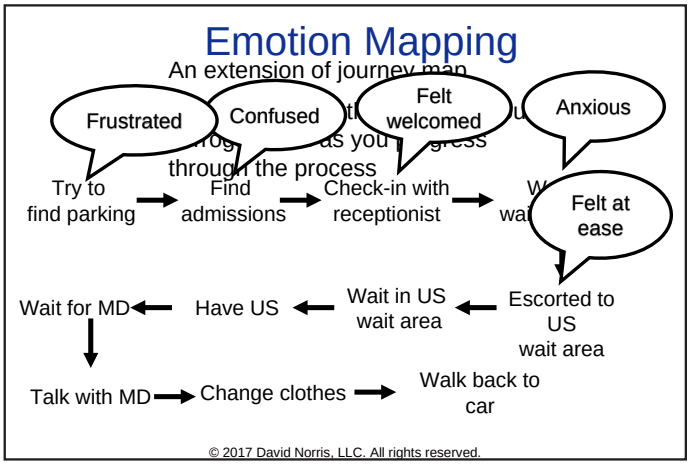
Emotion Mapping
An extension of journey map
Frustrated
Confused
Felt welcomed
Anxious
Try to find parking
Find admissions
Check-in with receptionist
Felt at ease
Escorted to US wait area
Wait in US wait area
Have US
Wait for MD
Talk with MD
Change clothes
Walk back to car
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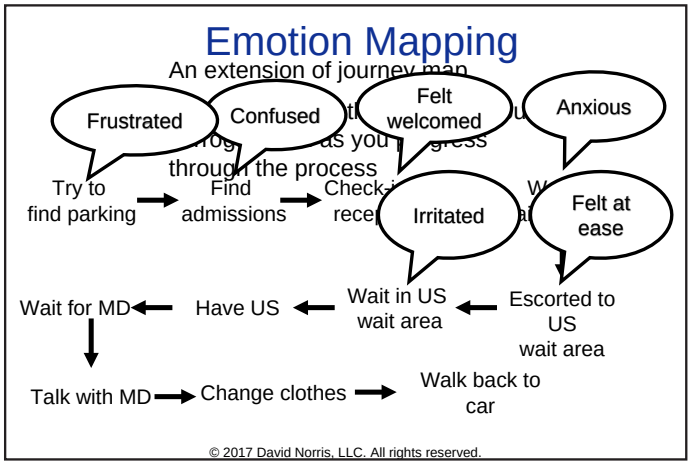
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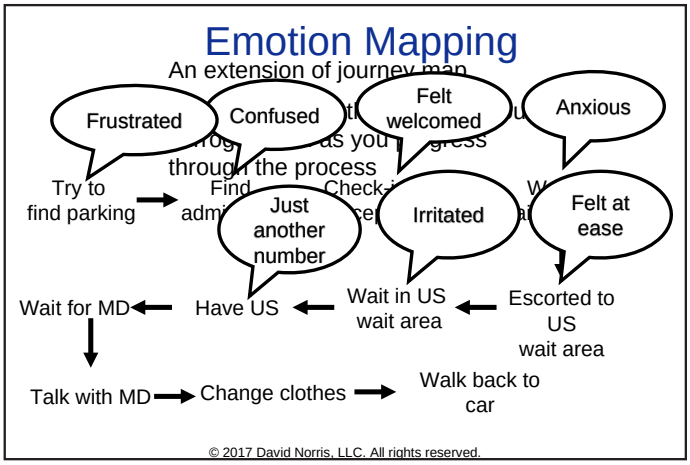

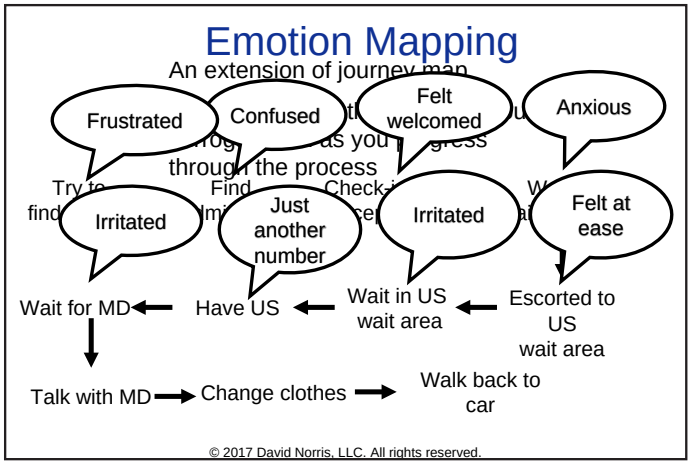

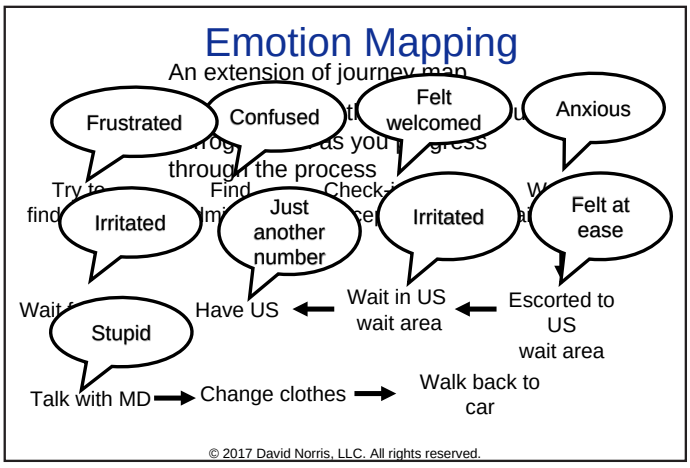

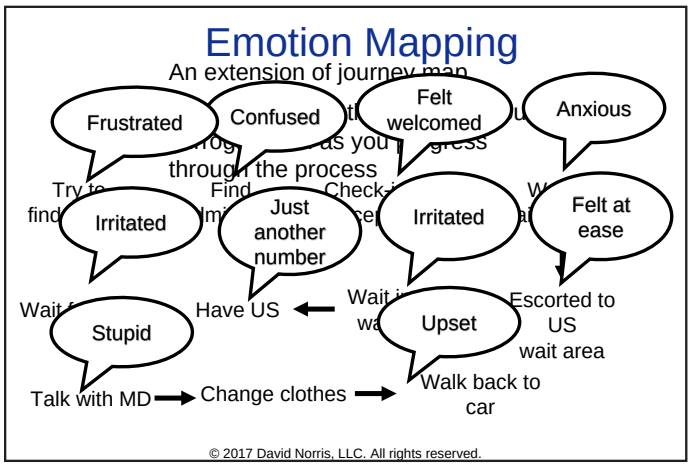

Customer Experience Analysis

Put together all three pieces

- Journey map
- Walk-through audit
- Emotion map

Create one large diagram of customer experience in your process

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Designing the Customer Experience

THE FINANCIALLY INTELLIGENT PHYSICIAN
WHAT THEY DIDN'T TEACH YOU IN MEDICAL SCHOOL

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Types of Flowcharts

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Workflow Mapping

AKA
- Flowcharts
- Flow maps
- Flow diagrams
- Flow sheets
- Process maps

Simply a visual representation of a process

The sequence of events of a process from start point to end point

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Workflow Map Uses

Provide visual representation of process
- Are things really happening the way we think?

Provide starting point for improvement of the process

Ability to identify roles and responsibilities of the process

Ability to maintain the process

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Types of Flowcharts

High level - provide brief overview of the process

Detailed - maps out every step in the process
- Includes decision points, waiting times, feedback loops

Swim-lane - displays process as carried out by the different roles across multiple stages of the process

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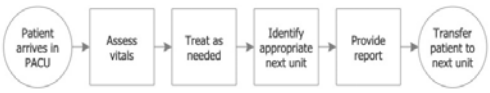
High Level



Detailed

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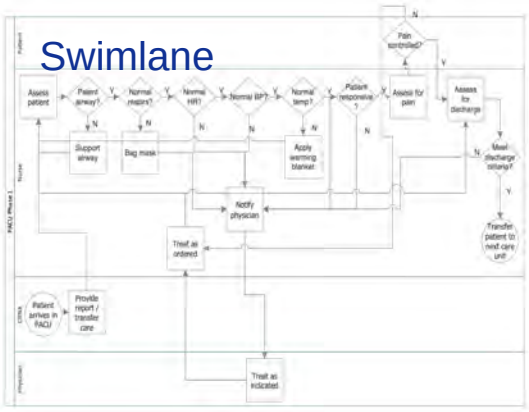
Swimlane



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Creating the Maps

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Questions to Ask

Does this process support the mission and purpose of the business?

Does each activity add value?

Who is responsible for the process?

Who owns the process?

Is the process "in control"?

How efficient is the process?

How can the process be improved?

Is it possible to develop a standard for this process?

Does this process or a part of it need to be moved up or back in the timeline?

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Who is involved?

It'll take a team effort

Identify all parties involved in the process

Pick a champion or two

Gather all the facts, data, and material

Have those selected members craft the process map

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Start Simple

Craft the overview map first

Then the detailed map

Finally, craft a swim lane map

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The Process

1. Identify the process to map
2. Being with high level map
3. Move to detailed map
4. Walk through process once or twice
   1. Note the roles involved in the process
   2. Use this data to create swim lane map
5. Validate the map
6. Identify quick fixes

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Start with M&P

Begin with end in mind

Identify all the processes in your organization or area

Rank them according to how well they work, the number complaints each has, etc

Agree upon a start and finish point of the process to be mapped

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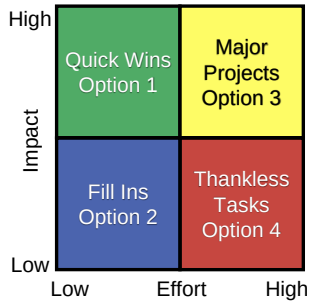
Rank the Processes



Avoid the Thankless Tasks

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Analyze the Map

Questions to ponder

- Where are the bottlenecks? What might be causing delays?
- How much rework is required?
- Where are the errors occurring?
- Where might role ambiguity be present?
- Where are steps duplicated? What steps are unnecessary?
- Where are the hand-offs?

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Start with This Exercise

Get the team together

Outline the following process

Make a cup of coffee

Define the start and end points

You have coffee, the coffee maker (no single cup machines)

Map the process to illustrate what they'll be doing for the company's processes

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During the Exercise

Did everyone discover what a process map is?

Does everyone understand the importance of a process map?

How did the team determine the start and end points?

How did the team deal with disagreements? How might these types of disagreements be handled in the future?

Did everyone participate? If not, why?

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Once You've Got Your Map

USE IT

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What to Avoid

Interview only a handful of people

Map the process you wish you had rather than the one that exists

Ignore the opinions of those who know the process the best

Put your map on a shelf or in a drawer and never look at it again

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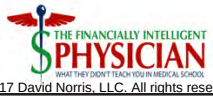
Bottlenecks and Queues



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Bottlenecks

Part of a process that constrains or restricts capacity

Result in queues

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Managing Bottlenecks

Theory of constraints

Ensure only essential work passes through the bottleneck

Eliminate non-essential tasks from the bottleneck

Ensure substandard work doesn't pass through the bottleneck

Once bottleneck has been identified, devote more attention and resources to ensure maximum throughput

Once you find the bottleneck, move it only if necessary. Sometimes simply knowing where it exists is enough in complex systems

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Queues - Rules of Time

Perceived waiting time > actual waiting time

Unoccupied time feels > than occupied time

Anxiety only makes wait seem longer

Uncertain waits feel > than known wait times

Unexplained waits feel > than explained wait times

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Queues - Rules of Time

Unfair waits feel > than equitable waits

Greater the value of service > longer patient will wait

Waiting by yourself feels longer than when with someone else

Discomfort wait feels > than comfortable wait

New patients will experience wait longer than established patients

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Factors Creating Your Queues

Three key aspects

- Patient arrival rate
- Rate patients can be seen
- Number of providers available

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Dealing with Queues

Theory of constraints

- Stage with lowest throughput is rate limiting step

Ensure only essential work passes through the bottleneck

Remove non-essential activities at the bottleneck

Take steps to ensure maximum throughput and effectiveness of the bottleneck

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Effects of Your People

Dealing with queues can be stressful for your people

They can cope with the demand up to a point, then they might "break"

Help your people "cope" with the queue

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Coping with Queues

Start with the service concept - the mission and purpose

Determine how capacity utilization is measured

Understand the nature and impact of the "coping" zone

Determine the ideal operational area

Develop coping strategies

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Coping Questions

What does the customer perceived quality/capacity look like?

What measures or early signals tell you when you're nearing the breaking point?

How does the patient suffer when you reach the breaking point?

How do your employees suffer?

What can be done to reduce the impact on patients and employees?

What can be done to keep you from the breaking point?

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Dealing with Complaints

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Why Customers Complain

Want problem corrected
Prevent problem from happening again to others
Want an explanation of what occurred
Want someone punished
Want money
Want to feel better

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Tips on Dealing with Complaining Customers

Acknowledge the problem happened
Empathize with them - understand their POV
Apologize (might be enough) “I’m sorry this happened to you.”
Own the problem
Involve leadership when problem/complaint serious

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Most Customers Don’t Complain

49% of dissatisfied customers don’t complain in a restaurant
44% of dissatisfied customers don’t complain in a store
They will complain to others, just not you
  50% don’t believe it will fix anything
Comment cards, website, feedback

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Biases

Halo Effect	Good at one thing, good at another. Bad at one thing, bad at another.
Availability	Because I’ve seen it, it must happen a lot
Spurious Awareness	I think I know things that really are not so
Anchoring	People tend to latch onto information presented early and then fail to update when new information is presented
Recency	People tend to pay more attention to what has happened recently, even if it’s not representative of what usually happens
Selective Preception	People tend to give credence to what confirms their beliefs and discount those things that contradict their beliefs
Memory/hindsight	People remember things differently from what actually happened
Confirmation bias	People tend to see only that part of the data that supports their positions

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What’s Your Progress

Analyze your metrics at each milestone
  Are goals being achieved?
  Are any adjustments needed?
  Are there any morale or attitude issues?
  Should any adjustments be made?

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Document the Results

Revisit each countermeasure
  Did the change support the mission and purpose?
  Was the patient experience improved?
  Was complexity eliminated?
  Was confusion eliminated?
  Was target met and did it support the objectives?

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Document the Results

Revisit each countermeasure

- Was the root cause addressed?
- Did positive change occur?
- What was the financial impact of the countermeasure?
- Are you better off now than before?

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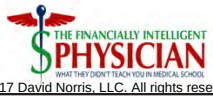
Conclusion



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Have a Plan

SOAP Note approach

Subjective - How are you performing? What did the last period feel like?

Objective - Examine the metrics and reports.

Assessment - Pool all the data and determine how you are trending

PLAN - Know where you want to go and make a plan to get there

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SELF EVALUATION

Practice Process Evaluation and Improvement

1. Aspects of a service include the following:

a. Intangibility
b. Simultaneous production and consumption
c. Close proximity to the patient
d. Cannot be inventoried
e. All of the above

2. Before you begin any process improvement program, an understanding of your service concept is necessary. Which of the following should be defined prior to beginning any improvement efforts?

a. The mission and purpose of the organization
b. The mission and purpose of the process
c. The service being provided
d. What you want the customer to experience
e. What outcomes for the customer you desire
f. All of the above

3. Items that must be in place to satisfy patients, but will not delight them include:

a. Reliability
b. Availability
c. Friendliness
d. Integrity

4. T/F - One of the more effective tools in designing a service that delights the patient is emotion mapping.

5. Queues and bottlenecks are inherent in any process. Understanding how your patient experiences the wait is critical as you design your services. Which of the following is FALSE:

a. Perceived wait times feel longer than actual wait times
b. Anxiety makes waiting feel longer for the patient
c. Waiting alone makes the wait seem longer for the patient
d. Pain makes the wait seem longer
e. Explained wait times feel longer than unexplained wait times

6. T/F - Almost half of dissatisfied customers do not complain about the service they receive.

7. T/F - Bottlenecks not only effect your patients, but your staff as well.

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

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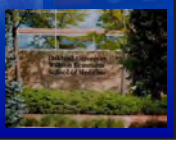
Director of Preventive Cardiology and Cardiac Rehabilitation

Acute Cardiac Event Triggers and Novel Preventive Strategies

Acute Cardiac Event Triggers and Novel Preventive Strategies



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NO DISCLOSURES

CLINICAL FOCUS: CARDIOVASCULAR DISEASE

Triggers of Acute Cardiovascular Events and Potential Preventive Strategies: Prophylactic Role of Regular Exercise

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DOI: 10.1016/j.pcad.2011.11.1934

Abstract: There is now considerable evidence to suggest that acute myocardial infarction, sudden cardiac death, and stroke can be triggered by physical, chemical, and psychological stressors, including heavy physical exertion and situations that create heightened emotional stress. The increased risk appears to be largely limited to a susceptible subset of the population, that is, individuals with known or occult cardiovascular (CV) disease. In this article, we summarize the evidence supporting the impact of selected triggers in the pathogenesis of acute CV events, as well as the potential role of various preventive strategies, especially regular exercise training and improvements in cardiorespiratory fitness to reduce the CV risk imposed by various triggers.

Keywords: acute cardiovascular event; exercise; physical activity; exercise training

Introduction

Considerable evidence indicates that acute cardiovascular (CV) events, including acute myocardial infarction (AMI), sudden cardiac death (SCD), and stroke, can be triggered by physical, chemical, and psychological stressors, including acute intense physical exertion and situations of considerable emotional stress.[1-3] This risk may be particularly high for individuals with known CV disease (CVD) or high CVD risk. In this article, we review the evidence supporting the role of various triggers in CV events, as well as the evidence supporting potential preventive strategies. In particular, we review the role of regular exercise training (ET) and improvements in cardiorespiratory fitness (CRF) to reduce the risk imposed by these specific CV triggers.

Recent Advances in Preventive Cardiology and Lifestyle Medicine

Physical, Psychological and Chemical Triggers of Acute Cardiovascular Events

Preventive Strategies

Murray A. Mittleman, MD, DrPH; Elizabeth Mostofsky, MPH

In addition to the impact of long-term stressors such as sedentary lifestyle and long-term exposure to high levels of air pollution, many studies have shown that there is an increased risk of acute cardiovascular events immediately after behavioral, psychosocial, and environmental triggers.[1-4] After the landmark study documenting the increased rates of myocardial infarction (MI) related to the 1981 earthquake in Athens[5] and the description of the circadian variation in the incidence of MI by Muller et al,[6] various studies documented the frequency of potential triggers in the period immediately preceding MI onset.

Although the observational studies examining physical, psychological, and chemical triggers of acute cardiovascular events are not without limitations, studies continue to show that short-term exposures appear to play a role in the occurrence of cardiovascular events. These triggers have been discussed in previous reviews,[1-4] with a general consensus that different preventive strategies may be appropriate for particular triggers. The purpose of this review is to bring together the evidence of the association between several triggers and cardiovascular outcomes and to discuss the common underlying pathophysiology of these triggers.

Proposed Mechanisms of Triggers of Acute Cardiovascular Events

Rather than leading to slowly progressive atherosclerosis, triggers represent the final step in the pathophysiological

Triggering of Acute Cardiovascular Events: Circadian Rhythms

Exposures that sporadically and acutely increase sympathetic activity(elevating cortisol & catecholamine levels, heart rate & coronary as well as systemic vasoconstriction) have the potential to trigger acute coronary events. **There is a peak of acute myocardial infarction and cardiac arrest from 6 a.m. to noon, and beta-blocker therapy appears to blunt this morning increase in risk.**

Muller JE. Am Heart J 1999;137:S1-S8
Muller JE et al. NEJM 1985;313:1315-1322

Triggering of Acute Cardiovascular Events (INTERHEART study)*

In 12,461 cases of acute myocardial infarction (AMI), 13.6% had engaged in physical exertion and 14.4% were angry or emotionally upset in the case period (1 hour before symptom onset).

Physical Activity and Anger or Emotional Upset as Triggers of Acute Myocardial Infarction

Heavy physical exertion and anger/emotional upset were common in the case period (~ 29%) and confirm that both may act as external triggers for AMI.

**Circulation 2016;134:1059-1067*

bottomline HEALTH

NEW INSIGHTS

LITTLE-KNOWN HEART ATTACK AND STROKE TRIGGERS

...can increase your risk by up to 50%

WINTER WELLNESS

Barry A. Franklin, PhD

In this presentation we describe certain adrenergic triggers can precipitate a cardiovascular event within minutes or hours. Healthcare providers should counsel high-risk patients on the topic, advise them to avoid such triggers, take protective measures against these stressors, and seek emergency care immediately after becoming symptomatic.

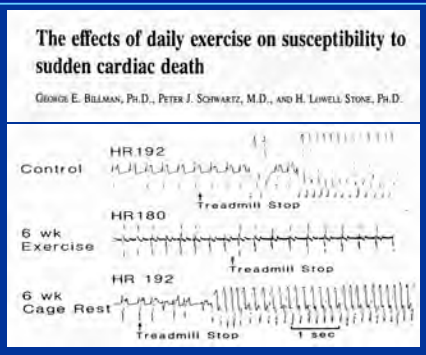
Issue

Outline (4 Topics)

Topic 1

- Physical Stress
- Psychological Stress
- Chemical Stress
- Sleep Deprivation, Acute Infection, Weather Conditions, Dangerous Days

Exercise both Protects Against (Ischemic Preconditioning) and Provokes Acute Cardiac Events



Aerobic exercise conditioning can improve cardiac autonomic balance by both increasing cardiac parasympathetic tone and decreasing cardiac sympathetic activity, thereby enhancing cardiac electrical stability and preventing the triggering of sudden cardiac death.

Billman GE et al. Circ 1984; J Appl Physiol 2

Fixx's 1978 "The Complete Book of Running" earned him more than $1 million and put him in great demand as a lecturer on running.

Heart attack during run kills Jim Fixx, expert on jogging

Author of sci-fi cult classic dies at 49

Douglas Adams, whose cult science fiction comedy *The Hitchhiker's Guide to the Galaxy* drew millions of fans and spawned a mini-industry, has died at age 49. The British-born Adams died Friday of an apparent heart attack in Santa Barbara, Calif., a family friend, **Elizabeth Gibson**, said Saturday. She said Adams collapsed while working out at a gym. "He was not ill," Gibson said. "This was completely unexpected." *The Hitchhiker's Guide to the Galaxy*, which began as a British broadcasting Corp. radio series in 1978, is a satirical adventure about a group of interplanetary travelers; it opens with the Earth being destroyed to make way for an intergalactic highway. It was turned into a book, which sold 14 million copies around the world, and later into a television series. Adams married

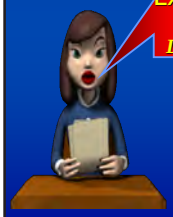
Associated Press

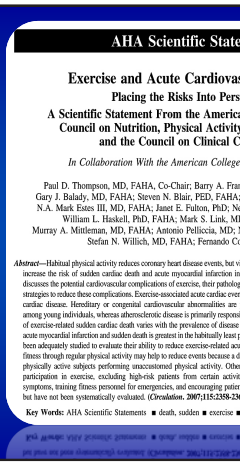
Douglas Adams, author of "The Hitchhiker's Guide to the Galaxy," died Friday of an apparent heart attack while working out at a gym. He was 49.

Jane Belson, a lawyer, in 1991. The couple, who had lived in Santa Barbara since 1999, had a 6-year-old daughter, **Polly**. Adams is also survived by his mother, **Jan Thrift** of England.

Tragedy in Detroit

MARATHON MRI





AHA Scientific Statement

Exercise and Acute Cardiovascular Events

Placing the Risks Into Perspective

A Scientific Statement From the American Heart Association Council on Nutrition, Physical Activity, and Metabolism and the Council on Clinical Cardiology

In Collaboration With the American College of Sports Medicine

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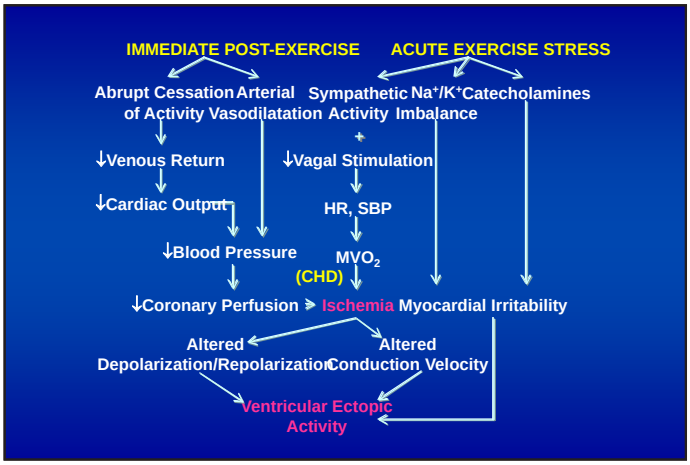
Abstract—Habitual physical activity reduces coronary heart disease events, but vigorous activity can also acutely and transiently increase the risk of sudden cardiac death and acute myocardial infarction in susceptible persons. This scientific statement discusses the potential cardiovascular complications of exercise, their pathological substrate, and their incidence and suggests strategies to reduce these complications. Exercise-associated acute cardiac events generally occur in individuals with structural cardiac disease. Hereditary or congenital cardiovascular abnormalities are predominantly responsible for cardiac events among young individuals, whereas atherosclerotic disease is primarily responsible for these events in adults. The absolute rate of exercise-related sudden cardiac death varies with the prevalence of disease in the study population. The incidence of both acute myocardial infarction and sudden death is greatest in the habitually least physically active individuals. No strategies have been adequately studied to evaluate their ability to reduce exercise-related acute cardiovascular events. Maintaining physical fitness through regular physical activity may help to reduce events because a disproportionate number of events occur in least physically active subjects performing unaccustomed physical activity. Other strategies, such as screening patients before participation in exercise, excluding high-risk patients from certain activities, promptly evaluating possible prodromal symptoms, training fitness personnel for emergencies, and encouraging patients to avoid high-risk activities, appear prudent but have not been systematically evaluated. (*Circulation*. 2007;115:2358-2368.)

Key Words: AHA Scientific Statements ■ death, sudden ■ exercise ■ myocardial infarction ■ coronary disease

Circulation 2007; 115:2358-2368



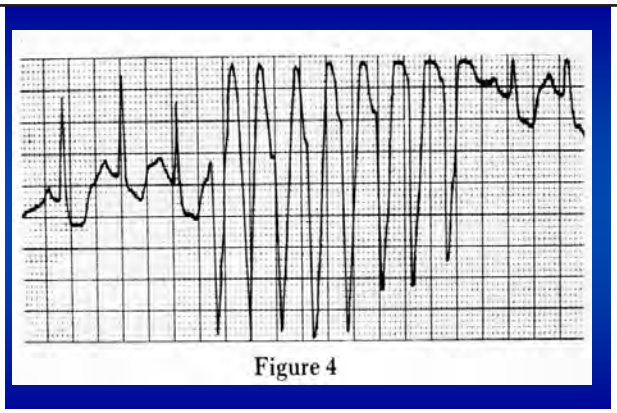
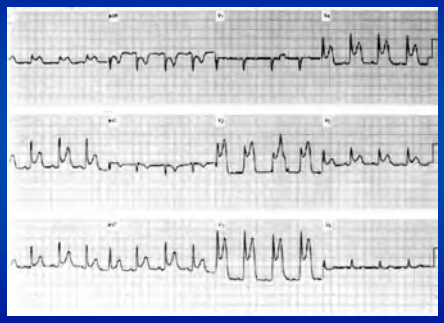
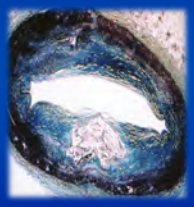


Figure 4

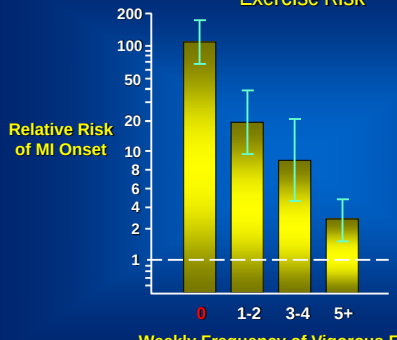
Exercise May Provoke Plaque Rupture and Coronary Thrombosis





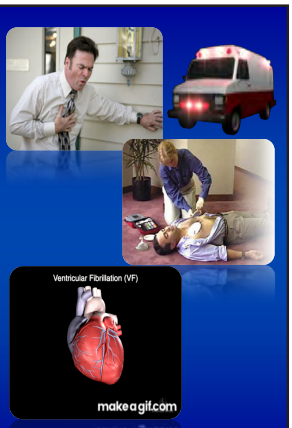
Thompson P. Arch Intern Med 1996;156:2297

Habitual Physical Activity (PA) & Unaccustomed PA as Modulators of Exercise Risk



Mittleman MA et al. NEJM 1993;329:1677

Unaccustomed vigorous physical activity, particularly when performed by inactive, unfit, susceptible individuals, can actually increase the risk of sudden cardiac death and acute myocardial infarction. For those who are highly sedentary, it is important to start exercise in an incremental way. Acute CV events are often preceded by warning symptoms—which require immediate cessation of training and medical review and clearance before resuming exercise.



Circulation 2020;141: February 26, 2020

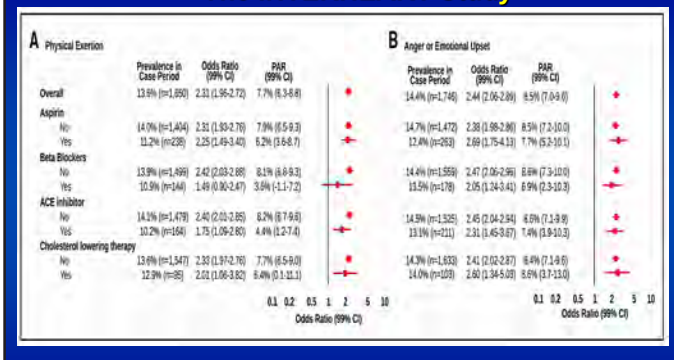
Prophylactic Use of Cardiprotective Medications Before Exercise+

Although some authors have suggested that individuals at risk for CAD may benefit from taking prophylactic aspirin or beta-blockers shortly before vigorous/competitive exercise, there are no definitive data to recommend the routine use of either medication before strenuous physical activity or sports participation.

Study	Benefit	No Benefit
TIMI II*		✓
Myocardial Infarction Onset*		✓
RACER		✓
INTERHEART		✓

** Trend toward slightly lower relative risk with beta-blocker therapy; + Franklin B et al. Circulation February 2020*

The INTERHEART Study*



- CLINICAL IMPLICATIONS: Cardioprotective medications had no effect on preventing AMI associated with these particular stressors

* Smyth et al. Circulation 2016;134:1059-1067

Cardiac Arrest During Long-Distance Running Races*

To clarify the risk of cardiac arrest associated with marathon and half-marathon races in the U.S. from January 1, 2000, to May 31, 2010, investigators reported on the incidences and outcomes of events among 10.9 million registered marathon runners. Of the 59 cases of cardiac arrest (mean ± SD age, 42 ± 13 years; 51 men), 42 (71%) were fatal (~4 fatalities/year).

Conclusion: Marathoners are at a low risk for acute cardiac events. The final mile, < 5% of the whole marathon distance, accounts for ~ 50% of the sudden cardiac deaths.

The most frequent clinical and autopsy findings were hyper-trophic cardiomyopathy and atherosclerotic CVD, respectively.

**Kim JH et al. NEJM 2012;366:130-140*

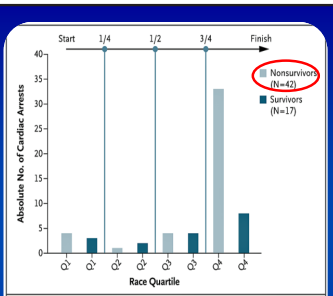


Figure 1. Location of Cardiac Arrest According to Race Quartile.

To account for differences in race distance between the marathon (26.2 mi) and half-marathon (13.1 mi), the point in the race course where the cardiac arrest occurred was examined as a function of the total race-distance quartile. Q1 denotes 0 to 6.5 mi (marathon) and 0 to 3.3 mi (half-marathon), Q2 6.5 to 13.1 mi (marathon) and 3.3 to 6.5 mi (half-marathon), Q3 13.1 to 20 mi (marathon) and 6.5 to 10 mi (half-marathon), and Q4 20 mi to finish (marathon) and 10 mi to finish (half-marathon).

NEJM 2012;366[2]:130


Annals of Internal Medicine ORIGINAL RESEARCH

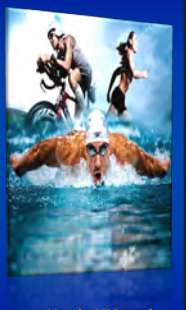
Death and Cardiac Arrest in U.S. Triathlon Participants, 1985 to 2016

A Case Series

Harris K et al.
Ann Intern Med 2017;167:529-535

Death and Cardiac Arrest in U.S. Triathlon Participants*

- > 9 million participants over 30 years
- 135 sudden cardiac deaths(SCDs, 86% men; 13 survivors); incidence of 1.74/100,000 participants versus 1.01/100,000 for marathon running
- Women ~ 15% of the study population, and their incidence of SCD was 3.5 – fold less than men
- Most SCDs occurred during the swim (n=90; 67%) followed by the bicycle, run, and post-race periods, 22, 15, and 8 respectively
- Many of the SCDs (38%) were competing in their first triathlon
- Autopsies performed on 61 of the 135 victims, revealed that 27 (44%) had atherosclerotic CAD and/or cardiomyopathy

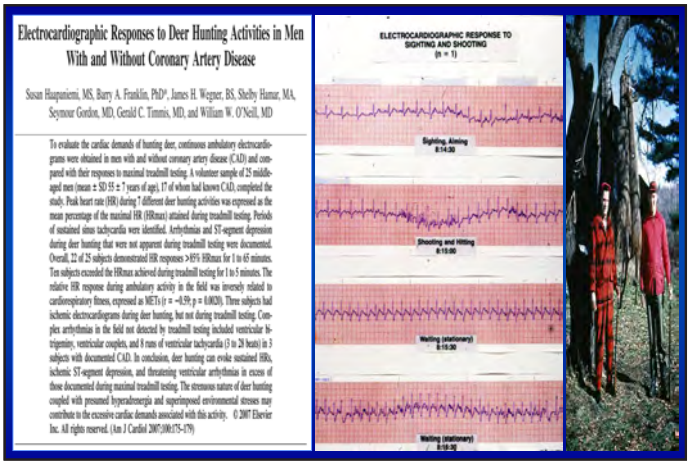


Harris KM et al
Ann Intern Med 2017
167:529-535

High-Risk Activities

Mark Jahnke died of a heart attack Wednesday while playing racquetball at a local club. He was 55.

Northcote RJ, Flannigan C, Ballantyne D. **Sudden death and vigorous exercise – a study of 60 deaths associated with squash. Br. Heart J 1986;55:198-203**



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

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

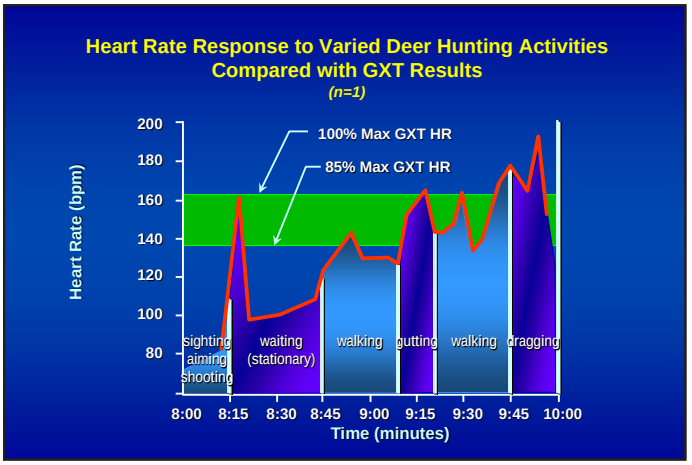
ELECTROCARDIOGRAPHIC RESPONSE TO SIGHTING AND SHOOTING (n = 1)

Sighting, Aiming 8:14:30

Shooting and Hitting 8:15:00

Waiting (stationary) 8:15:30

Waiting (stationary) 8:16:30



"At least 8 people died Wednesday in the Detroit area after snow-related exertion. In Wayne County alone, 17 heart attack deaths were attributed to exertion since the snow began Tuesday. **Most of the victims were older men clearing their driveways and walks."**

Cardiac Demands of Heavy Snow Shoveling

Barry A. Franklin, PhD; Patrick Hogan, MA; Kim Bonzheim, MSA; Donovan Bakalyar, PhD; Edward Terrien, MD; Seymour Gordon, MD; Gerald C. Timmis, MD

JAMA 1995;273:880

Acute Myocardial Infarction After Manual or Automated Snow Removal

Barry A. Franklin, PhD, Peter George, MD, Richard Henry, DO, Seymour Gordon, MD, Gerald C. Timmis, MD, and William W. O'Neill, MD

AJC 2001;87:1282

Sudden Cardiac Death After Manual or Automated Snow Removal

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

AJC 2003;92:833

Cardiorespiratory Measurements During Treadmill Testing and Snow Shoveling

(12 lifts/min x 16 lbs/lift x 10 min)*

Variable	Treadmill Testing	Snow Shoveling
Heart rate (beats/min)	179 ± 17	175 ± 15
Systolic blood pressure (mm Hg)	181 ± 25	198 ± 17
Rate-pressure product (mm Hg x beats/min x 10^{-2})	322 ± 40	342 ± 34
Oxygen consumption (METs)	9.3 ± 1.8	5.7 ± 0.8
Rating of perceived exertion (6-20 scale)	17.9 ± 1.5	16.7 ± 1.7

Acute Myocardial Infarction After Manual or Automated Snow Removal

Barry A. Franklin, PhD, Peter George, MD, Richard Henry, DO, Seymour Gordon, MD, Gerald C. Timmis, MD, and William W. O'Neill, MD

Cardiovascular Clinical Data in the 5 Sedentary Men*

Patient	Age (Years)	SH	CS	↑C	Previous AP	Previous AMI	Previous PTCA	BMI (kg/m²)	Snow Removal Technique: Shoveling	Snow Removal Technique: EST	Symptoms During Snow Removal: Substernal CP	Symptoms During Snow Removal: Sweating	Confirmed AMI	Time of AMI
1	55	○	+	○	○	○	○	34.6	+	○	+	○	+	pm
2	58	○	○	+	○	+	+	30.7	○	+	+	+	+	am
3	64	○	○	○	+	○	○	33.8	○	+	+	○	+	am
4	70	○	○	○	○	○	+	27.7	+	○	+	○	+	am
5	77	+	+	+	○	○	○	30.8	+	○	+	+	+	am

*Persons not participating in a regular exercise program or meeting the minimal physical activity recommendations from the U.S. Surgeon General's report [13]
AP = angina pectoris; BMI = body mass index; C = cholesterol; CP = chest pain; CS = cigarette smoker; EST = electric snow thrower; PTCA = percutaneous transluminal coronary angioplasty; SH = systemic hypertension.

AJC 2001;87:1282

Sudden Cardiac Death After Manual or Automated Snow Removal

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

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

(Am J Cardiol 2003;92:000)

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

Time Frame	Exertion Related SCD	Total SCD (%)
Wk before storm	2*	73 (27)
Wk of storm	24†	102 (23.5)
Wk after storm	17‡	96 (17.7)

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

snowfall, were obtained from the National Weather Service database.

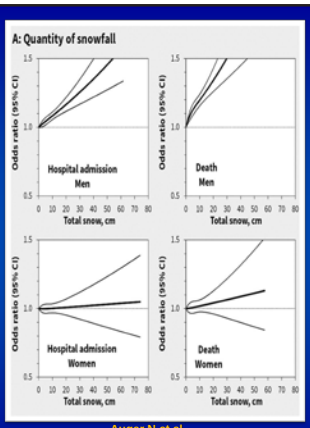
Records from the medical examiners' offices of 3 counties (Wayne, Oakland, and Macomb), encom-

RESEARCH

Association between quantity and duration of snowfall and risk of myocardial infarction

Methods: We used a case-crossover study design to investigate the association between snowfall and hospital admission or death due to MI in the province of Quebec, Canada, between November and April during 1981-2014.

The likelihood of MI was increased the day after a snowfall among men but not among women.



Auger N et al.
CMAJ 2017;February 13;189:E235-42

Why Snow Shoveling is the 'Perfect Storm' ? (Ischemia, Plaque Rupture or Aortic Dissection)

- The relative inefficiency of arm exercise as compared with leg exercise
- Working in an upright posture, especially when the legs are frequently motionless
- Isometric (static) exertion
- Expiratory strain (Valsalva maneuver)
- Inhalation of and exposure to cold air

Heart 2001;**86**:387–390 **Heart 2001;86:387-390** 387

Sexual activity as a trigger of myocardial infarction. A case-crossover analysis in the Stockholm Heart Epidemiology Programme (SHEEP)

The relative risk of myocardial infarction was 2.1 (95% confidence interval (CI) 0.7 to 6.5) during one hour after sexual activity, and the risk among patients with a sedentary life was 4.4 (95% CI 1.5 to 12.9). Implications for ischemic preconditioning…..

activity. However, the absolute risk per hour is very low, and exposure is relatively infrequent. Thus having sex once a week only increases the annual risk of myocardial infarction slightly. Counselling should focus on encouraging patients to live a physically active life and not on abstaining from sexual activity.
(*Heart* 2001;**86**:387–390)

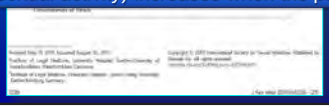
Keywords: myocardial infarction; sexual activity

Warning: Extramarital Sex May Be Hazardous to Your Health

Results: From 1972 to 2016 (45 yrs) approximately 38,000 medicolegal autopsies were performed of which 99 cases (91 men) of death were connected to sexual activities (0.26%). The women's and men's mean age was 45 and 57 yrs, respectively.

If sexual partners were identified, 34 men died during or after sexual contact with a female prostitute, 2 cases at least 2 female prostitutes. Nine men died during or after sexual intercourse with their wife, in 7 cases the sexual partner was a mistress, and in 4 cases the life partner.

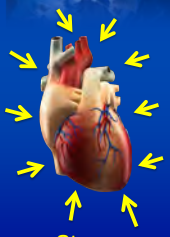
Conclusion: The risk of "love death" (cardiovascular death during sexual activity) increases when the partner is outside of marriage.



Lange L et al. J Sex Med 2017;14:1226-1231

Surgery – An Underrecognized Physical Trigger of AMI*

- Possible Triggering Mechanisms
  - ↑ catecholamines, cortisol, heart rate, blood pressure, coronary vasoconstriction and shear stress → procoagulant state (Type 1 plaque rupture).
  - Influencing myocardial oxygen supply/demand via hypotension, anemia, hypoxia, and hypervolemia → worsen systolic and diastolic dysfunction (Type 2 – MVO_2 supply-demand mismatch).



**Schwartz BG et al. Am J Cardiol 2018;122:2157-2165*

Short-Term Prognosis of Perioperative Myocardial Infarction in Patients Undergoing Noncardiac Surgery*

A widely-cited study which used surgical data from 56 countries, suggested that > 200 million patients worldwide have major noncardiac surgical procedures each year. Millions of these patients will have a major vascular complication within 30 days after surgery, and MI is the most common major perioperative vascular complication.

In this study, 5% of patients (1 in 20) had a perioperative MI, and the 3-day mortality rate was higher for patients who had an MI (12%) than for those who did not (2%). Independent predictors of perioperative MI included each 10-beat/min increase in resting heart rate.

**Devereaux PG et al. Ann Intern Med April 2011*

Major Adverse Cardiovascular and Cerebrovascular Events associated with Non-Cardiac Surgery*

Among > 10 million adults (age 45 and older) who underwent a major noncardiac operation (such as orthopedic, gynecologic, vascular and neurosurgery), 3% of patients (or one in 33), on average, had either a heart attack or stroke while hospitalized, according to a 9-year study.

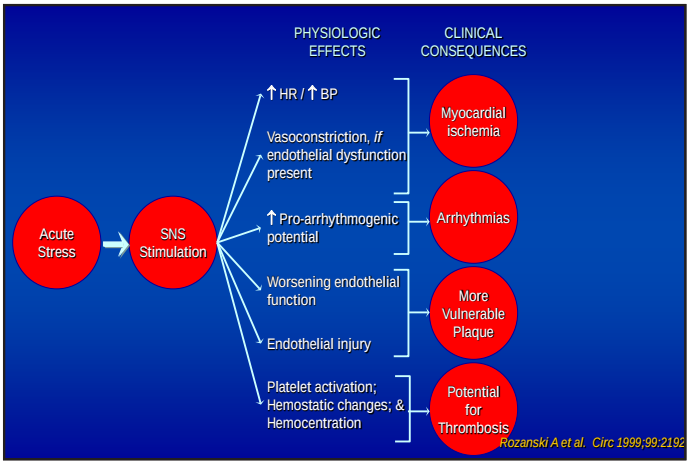
The risks were especially high for certain types of operations---nearly 8% of patients undergoing vascular surgery suffered a heart attack or stroke while hospitalized….and more than 6% undergoing chest (thoracic) surgery. Patients at greatest risk were older, unfit, obese, smoked or had chronic medical conditions.

**Smilowitz NR, JAMA Cardiol. 2017: 2; 181-187*

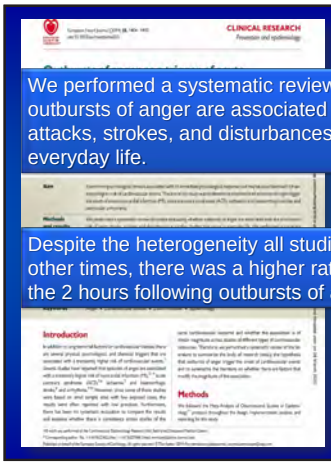
Outline

Topic 2

- Physical Stress
- Psychological Stress
- Chemical Stress
- Sleep Deprivation, Acute Infection, Weather Conditions, and Dangerous Days



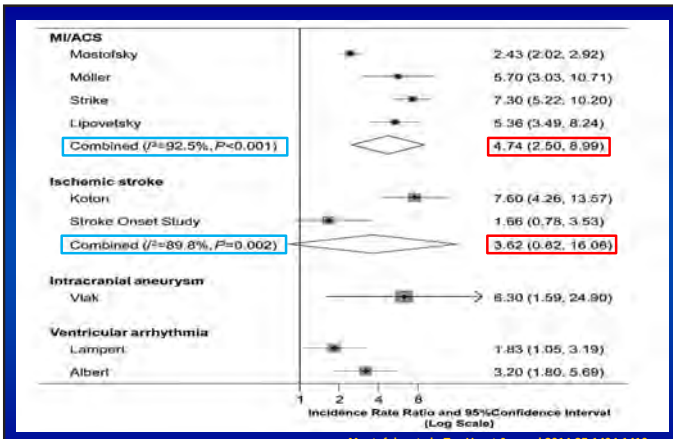
Rozanski A et al. Circ 1999;99:2192



We performed a systematic review of studies evaluating whether outbursts of anger are associated with the short-term risk of heart attacks, strokes, and disturbances in cardiac rhythm that occur in everyday life.

Despite the heterogeneity all studies found that, compared with other times, there was a higher rate of cardiovascular events in the 2 hours following outbursts of anger.

Mostofsky et al. Eur Heart Journal 2014;35:1404-1410



Mostofsky et al. Eur Heart Journal 2014;35:1404-1410

Potential Mechanisms Linking Anger Outbursts And Cardiovascular Events*

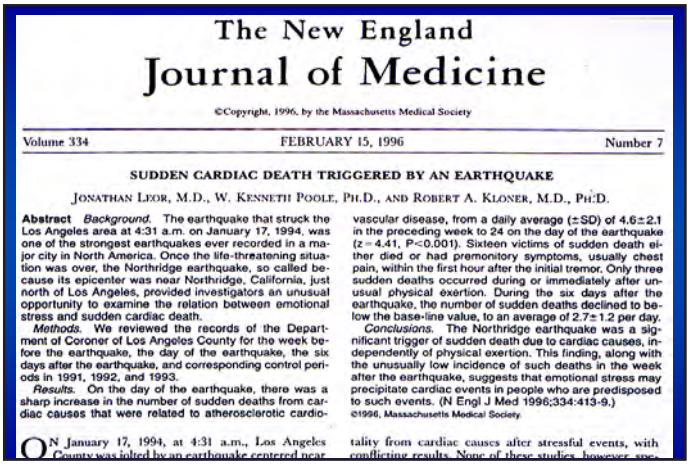
Increase heart rate, blood pressure, and vascular resistance

↓

Transient ischemia and/or disruption of vulnerable plaques → Threatening Ventricular Arrhythmias

Inflammatory and pro-thrombotic responses, including increased platelet aggregation and plasma viscosity and decreased fibrinolytic potential

** Mostofsky E et al. Eur Heart Journal 2014;35:1404-1410*



The New England Journal of Medicine

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Volume 334 FEBRUARY 15, 1996 Number 7

SUDDEN CARDIAC DEATH TRIGGERED BY AN EARTHQUAKE

JONATHAN LEOR, M.D., W. KENNETH POOLE, PH.D., AND ROBERT A. KLONER, M.D., PH.D.

Abstract *Background.* The earthquake that struck the Los Angeles area at 4:31 a.m. on January 17, 1994, was one of the strongest earthquakes ever recorded in a major city in North America. Once the life-threatening situation was over, the Northridge earthquake, so called because its epicenter was near Northridge, California, just north of Los Angeles, provided investigators an unusual opportunity to examine the relation between emotional stress and sudden cardiac death.

Methods. We reviewed the records of the Department of Coroner of Los Angeles County for the week before the earthquake, the day of the earthquake, the six days after the earthquake, and corresponding control periods in 1991, 1992, and 1993.

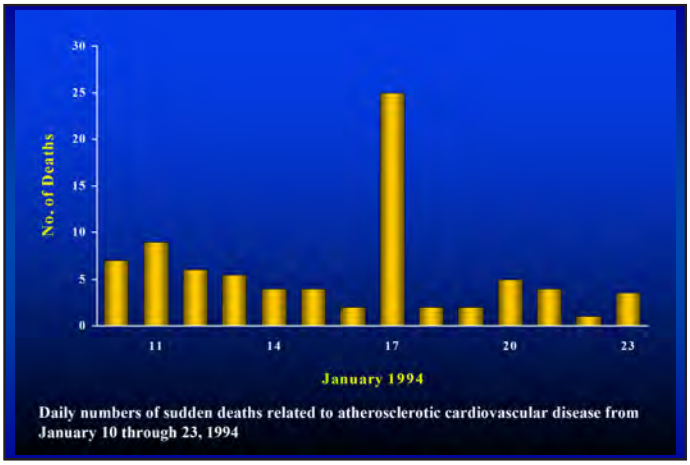
Results. On the day of the earthquake, there was a sharp increase in the number of sudden deaths from cardiac causes that were related to atherosclerotic cardiovascular disease, from a daily average (±SD) of 4.6±2.1 in the preceding week to 24 on the day of the earthquake ($z = 4.41$, $P<0.001$). Sixteen victims of sudden death either died or had premonitory symptoms, usually chest pain, within the first hour after the initial tremor. Only three sudden deaths occurred during or immediately after unusual physical exertion. During the six days after the earthquake, the number of sudden deaths declined to below the base-line value, to an average of 2.7±1.2 per day.

Conclusions. The Northridge earthquake was a significant trigger of sudden death due to cardiac causes, independently of physical exertion. This finding, along with the unusually low incidence of such deaths in the week after the earthquake, suggests that emotional stress may precipitate cardiac events in people who are predisposed to such events. (N Engl J Med 1996;334:413-9.)

©1996, Massachusetts Medical Society.

ON January 17, 1994, at 4:31 a.m., Los Angeles County was jolted by an earthquake centered near

tality from cardiac causes after stressful events, with conflicting results. None of these studies, however, spe-



Daily numbers of sudden deaths related to atherosclerotic cardiovascular disease from January 10 through 23, 1994

NEJM 2008;358-475-83

Cardiovascular Events during World Cup Soccer

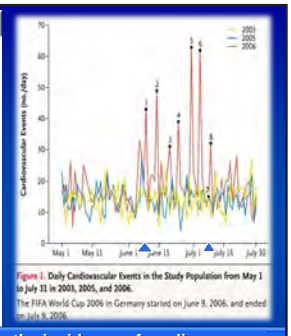


Figure 1. Daily Cardiovascular Events in the Study Population from May 1 to July 31 in 2003, 2005, and 2006.

The FIFA World Cup 2006 in Germany started on June 9, 2006, and ended on July 9, 2006.

On days of matches involving the German team, the incidence of cardiac emergencies was 2.66 times that during the control period (p<0.001); for men, the incidence was 3.26 times that during the control period (p<0.001), and for women, it was 1.82 times that during the control period (p<0.001). Viewing a stressful soccer match more than doubles the risk of an acute cardiac event.

"The Widowhood Effect"

Judith and Gerson Leiber were married for 72 years. She was a handbag designer . . . he was an artist. According to their New York Times obituaries, she was 97, and he was 96 when they died of dual heart attacks – just a few hours apart, earlier this year.

Epidemiology and Prevention

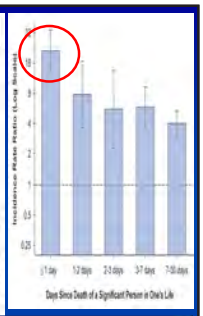
Risk of Acute Myocardial Infarction After the Death of a Significant Person in One's Life

The Determinants of Myocardial Infarction Onset Study

Elizabeth Mostofsky, MPH, ScD; Malcolm Maclure, ScD; Jane B. Sherwood, RN; Geoffrey H. Tofler, MD; James E. Muller, MD; Murray A. Mittleman, MD, DrPH

Background—Acute psychological stress is associated with an abrupt increase in the risk of cardiovascular events. Intense grief in the days after the death of a significant person may trigger the onset of acute myocardial infarction (MI), but this relationship has not been systematically studied.

Methods and Results—We conducted a case-crossover analysis of 1985 participants from the multicenter Determinants of Myocardial Infarction Onset Study interviewed during index hospitalization for an acute MI between 1989 and 1994. We compared the observed number of deaths in the days preceding MI symptom onset with its expected frequency based on each patient's control information, defined as the occurrence of deaths in the period from 1 to 6 months before infarction.



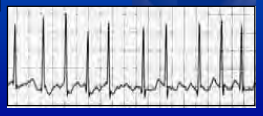
The incidence rate of acute MI onset was elevated 21.1 fold (95% CI, 13.1 – 34.1) within 24 hours of the death of a significant person and declined steadily on each subsequent day.

Key Words: bereavement ■ crossover studies ■ epidemiology ■ myocardial infarction

Circulation 2012;125:491-496

Atrial Fibrillation After the Death of a Spouse or Partner: Potential Mechanisms

- Acute stress may possess direct arrhythmogenic properties by impacting autonomic control, influencing heart rate variability and enhancing proinflammatory cytokines
- Patients with paroxysmal atrial fibrillation (AF) often claim that emotional stress is a common triggering factor and increasing levels of perceived stress are associated with prevalent AF

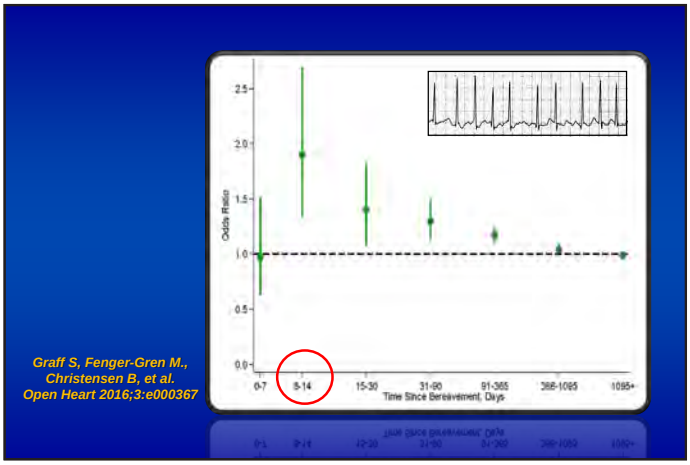


openheart Long-term risk of atrial fibrillation after the death of a partner

Patients with atrial fibrillation (AF) often claim that emotional stress is a triggering factor. We conducted a population-based case-control study using nationwide Danish health registers to examine the risk of AF after the death of a partner/spouse.

Results: Partner/spouse bereavement was experienced by 17,478 cases and 168,940 controls and was associated with a transiently higher risk of AF; the risk was highest 8-14 days after the loss (1.90; 95% CI 1.34 - 2.69), after which it gradually declined.

Conclusions: Losing a partner/spouse was followed by a transiently increased risk of AF lasting for 1 year, especially for the most unexpected losses.



Graff S, Fenger-Gren M., Christensen B, et al. Open Heart 2016;3:e000367

CARDIOLOGY PATIENT PAGE

Takotsubo (Stress) Cardiomyopathy

Scott W. Sharkey, MD; John R. Lesser, MD; Barry J. Maron, MD

Whenever a new and previously unrecognized medical condition enters our consciousness, considerable confusion and uncertainty can ensue. If a patient is afflicted by such a disease state, the natural reaction is, "I have never heard of what I have," triggering considerable personal and family anxiety. Such is the case with the condition we now call takotsubo cardiomyopathy, which has received considerable attention from the media and has been assigned a myriad of names in the literature.

Historical Background and Increasing Visibility

Initial recognition of takotsubo cardiomyopathy occurred in Japan in 1990, with the first report emerging from the United States in 1998. Thereafter, scientific interest in this condition has increased steadily and dramatically. For example, in 2000, only 2 publications were recorded, compared with nearly 300 in 2010 (Figure 1). Now, takotsubo is widely recognized, with reports from 6 continents and diverse countries, including France, Belgium, Mexico, Australia, Spain, South Korea, China, Brazil, Germany, Israel, South Africa, Turkey, and Iceland.

What Is Takotsubo?

The Acute Illness

Takotsubo cardiomyopathy starts abruptly and unpredictably, with symptoms of chest pain and, often, shortness of breath, usually triggered by an emotionally or physically stressful event, and with a predilection for women older than 50 years of age (only 10% in men). Most patients go to the emergency department because of concern they are experiencing a heart attack, a much more common acute heart condition caused by a blocked coronary artery (the Table). Although patients with takotsubo do not have significantly narrowed coronary arteries, in the early hours takotsubo and heart attacks share many similarities in presentation, including chest pain and breathlessness, as well as abnormalities in both the electrocardiogram and blood biochemical tests. Even experienced physicians can be challenged to distinguish between the two, at least until an x-ray study of the coronary arteries and left ventricle with dye establishes the absence of severe plaque buildup in a coronary artery as well as the unusual shape of the left ventricle (ie, pumping chamber)

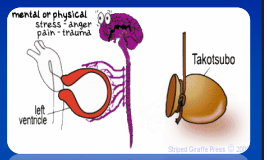
Table. Common Questions Asked About Tako-Tsubo

- Did I have a "heart attack"?
  No. Strictly speaking, the term "heart attack" indicates heart muscle injury due to a blocked coronary artery. The heart muscle injury in tako-tsubo cardiomyopathy is not caused by a blocked artery.
- Who is at risk?
  For reasons unknown, women above age 50 y are much more susceptible to the tako-tsubo cardiomyopathy. Traditional risk factors for heart disease (smoking, diabetes, high blood pressure, high cholesterol) do not apply to tako-tsubo.
- Will this happen to me again after future stressful events?
  Probably not. Fully 95% of patients do not have a recurrence and endure a variety of stressful events without harm to the heart.
- Is there something "wrong" with my ability to deal with stress?
  Current evidence suggests that tako-tsubo cardiomyopathy is a reflex response controlled by the autonomic nervous system.
- Can this affect my family members?
  There is no current evidence to suggest a familial inheritance of tako-tsubo cardiomyopathy.
- Will my heart be strong in the future?
  Long-term follow-up of patients suggests no deterioration of heart muscle strength after a tako-tsubo event.

Circulation 2011;124:e460-e462.

TAKOTSUBO (STRESS) CARDIOMYOPATHY*

Nearly 72% of patients with TCM had an identifiable trigger, including physical triggers (36%), emotional triggers (28%), or both (18%). Signs/symptoms mimic AMI.



Pathophysiology: TCM is a reflex response, controlled by the ANS, which may be due to catecholamine excess and/or direct neural innervation originating in the brain stem. Women > 50 years appear to be particularly susceptible (only 10 % in men).

*Templin C et al. N Eng J Med 2015;373:929-938
*Sachdeva J et al. J Am Heart Assoc 2014;3:e000921

Outline

Topic 3

- Physical Stress
- Psychological Stress
- Chemical Stress
- Sleep Deprivation, Acute Infection, and Dangerous Days

Triggering Myocardial Infarction by Marijuana

Murray A. Mittleman, MD, DrPH; Rebecca A. Lewis; Malcolm Maclure, ScD; Jane B. Sherwood, RN; James E. Muller, MD

The risk of myocardial infarction onset was elevated 4.8 times over baseline (95% CI, 2.4 to 9.5) in the 60 minutes after marijuana use.

Conclusions—Smoking marijuana is a rare trigger of acute myocardial infarction. Understanding the mechanism through which marijuana causes infarction may provide insight into the triggering of myocardial infarction by this and other, more common stressors. (*Circulation*. 2001;103:2805-2809.)

Key Words: cannabis ■ myocardial infarction ■ epidemiology ■ cross-over studies

Triggering of Myocardial Infarction by Cocaine

Murray A. Mittleman, MD, DrPH; David Mintzer; Malcolm Maclure, ScD; Geoffrey H. Tofler, MB; Jane B. Sherwood, RN; James E. Muller, MD

The risk of myocardial infarction onset was elevated 23.7 times over baseline (95% CI 8.5 to 66.3) in the 60 minutes after cocaine use.

in patients who are otherwise at relatively low risk. This finding suggests that studying the pathophysiological changes produced by cocaine may provide insights into the mechanisms by which myocardial infarction is triggered by other stressors. (*Circulation*. 1999;99:2737-2741.)

Key Words: cocaine ■ myocardial infarction ■ epidemiology

AHA Scientific Statement

Particulate Matter Air Pollution and Cardiovascular Disease

An Update to the Scientific Statement From the American Heart Association

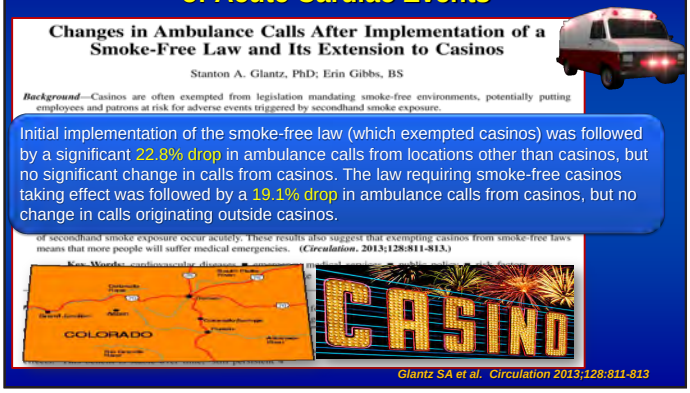
It is the opinion of the writing group that the overall evidence is consistent with a casual relationship between $PM_{2.5}$ exposure and cardiovascular morbidity and mortality.

associated with decreases in cardiovascular mortality within a time frame as short as a few years; and many credible pathological mechanisms have been elucidated that lend biological plausibility to these findings. It is the opinion of the writing group that the overall evidence is consistent with a causal relationship between $PM_{2.5}$ exposure and cardiovascular morbidity and mortality. This body of evidence has grown and been strengthened substantially since the first American Heart Association scientific statement was published. Finally, $PM_{2.5}$ exposure is deemed a modifiable factor that contributes to cardiovascular morbidity and mortality. (*Circulation*. 2010;121:2331-2378.)

Key Words: AHA Scientific Statements ■ atherosclerosis ■ epidemiology ■ prevention ■ air pollution ■ public policy

Circulation 2010;121:2331-2378

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

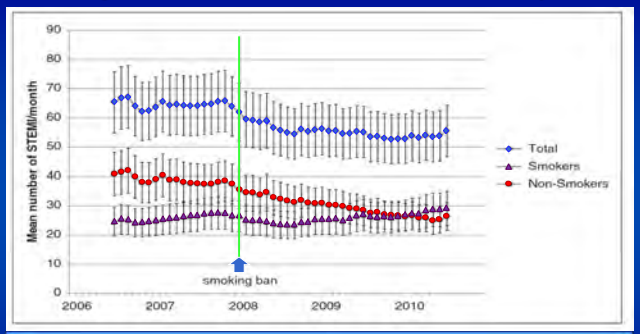
Background—Casinos are often exempted from legislation mandating smoke-free environments, potentially putting employees and patrons at risk for adverse events triggered by secondhand smoke exposure.

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.

of secondhand smoke exposure occur acutely. These results also suggest that exempting casinos from smoke-free laws 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

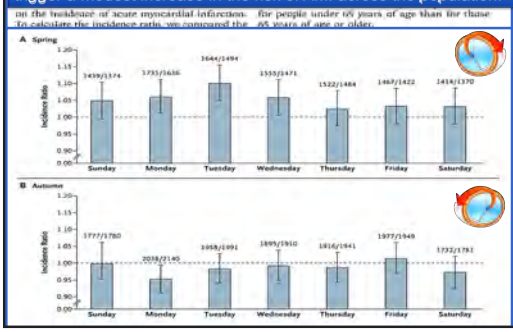
Outline

Topic 4

- Physical Stress
- Psychological Stress
- Chemical Stress
- Sleep Deprivation, Acute Infection, Weather Conditions,Dangerous Days

Shifts to and from Daylight Saving Time and Incidence of Myocardial Infarction

In the days after we "spring forward" for daylight savings time there is a spike in AMIs. These data, and other recent reports+, suggest that losing just one hour of sleep may trigger a modest increase in the risk of AMI across the population.



NEJM 2008; +Sleep Med 2012; Inter Emerg Med 2018; Eur Rev Med Pharmacol 2018

ORIGINAL ARTICLE

Risk of Myocardial Infarction and Stroke after Acute Infection or Vaccination

Liam Smeeth, Ph.D., Sara L. Thomas, Ph.D., Andrew J. Hall, Ph.D., Richard Hubbard, D.M., Paddy Farrington, Ph.D., and Patrick Vallance, M.D.

Our findings provide support for the concept that acute infections are associated with a transient increase in the risk of vascular events. By contrast, influenza, tetanus, and pneumococcal vaccinations do not produce a detectable increase in the risk of vascular events.

dence interval, 2.81 to 3.62). The risks then gradually fell during the following weeks. The risks were raised significantly but to a lesser degree after a diagnosis of urinary tract infection. The findings for recurrent myocardial infarctions and stroke were similar to those for first events.

CONCLUSIONS

Our findings provide support for the concept that acute infections are associated with a transient increase in the risk of vascular events. By contrast, influenza, tetanus, and pneumococcal vaccinations do not produce a detectable increase in the risk of vascular events.

NEJM 2004;351:2611-8

Flu Shot Linked to Lower Heart Attack and Stroke Risk*

Acute infections are associated with a transient increase in the risk of vascular events. Researchers pooled data from 6 clinical trials involving > 6,700 people (mean age, 67 years). About one-third had known heart disease; the others did not.

RISK

Results: Those who got a flu vaccination were 36% less likely to suffer cardiovascular events during the following year than those who weren't vaccinated. And for those who recently had a heart attack or stroke, a flu shot cut the risk by 55%!

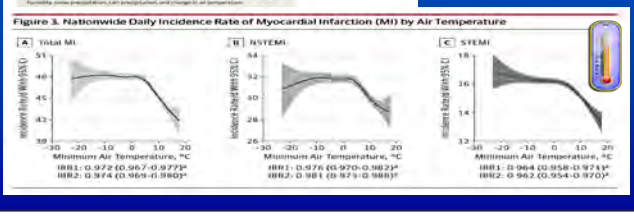
** Udell J et al. JAMA 2013*

Mohammad MA et al.
JAMA Cardio.2018.3466
Published online October 24, 2018.

Association of Weather With Day-to-Day Incidence of Myocardial Infarction
A SWEDEHEART Nationwide Observational Study

Objective: To determine if weather is associated with day-to-day incidence of MI

Results: In 274,029 patients, mean (SD) age was 71.7 (12) years. Incidence of MI increased with lower air temperature, higher wind velocity, and shorter sunshine duration. The most pronounced association was observed for air temperature, where a 1-SD increase in air temperature (7.4º C) was associated with a 2.8% reduction in risk of MI .



Weekly Frequency of Acute Cardiovascular Events?*

Cardiovascular events occur least frequently on Sundays (when most people are not working) and occur with 33% increased relative risk on Mondays in working people.

Schwartz BG et al. Am J Cardiol 2015;116:1290

SWEDEHEART: Observational Study*

283,014 cases of myocardial infarction (MI) reported in Sweden between 1998 and 2013.

Methodology: Evaluate the risk of MI during national holidays, sports events, and various time periods, using data on date and time of symptom onset , in a large nationwide setting with 16 years of data on MI.

* Mohammed M et al. BMJ 2018;363:K4811*

Most Dangerous "Day of the Year" for Heart Attacks?*

On average, Swedes suffered 50 heart attacks per day during the control or baseline period, versus 69 on December 24th – 37% higher on Christmas Eve. In addition, myocardial infarctions peaked that day at around 10 pm. The risk was highest in patients aged ≥ 75, patients with diabetes, and those with a history of CAD, suggesting a role of external triggers in vulnerable patients.

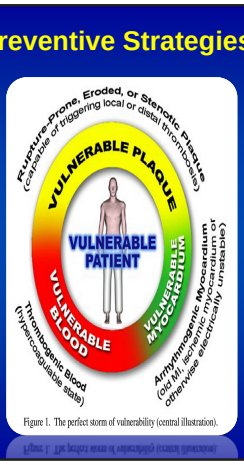
* Mohammed M et al. BMJ 2018;363:K4811*

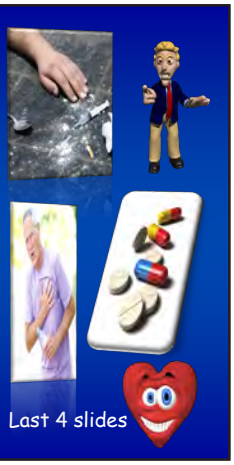
Possible Triggers of MI on Christmas Eve?*

- Excessive food intake
- Increased alcohol consumption
- Long distance travel
- Heavy physical exertion (e.g., packages, snow removal)
- Psychological stressors: anger, anxiety, sadness, grief, stress, coping with bereavement
- Cold temperatures

* Mohammed M et al. BMJ 2018;363:K4811*

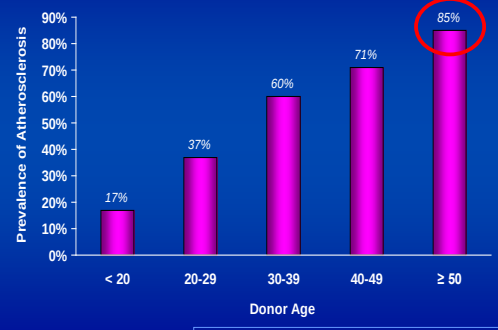
Conclusion: Preventive Strategies





Last 4 slides

IVUS Prevalence of Atherosclerosis by Age: Implications for Prevention?



Tuzcu EM, et al. Circulation 2001; 103: 2705-2710.

Critical Question: Do You Have Coronary Artery Disease?

"Cleveland Clinic studies (using IVUS) show that ~85% of individuals in the U.S. over 50 have atherosclerotic CAD. So for me, the question isn't whether middle-aged and older adults have heart disease – they probably do. It's how to prevent acute catastrophic cardiac events."

Ira M. Grais, MD

Strategies to Potentially Prevent Triggered Acute Cardiac Events: Counseling Implications*

- Chronic moderate-to-vigorous exercise (subjecting the body to regular increases in heart rate and metabolism) – called ischemic preconditioning
- Taking prescribed cardioprotective medications may reduce the risk of some ASCVD events and/or link between triggers and their potential pathophysiologic consequences (ie, BB & AMIs)
- Avoid prolonged periods of sleep deprivation, illicit drug use (e.g., marijuana, cocaine), as well as varied high caffeine stimulants (e.g., energy drinks)

**Franklin BA et al. Phys Sportsmed 2011;39:11-21*

Strategies to Potentially Prevent Triggered Acute Cardiac Events: Counseling Implications*

- Embrace mental stress-reducing exercises and anger-management strategies
- Counseling unfit, habitually sedentary patients with known or suspected CVD to avoid unaccustomed heavy physical exertion and high-risk activities (e.g., racquetball, snow removal)
- Strict enforcement of environmental regulations regarding air pollution; limit outdoor activities when pollution levels are high

**Franklin BA et al. Phys Sportsmed 2011;39:11-21*

Thank You

SELF EVALUATION

Acute Cardiac Event Triggers and Novel Preventive Strategies

1. According to the INTERHEART Study, heavy physical exertion and anger/emotional upset serve as triggers for acute myocardial infarction in approximately ___% of all cases.

a. 9
b. 19
c. 29
d. 39
e. 50

2. Patients at greatest risk for cardiovascular events following non-cardiac surgery were:

a. Unfit
b. Obese
c. Cigarette smokers
d. Afflicted with chronic diseases
e. All the above

3. Intense grief in the days after the death of a significant person in one's life may trigger the onset of acute myocardial infarction. According to one study, the incidence rate of acute myocardial infarction was elevated ___-fold within 24 hours of the death of a significant person and declined steadily on each subsequent day.

a. 11
b. 21
c. 31
d. 41
e. None of the above

4. According to a classic, widely cited report, the risk of heart attack was elevated ___ times over baseline in the 60 minutes after marijuana use.

a. 5
b. 10
c. 15
d. 20
e. 24

5. T/F - Smoking bans appear to significantly reduce the incidence of acute cardiac events and the effect appears most pronounced in non-smokers.

6. T/F - In the days after we "spring forward" for daylight savings time there is a decrease in the incidence of acute myocardial infarctions.

7. T/F - The most dangerous day of the year for heart attacks is Christmas Eve.

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

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Effective Time Management: Challenges and Strategies

Managing multiple responsibilities and time lines in a time-effective and time-efficient way can be challenging for helping professionals. Even if you happen to be a reasonably good manager of time, it can be especially difficult to address barriers that can potentially sabotage your achieving critical personal and professional goals. These barriers include: procrastination, managing various types of correspondence and data, having to balance multiple roles and responsibilities, answering to more than one boss or supervisor and having difficulty prioritizing and delegating tasks.

This program is designed to assist helping professionals develop specific skill sets that are essential in managing time and multiple tasks successfully. As a result of completing this course, participants will be able to:

1. Assess their current level of skill in managing time and multiple priorities;
2. Reduce/eliminate chronic procrastination and other barriers to managing time effectively;
3. Reduce unnecessary stress and anxiety associated with managing multiple tasks and deadlines;
4. Set realistic, action-oriented goals;
5. Delegate tasks more effectively; and
6. Negotiate multiple tasks and deadlines when answering to multiple bosses or supervisors.

I. Introduction

A. How well do you think you manage your time? (see inventory, Handout A.)

B. Are you a procrastinator?
   e.g., Do you often wait until the last minute to start a project?
   e.g., Do you often put off making a decision about something?
   e.g., Do you find that you miss deadlines at work?

C. Time management is a skill which can be learned; it will take work and practice to overcome the old habits.

II. A Major Problem: Procrastination

A. Reasons we procrastinate: (Refer to Handout B)

B. Addressing procrastination strategically (Refer to Handout B)

III. Another Major Problem: Interruptions

A. Most interruptions come about because the priorities of someone else come into conflict with what you have planned.

B. How to manage:
   1. Setting limits is critical.
   2. Don't prolong a conversation or do anything to extend an interruption.
   3. Plan for the fact that there will be interruptions and anticipate how you will deal with them, e.g., using voicemail to screen calls.
   4. Don't use interruptions as an excuse to avoid your work; this fuels procrastination.
   5. Don't encourage unnecessary telephone calls from family and friends.
   6. Don't start another project before you finish the first one. When you have too much going on at once, you interrupt yourself mentally by focusing on the wrong project at the wrong time.
   7. Don't procrastinate. Once you have the time, use it wisely.
   8. Set aside blocks of time each day to "delete" or respond to emails. Do not check emails multiple times a day; this will create unnecessary stress and may prevent you from completing more important tasks.
   9. Be assertive with your superiors about what you can reasonably accomplish if they are going to interrupt you throughout the day. Constant interruptions undermine forward momentum with any project; they also increase the likelihood of errors and missed deadlines.

10. Be realistic with yourself. "Guesstimate" how long it will take you to complete a project and then double that estimate. This estimate of extra time required will allow for interruptions.
11. Reward yourself for managing interruptions; reward others for respecting your limits and boundaries.

IV. Learn to handle correspondence…

A. Emails out:
   1. Brief, to-the-point; excellent grammar/spelling
   2. Refrain from using all "CAPS"; this implies anger; strong emotions, such as anger, should not be expressed in an email.
   3. Would it be more efficient to just call this person and have a short telephone conversation?

B. Emails in:
   1. Set aside blocks of time at beginning or end of each day to attend to these.
   2. "Delete" as many as possible.
   3. Prioritize those which require an immediate response.
   4. Delay responding to other emails that require greater thought/preparation and that are not urgent.

C. Learn how to handle paper correspondence:
   1. Sort all incoming paper:
      a. To-do file
      b. To-file file
      c. Trash/to be shredded file
   2. Set aside a block of time each day to handle current business.
   3. Develop a personal filing system for paper that you will need to retrieve.
      a. Label file with the broadest possible category (e.g., certificates, reports, job descriptions, etc.)
      b. Arrange strictly alphabetically
      c. Avoid a miscellaneous file
      d. If you think that you might possibly need the item someday, that's a clue that you should not throw it away
   4. Create electronic files for email correspondence using same guidelines as above.

V. Time Management: Additional Pointers/Strategies:

A. Ways of gaining extra time
   1. Do the job more efficiently in less time than usual.
   2. Use small blocks of time that you normally waste.

B. Values of time scheduling
   1. You waste less time; have more free time.
   2. Scheduling priorities in advance frees the mind.
   3. Gets you started; provides direction and focus
   4. Prevents avoidance of disliked tasks
   5. Monitors slacking off process
   6. Eliminates cramming; goal-achieving vs. tension-relieving
   7. You don't overlook recreation.
   8. Regulates daily living; keeps crises to a minimum
   9. Will help you advance within an organization

C. How to make a time schedule
   1. Eliminate dead hours – make each unit productive.
   2. Use daylight hours for difficult mental tasks.
   3. List according to priorities.
   4. Do not over-organize.
   5. Know your sleep pattern and natural cycles.
   6. Discover how long it takes to complete a given task and then schedule accordingly.
   7. Plan in blocks of time – 50 minute work, 10 minute break.
   8. Allow plenty of time for sleep, meals, recreation.

D. Types of schedules
   e.g., weekly, daily

E. Use of reward in time management
   e.g., give yourself a special "treat" when you complete an especially difficult task.

VI. Special Tips for the Chronically Late:

A. Put yourself on a tight and consistent schedule; routines soon become second nature and make it easier to get moving and get things done.

B. Have a clock in every room – even the bathroom.

C. Set the clock 10 minutes ahead.

D. In your calendar, mark your appointments a little earlier than they really are.

E. Use timer to limit phone calls or to time how long it takes to complete a given task.

F. Double estimate of time for travel to account for traffic delays.

VII. Reducing unnecessary stress/anxiety

A. We create stress/anxiety through:
   1. Worrying about situations we have little or no control over
   2. Perfectionism, i.e., expecting too much of ourselves or others
   3. Competition, i.e., turning every encounter into a win-lose situation
   4. Self-criticism, i.e., you focus inordinately on real or perceived faults and do not acknowledge your strengths
   5. Insecurity, e.g., looking to others for something that must come from within
   6. Unverifiable assumptions about how others feel and what they want from you
   7. Powerlessness, e.g., failing to see the choices that are available
   8. Hurrying, e.g., constantly pushing yourself to perform better and faster
   9. Comparisons of your achievements, or lack of them, to those of others
   10. Pessimism, e.g., you expect failure or the worst from life
   11. Unrealistic expectations, e.g., that life should be easy or problem-free

B. Tips for reducing job-related stress:
   1. Take charge of your situation. To the extent possible, set and re-set priorities. Take care of important (and difficult) things first. Organize your time.
   2. Be realistic about what you CAN change. Don't doom yourself to frustration and failure. Do what's possible. Accept the rest.
   3. Take one step at a time. Divide each project into manageable steps. Decide on a first step. Do it. Feel better?
   4. Be honest with colleagues. This includes the boss. Make it plain you feel in a bind. Chances are others are feeling the same. Don't just complain. Be constructive and make practical suggestions for improvement.
   5. Let your employer help. Many companies help their employees deal with the effects of stress through diet, smoking and alcohol clinics, corporate fitness programs and personal counseling and employee assistance programs. Find out what's available to you.
   6. Slow down. Learn to say "no". Drop activities that are not crucial.
   7. Recognize danger signals. Learn the symptoms of job stress and take action as soon as they appear to be getting out of hand.
   8. Take care of your physical health. It increases your stress tolerance and stamina. Eat and sleep sensibly. Cut down on alcohol, tobacco and drugs. Get plenty of exercise.
   9. Learn to relax. Find a safety valve, whether it is a sport, hobby, music, reading or just walking. Use it to create a "bridge" between work and home life.
   10. Don't neglect your private life. Work out a schedule which allows you to do justice to both work and personal life. Stick to it.
   11. Share your stress – talk about your concerns with a colleague, friend or counselor.
   12. Know your limits – set realistic goals for yourself and others.
   13. Learn how to manage your time and priorities more effectively.
   14. Assess and address any job-related skill deficits, i.e., additional training and education.
   15. Limit major changes; avoid making too many major changes in your life at one time; allow for a period of adjustment for each major change.

VIII. Special Focus: Goal-Setting

A. Are measurable and realistic
B. Compatible with your mission/objective
C. Time specific
D. In writing (well-defined) and important
E. Ownership (commitment) and accountability
F. Negotiated (agreed-upon)

IX. Special Focus: Delegation Skills

A. Why we do not delegate:
   1. "I can do it better."
   2. "It's easier if I just do it."
   3. "I'm not sure I can trust this person to do the job well."
   4. "If they screw-up, it reflects badly on me."
   5. "It must be done perfectly."

B. Key guidelines for delegating effectively:
   1. Explain the task thoroughly and specifically.
   2. Define the purpose of the task.
   3. Give and get feedback about how to do the task.
   4. Give the delegates authority and responsibility.
   5. Do not hover/"micro-manage". Be methodical.
   6. Make the delegates accountable. Establish interim deadlines for accomplishments.
   7. Give positive and corrective feedback as needed.
   8. Recognition, recognition, recognition.

C. When you are the delegatee:
   1. Ask for resources.
   2. Seek out authority.
   3. Have regular meetings with the delegator to get feedback.
   4. Follow up with email clarifying your understanding of expectations.
   5. Find out what potential traps exist, e.g., does the delegator have a history of being inordinately controlling or critical?
   6. Say NO assertively to new tasks when you are already overloaded.

D. Answering to more than one boss:
   1. Clarify the priority of the task in comparison to other tasks assigned by different bosses.
   2. Encourage your bosses/supervisors to have conversations with each other when there is a conflict regarding each's priorities.
   3. Have regular meetings with each boss/supervisor.
   4. Put tasks on paper and diagram time lines for each task.
   5. Ask each boss/supervisor to give you more specific deadlines for each task.

X. Questions/Closure

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SELF EVALUATION

Effective Time Management: Challenges and Strategies

1. Which of the following are examples of procrastination?
   a. You wait until the last minute to start a project.
   b. You often put off making decisions.
   c. You have a tendency to miss deadlines at work.
   d. All of the above are examples of procrastination.

2. Which of the following is not a primary cause for procrastination?
   a. You are not perfectionistic and rarely have a fear of failure.
   b. You feel overwhelmed.
   c. You may overestimate the time required to complete a task, making the task seem more daunting.
   d. You really don't want to do the task in question and would rather be doing something else.

3. Which of the following reduces procrastination?
   a. Proceeding one-step-at-a-time is helpful.
   b. Learn how to prioritize tasks.
   c. Take a large task and break it down into smaller tasks.
   d. All of the above should reduce procrastination.

4. Which of the following is not true about managing interruptions?
   a. Most interruptions occur because the priorities of someone else come into conflict with what you have planned to do.
   b. Managing interruptions rarely involves setting limits or boundaries with others.
   c. You should not use interruptions to avoid your work; this fuels procrastination.
   d. It is better to complete one project before moving on to the next task.

5. Which of the following is recommended for handling outgoing emails?
   a. They should be brief, to-the-point and have excellent grammar, punctuation and spelling, e.g., no "run-on" sentences.
   b. Refrain from using all "CAPS"; this implies frustration, anger or other strong emotions; not appropriate for an email.
   c. Would it be faster, more efficient to call this person and have a brief telephone conversation?
   d. All of the above are recommendations for handling outgoing emails.

6. When dealing with in-coming emails:
   a. Set aside specific blocks of time at the beginning and end of each day to respond to these.
   b. "Delete" as many as possible.
   c. Prioritize those emails which require an immediate response.
   d. All of the above are true.
   e. Only "A" and "C" are true.

7. Which of the following strategies is not recommended when managing time?
   a. You can gain extra time if you can do a given job more efficiently in less time than usual.
   b. It is often helpful to use small blocks of time that you might normally waste.
   c. Use late afternoon or evening hours to tackle more difficult tasks.
   d. Allow plenty of time for sleep, meals and recreation.

8. If you tend to be chronically late for meetings and appointments:
   a. Set all of your clocks ten minutes ahead.
   b. On your calendar, record your appointments a little earlier than they are.
   c. Put yourself on a tight and consistent schedule.
   d. Double estimates of time for travel to account for traffic delays.
   e. All of the above strategies will reduce chronic lateness.

9. Professional caregivers can create unnecessary stress through which of the following?
   a. Perfectionism
   b. Excessive self-criticism
   c. Hurrying, i.e., constantly pushing yourself to perform better and faster
   d. All of the above

10. Which of the following is not a tip for reducing job-related stress?
   a. Learn how to relax.
   b. Do not worry about job-related skill deficits.
   c. Limit major changes.
   d. Be realistic about what you can change.

Answer Key: 1. D, 2. A, 3. D, 4. B, 5. D, 6. D, 7. C, 8. E, 9. D, 10. B

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You may contact Dr. Howell with your questions and comments at REMwalkers@gmail.com.

Introduction to Sleep and Circadian Rhythm Well Being

Contents

- Find a new motivation for healthy sleep
- Understanding and identifying your circadian rhythm
  - Adjusting your circadian rhythm
- What to do when you can't fall asleep
- Evidence based review on supplements for sleep and wakefulness
- Screening for sleep disorders across the day
- Become a good napper

Finding motivation that resonates

- Improving sleep often takes behavioral change.
- Benefits of sleep on:
  - The Brain
  - Cardiovascular health
  - Weight Management
  - Immune Health
  - Athletic, Professional and Artistic Performance

Better sleep and the brain

- Vigilance and alertness
  - Improve safety
  - Fewer accidents
- Mood and temper
  - Decrease depression
  - Decreased suicidal ideation
- Anxiety
  - Decreased anxiety and more manageable phobias

(Olaithe et al 2018, de Zambotti et al 2018, Steel et al 2018)

Better sleep and the brain

- Substance abuse
  - Helps those trying to modify substance use and abuse
- Glymphatic clearance
  - Removes toxic metabolic by products.
  - Relationship to Alzheimer's disease and concussion pathology
- Chronic pain
  - Decreases the likelihood of developing chronic pain
  - Lessens pain burden for those already in chronic pain

(Finan et al 2013, Sun et al 2019, Cordone et al 2019)

Better sleep and cardiovascular health

- Coronary artery disease
  - Fewer heart attacks
- Heart function
  - Improved cardiac performance
- Heart rhythm
  - Decreased cardiac arrhythmia's
- Cerebral artery disease
  - Fewer Strokes

(McDermott et al 2018, Kwon et al 2018)

Better sleep and weight management

- Appetite
  - Decreased hunger
  - Increased satiety
- Thermogenesis
  - Increased capacity and motivation for exercise
  - Increased NEAT: Non-Exercise Activity Thermogenesis
- Nutrition choices
  - Improved selection of healthy foods

(Sun et al 2019, Zhu et al 2019)

Better sleep and the immune system

- Pathogens
  - Decreases infections
  - Shortens response time
- Malignancy
  - Improve immune surveillance
- Vaccination Response
  - Promotes stronger immune response

(Faraut et al 2012)

Better sleep and performance

- Professional
  - Decreased burnout for health care providers
  - Better interpersonal interactions
  - More creativity and better problem solving
- Athletic
  - Faster reaction times
  - Fewer errors
  - Greater accuracy

(Mah et al 2011, Benton et al 2013, Stewart et al 2019)

Circadian Rhythm

- Your bodies 24-hour biological clock.
- Ubiquitous through out nature
- Cellular genetic machinery operates in 24 hour DNA-RNA-Protein feedback loop.
- Controlled by the suprachiasmatic nucleus in the hypothalamus
- A primary determinant of the wake-sleep cycle

Circadian Rhythm diversity

- Circadian rhythms exist upon a diverse range.
  - Early Birds-Circadian Advance
  - Night Owls-Circadian Delay
- Circadian diversity can be clearly advantageous for a population.
- Conversely, circadian diversity can be a challenge when work, school and social life misaligns with inherited trait.

Circadian Rhythm disorders

- When environment and lifestyle are misaligned with intrinsic biological clock.
  - Jet Lag
  - Social Jet Lag
- Circadian Rhythm disorders commonly present as sleep problems.
  - Circadian Rhythm Delay
  - Circadian Rhythm Advance

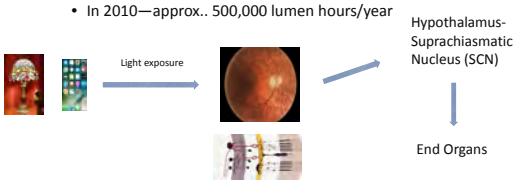
Circadian Rhythm disorder Delay

- Difficulty initiating sleep.
  - Often misdiagnosed as an Insomniac
- Difficulty waking up the AM.
  - Often misdiagnosed as a narcoleptic or related disorder of hypersomnia.

(Culnan et al 2019)

Circadian Rhythm Delay

- Common especially among adolescents and young adults.
- Related to the brains response to evening light exposure.
  - In large part a modern disorder.
    - In 1700—approx. 500 lumen hours/year
    - In 2010—approx.. 500,000 lumen hours/year



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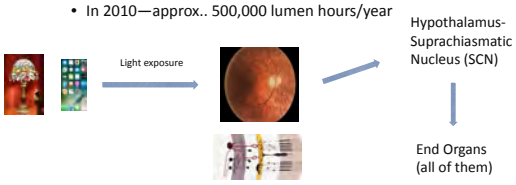


Treatment-Circadian Rhythm Delay

- Avoid sleeping pills and avoid daytime stimulants
- Morning
  - Sunlight or a 10,000 lux light box
  - Use at a consistent time (7 days a week) for 30—120 minutes
- Evening
  - Melatonin 0.5-1.0mg po 3-4 hours before bedtime.
  - Dim screens and use blue light blocking software
- Be mindful of meal timing

(Culnan et al 2019)

Circadian Rhythm Advance

- Difficulty staying awake in the evening.
  - Falling asleep socially.
  - Troubles at movies, plays, dinner parties
- Difficulty waking up early and not being able to fall back asleep.
  - May lay in bed for several hours before getting up for the day.

(Culnan et al 2019)

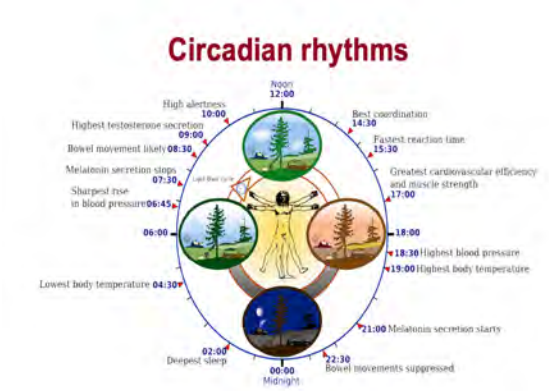
Treatment-Circadian Rhythm Advance

- Avoid evening stimulants and middle of the night sleeping pills
- Evening
  - Sunlight or a 10,000 lux light box
  - Use at a consistent time (7 days a week) for 30—120 minutes
- Morning
  - Melatonin 0.5-1.0mg po during an early morning (for example 2AM) wakeup.
- Be mindful of meal timing

(Culnan et al 2019)

Circadian Rhythm Disorders-Challenging

- Persistent sleep wake disorders resistant to conventional sleeping medications.
- More then just sleep and wake problems.
  - Appetite and weight management problems
  - Gut Motility issues
  - Difficulty concentrating for work/school
  - Hormonal disruption



(Zaki et al 2019)

Insomnia-The experience

- Laying awake in a dark room trying to sleep
  - Frustrating
  - Ruminating thoughts
  - Non-stressful upcoming events become anxiety provoking
- The harder you try to sleep the more elusive sleep becomes.

Insomnia Etiology-a conditioned response

- Trying to sleep becomes an insomnia trap
  - Despite feeling tired the act of climbing into bed is an alerting not sedating response. Psychophysiological Insomnia develops as a conditioned response.
- Feel tired and sleepy outside of the bedroom
  - Alert once an insomniac climb into bed.
  - May sleep better in hotel's and out of the typical sleeping environment.
- Daytime consequences
  - Hypervigilance
  - CNS hypermetabolism

(Mitchel et al 2019)

First step in insomnia treatment:

- **Primum non nocere** – First do no harm
- Stop promoting the adverse conditioned response
  - Stop lying in bed when not sleeping
  - The bedroom should be reserved for sleeping and sexual activity.
- Often requires difficult behavioral change
  - Patient often see recommendations as paradoxical

(Mitchel et al 2019)

Insomnia Treatment-Cognitive Behavioral Therapy

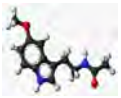
- Cognitive Behavioral Therapy for Insomnia
  - Using Stimulus control, bedroom restriction and mindfulness you gradually decrease the adverse (wakeful) conditioning and promote positive (soporific) conditioning to the bedroom environment.
- Usually administered by a licensed psychologist
  - Unique skill set from practitioners in other forms of CBT
  - Also available with evidence-based online programs.
- Very compelling evidence
  - Most effective strategy to cure insomnia.
- The two rules:
  - Get out of bed if you are not sleeping
  - Don't fall asleep outside of the bedroom.

(Mitchel et al 2019)

Supplements for sleep and wakefulness

- Melatonin
- Iron
- Vitamin D

Melatonin



- Endogenous compound released from the pineal gland
  - Located at the base of the brain
- Molecular signal of darkness.
  - Ganglion Cell Layer in retina → Suprachiasmatic nucleus → Pineal Gland → Melatonin secreted into vascular bed.

Melatonin-most important point

Melatonin is a circadian agent not a sleeping agent

Melatonin-evidenced based use

- For Circadian Disorders
  - Circadian Rhythm Delay
    - Small dose (0.5mg) 4-6 hours before bedtime
  - Circadian Rhythm Advance
    - Small dose (0.5mg) during middle of the night awakening
  - Jet Lag Disorder
    - Small dose (0.5mg) taken 1-2 hour before new bedtime.
    - If possible begin 2-3 days prior to departure.

(Culnan et al 2019)

Melatonin-setting expectations

- Lower expectations that the treatment will immediately be effective.
- Increase expectations that treatment will be effective over days to weeks.
  - Especially when used in combination with light therapy.
    - Circadian Rhythm Delay-AM Light
    - Circadian Rhythm Advance-PM Light
    - Jet Lag Disorder-Light at time of desired destination wake up time.

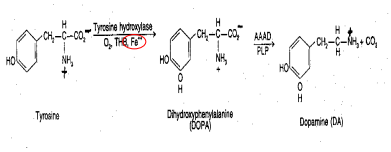
(Culnan et al 2019)

Melatonin-Use in other disorders

- Most effective when used in setting of conditions that affect circadian rhythms.
- Neurodegeneration-Alzheimer's and Parkinson's disease
  - Breakdown in the night-day cycle is the strongest predictor of institutionalization.
- Circadian Strategy in Neurodegeneration
  - Address early
  - Small Doses 0.5mg 1 hour before desired bedtime.
  - Combine with morning light therapy.

(Videnovic et al 2015)

Iron



- Co-factor in the tyrosine hydroxylase
  - Rate limiting step in the production of CNS dopamine
  - In addition to its essential role in Red Blood Cells
- CNS dopamine deficiency a primary cause of restlessness.
  - Common in young healthy women.
    - Vegans/Vegetarians at higher risk.
    - Pregnancy exacerbates relative iron deficiency

Iron and restlessness

- Common reason for trouble falling asleep
- Often difficulty for patients to describe the discomfort
  - Discomfort causes an urge to move
  - Movement relieves the urge (although often only momentarily)
  - Worsens at night thus interferes with sleep
- Frequently the presenting complaint is often only "I cant fall asleep"

(Avni et al 2019)

Iron

- Difficult to measure
  - CNS iron stores v. serum iron
- Serum ferritin is the most readily available marker
  - However hospital labs base low thresholds for iron deficiency anemia not for health CNS iron stores.
    - Low normal values are often listed at 10mcg/l.
    - More appropriate low value would be 50mcg/l.
    - Sleep medicine consensus is even higher at 75mcg/l.

(Allen et al 2018, Avni et al 2019)

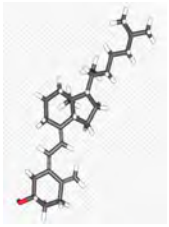
Iron-supplementation

- Oral supplementation is challenging
  - Poor intestinal absorption of elemental iron
  - GI side effects.
- Increased absorption with iron gluconate formulation.
  - Recommend 325mg
  - Absorption improved when combined with 100mg Vitamin C.
- IV Iron replacement an option
  - Ferric carboxymaltose

(Avni et al 2019)

Vitamin D

- Collection of fat-soluble hormones
  - Diet
  - UV exposed skin
- DNA transcription Effects
  - Mineralization
  - Inflammation
  - Immune function
  - Muscle tissue



(McCarty et al 2014)

Vitamin D-severe deficiency

- Demineralization
  - Osteomalacia
  - Rickets
- Myopathy
- Hyperparathyroidism

(McCarty et al 2014)

Vitamin D deficiency and the immune system

- Low levels promote Th-1 over Th-2 immunity
  - Pro-inflammatory
  - TNF-alpha promotes tissue destruction
- Upper airway inflammation
  - Asthma
  - Allergic Rhinitis
- Possible increased risk for autoimmune disorders
  - Multiple Sclerosis
  - Rheumatoid Arthritis
- Increased infection risk

(McCarty et al 2014)

Vitamin D deficiency and sleep disorders

- Promote obstructive sleep apnea
  - Due to
    - tonsillar hypertrophy
    - rhinitis
    - upper airway myopathy
    - Independently promotes cardiovascular disease
- Excessive daytime sleepiness
  - Small studies suggest vitamin D replacement can address hypersomnia in some cases.

(McCarty et al 2014)

Vitamin D

- Measuring Vitamin D
  - Conventional definition of deficiency <20ng/ml
  - Based primarily upon rickets demineralization data
- Limitations on single point testing
  - Variations by season and uncertain durations
- Dosing recommendations (primarily based upon consensus)
  - < 12 ng/ml=50,000 IU for 8 weeks
  - 12-20ng=5,000 IU
  - 20-30ng/ml=3,000 IU
  - 30-40ng/ml=1,000 IU

(McCarty et al 2014)

In the morning and during the day

- When you wake up in the morning
  - You should feel like you are done sleeping.
  - Could not sleep in longer even if you tried
  - Should feel hungry within an hour
- During the day
  - You should feel alert even when sedentary and without caffeine or other stimulant
    - Exception: afternoon nap time

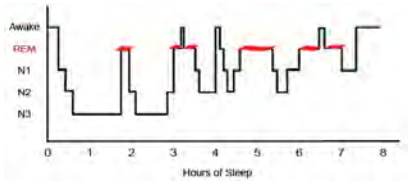
In the evening

- Should feel alert after dinner
  - Able to stay awake even during passive activities
    - Watching a show or sporting event
    - Reading
- In the hour leading up to sleep
  - Should feel progressively sleepy
- Climbing into bed
  - Should feel comfortable
  - Should feel somnolent

At night-breathing

- Watch for snoring
  - Labored breathing
    - Gasping
  - Apneas
    - May be silent

Sleep Cycle



At night-behaviors

- Normal to wake up intermittently at night
  - Abnormal to wake up and not be able to fall back asleep
- Amnestic behaviors
  - Sleepwalking
  - Sleep eating
- Dream enactment
  - Common-1% general population; 5% in the elderly
  - Potentially injurious and can be a prodromal syndrome for Parkinson's disease

Become a good napper

How do you know if you are a bad napper?

Nap drunkenness

- Occurs when napping brain is trying to fall asleep for the "night"
- Occurs when naps are
  - Out of timing
  - Out of duration
  - Out of practice
- Untreated sleep disorder
  - Sleep deprived

Nap timing and duration

- Circadian Rhythm of Naps
  - Varies person to person
  - 12 hours from midpoint of natural sleep rhythm
- Duration
  - 10-20 minutes
    - Stages N1 and N2 Sleep (light NREM sleep)
    - Power Nap
  - 70-90 minutes
    - Stages N1, N2, N3 (Light and Deep NREM sleep), R (REM sleep)

Power napping routine

- Identify and practice during ideal nap timing
- Don't lay down or cover yourself
  - Drop in body temperature (0.5C) during N1 and N2 will act as a snooze alarm.
- Practice, Practice, Practice

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SELF EVALUATION

Introduction to Sleep and Circadian Rhythm Well Being

1. Iron is a critical cofactor for the metabolism of which neurotransmitter?

a. Dopamine
b. Acetyl choline
c. Gaba
d. All of the above
e. Non-of the above

2. Vitamin D Deficiency can promote obstructive sleep apnea through the following pathway(s)

a. Tonsillar hypertrophy
b. Upper airway myopathy
c. Rhinitis
d. All of the above
e. Non-of the above

3. A person with a Circadian Rhythm Advance…

a. Will have difficulty falling asleep at night
b. Will wake up several hours early and have trouble falling aback asleep.
c. Will sleep in late into the morning when given the opportunity (weekends, vacation)
d. Non-of the above
e. All of the above

4. Improved sleep can...

a. Decrease suicidal ideation
b. Decrease the likelihood of developing chronic pain
c. Decrease pain burden for those already in chronic pain.
d. Non-of the above
e. All of the above

5. Waking up extra early in the morning is helpful for those trying to lose weight because…

a. They will get exercise and burn more calories
b. Establishes the discipline to limit caloric intake.
c. They will make better food choices.
d. Non-of the above
e. All of the above.

6. The following strategy(s) have been demonstrated to be effective in treating a Circadian Rhythm Delay.

a. 10,000 lux light box for 60 minutes at the same time in the morning.
b. 10,000 lux light box for 60 minutes when ever an individual wakes up in the morning.
c. 10,000 lux light box for 60 minutes in the evening
d. Melatonin 0.5 mg at bedtime.
e. All of the above

7. The following strategy(s) have been demonstrated to be effective in helping people with insomnia fall asleep.

a. An evening bath and chamomile tea.
b. Evening exercise
c. Bedroom restriction
d. Take afternoon naps
e. Non-of the above

8. Evening melatonin is effective for people with

a. A Circadian Rhythm Advance
b. A Circadian Rhythm Delay
c. Hypervigilant Insomnia
d. Restless Legs Syndrome
e. All of the above

9. Napping…

a. In an adult is indicative of excessive daytime sleepiness
b. In a child is Indicative of excessive daytime sleepiness
c. Is a normal human physiological need across the lifespan
d. Is to be avoided if a person has to perform (such as an athlete) in the evening.

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

Kathy Gaughan

Kathy Gaughan of Irvine, California is Senior Marketing Strategist at Healthcare Success Strategies, a data driven healthcare marketing company. She has over 25 years experience in healthcare marketing having personally consulted with over 7,000 clients and created thousands of strategic plans for clients in myriad medical and institutional clients. Kathy has authored numerous articles in her field and has spoken to hundreds of audiences across the country.

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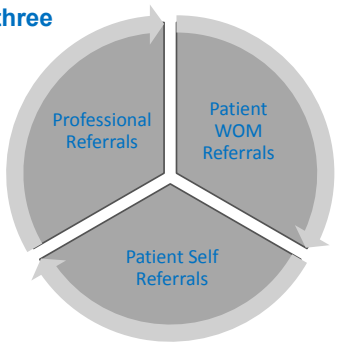
HEALTHCARE SUCCESS®
Scientific Marketing That Delivers Patients

Building Physician and Patient Referral Relationships

Kathy Gaughan

Diversify New Patient Paths – Three Primary Points of Entry

Leverage all three



Diversify New Patient Paths – Points of Entry

Developing a strong referral network is critical to ensuring the success of your medical practice. In order to grow your medical practice's revenue, it is important to attract new patients consistently. In addition to advertising and connecting with insurance agencies, establishing a reliable referral network is an excellent way to bring in new business.

Marketing to doctors for referrals works to build connections among healthcare offices to provide the best care for all of your patients. The majority of doctors in practices of every size recognize the importance of referrals in building a sustainable practice. In one survey, 78% of physicians ranked doctor-to-doctor referrals as very or extremely important. For specialists, that number jumps to 87%.

Specialist and PCP – Think "Outside of the Box"

The Importance of a GREAT Patient Experience

- Enhancing patients' health care experiences means more than just providing top-notch clinical care. It requires care that addresses every aspect of the patients' encounters at the clinic – their physical comfort, their understanding of what's happening and their emotional needs.
- A better patient experience results in improved clinical and business outcomes. As competition for patients increases, patients may make provider choices based not only on clinical outcomes, but also on whether their doctor or mental health clinician delivers compassionate patient-centered care.

Effective Patient Referral Tactics

Put Fear Behind You
Simply Ask for the Referral
Obtain and expression of satisfaction, then ask
Go Above and Beyond
Follow Up With Patient Ambassador Program
One Minute Messages Delivered Verbally
Internal Signage, Sales Collateral and Looping Video
Your Website Content – Tell the Story, Make Sure You are Easily Accessible
Make referring easy - KISS
Be Grateful
Reward referrals according to standards in your area

QUICK QUIZ

Which internal marketing strategy works incredibly well and costs *nothing* to implement, yet few do it even though most have heard they should?

Answer:

Ask patients for referrals

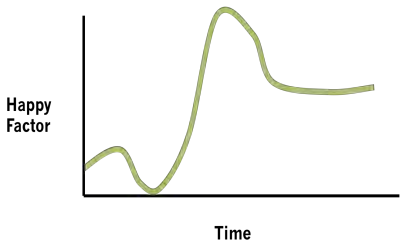
2860 Michelle Drive, Suite 230 • Irvine, CA 92606 • (800) 656-0907 • www.HealthcareSuccess.com

ASKING PATIENTS FOR REFERRALS

Things to remember:

- No cost = infinite ROI
- It works
- Doctors and staff can all participate
- Mark the patient chart with "AFR" code after they have been asked to refer
- Ask at the peak of their experience

ASK FOR REFERRALS AT THE PEAK OF THE PATIENT EXPERIENCE



ASK FOR REFERRAL SAMPLE SCRIPT

"Mrs. Smith, we think you are just terrific.

We would love to treat more patients like you in our practice.

If you know of anyone who can benefit from our care, please let them know about us and we promise to take good care of them"

CREATING PATIENT AMBASSADORS

Acknowledge all referrals with positive reinforcement

- Warm phone call
- Thank you note

Encourage frequent referrers to become "Health Ambassadors"

- Arm them with your marketing materials
- Make them feel special

PATIENT EMAILS

- Build opt-in email list
  - Intake forms
  - Incentives at front desk
- Promote specific services and ask for referrals
- Special offers
- Frequency varies
- Postal mail too for special cases

Think of your long-term content plan like a savings account.

SOURCE: PIXABAY

SOURCE: PIXABAY

If you make a plan and are consistent in approach, then you're giving yourself the best chance at achieving ROI from your content efforts.

PROMOTE KEY SERVICES IN BROCHURES

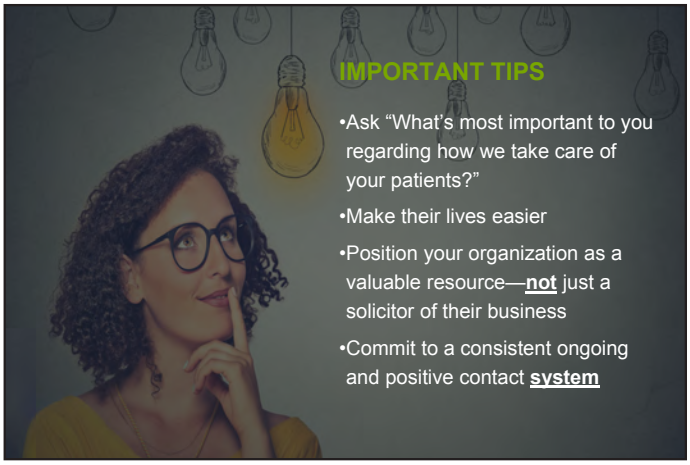
INTERNAL SIGNAGE

Effective Physician Referral Tactics

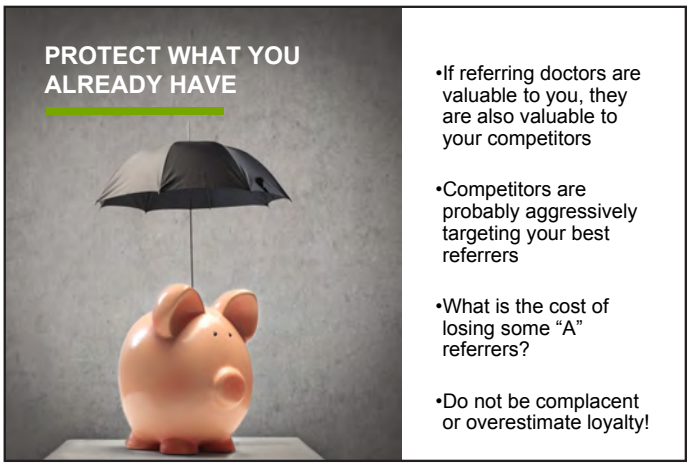
- Put fear behind you
- Introduce yourself to new physicians or providers in the area
- If you're the "newbie" meet your neighbors
- Be selective
- Go Above and Beyond
- Create and implement a digital doctor referral strategy
- Make it easy on referrers - KISS
- Be visible and easily accessible online and on the phone
- Use a customer relationship management (CRM) tool
- Follow up with referring doctor
- Meet the doctor
- Update promptly according their communication preferences
- Designate a referral ambassador
- Become a Contact
- Differs by specialty

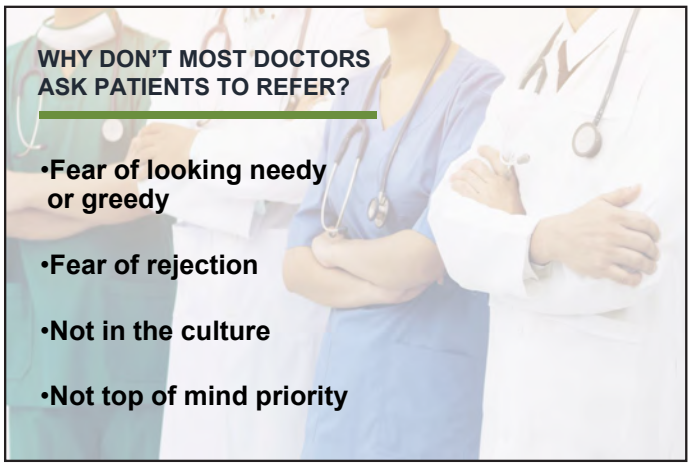
What professional referral sources want…

- **High quality care**
- **Prompt understandable reports**
- **Hassle-free interactions with your office**
- **Patients get in quickly and are treated well**
- **You take your fair share of tough cases**
- **Accept their insurances**
- **To deal with likable people**

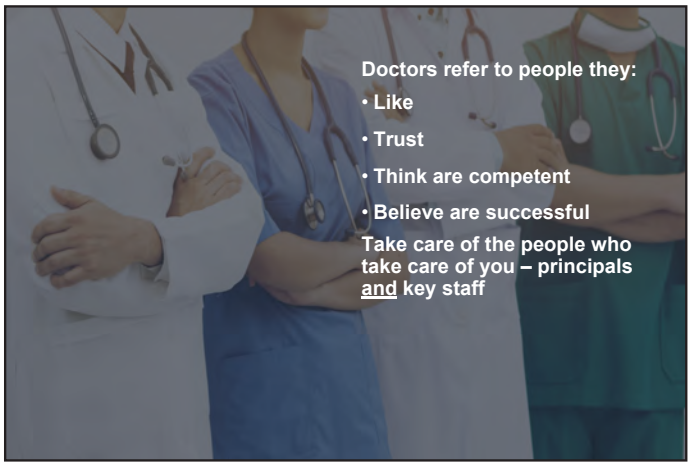

IMPORTANT TIPS
•Ask "What's most important to you regarding how we take care of your patients?"
•Make their lives easier
•Position your organization as a valuable resource—**not** just a solicitor of their business
•Commit to a consistent ongoing and positive contact **system**


PROTECT WHAT YOU ALREADY HAVE


PROTECT WHAT YOU ALREADY HAVE
•If referring doctors are valuable to you, they are also valuable to your competitors
•Competitors are probably aggressively targeting your best referrers
•What is the cost of losing some "A" referrers?
•Do not be complacent or overestimate loyalty!


WHY DON'T MOST DOCTORS ASK PATIENTS TO REFER?
•Fear of looking needy or greedy
•Fear of rejection
•Not in the culture
•Not top of mind priority


Doctor referrals are all about relationships

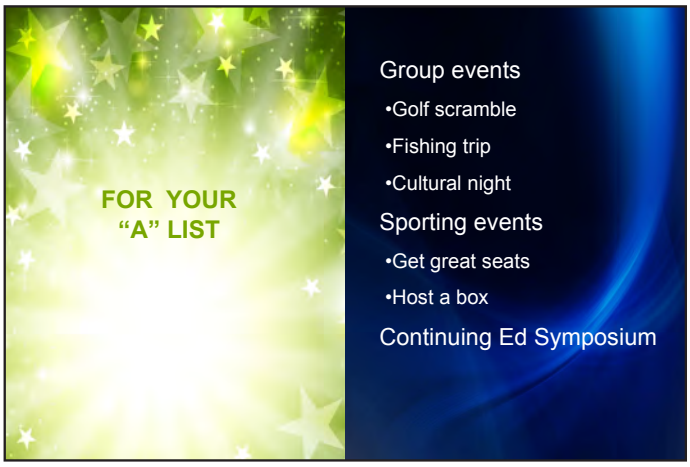

Doctors refer to people they:
• Like
• Trust
• Think are competent
• Believe are successful
Take care of the people who take care of you – principals and key staff

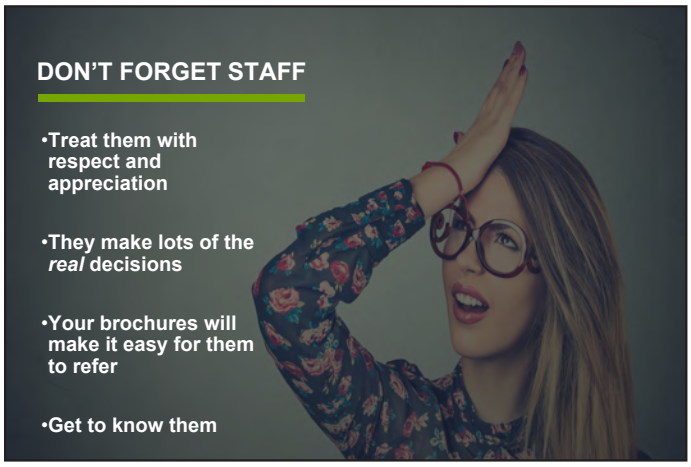

Identifying Your Best Prospects
• Existing Referrers
• For PCP, FP and IM - target OB/GYNs, ER, DDS, Pediatricians, Pain Care, Eyecare, etc.
• ENT, GI, Plastic Surgeons, Dermatologists, Cardiologists, Endocrinologists, Urologists
• Lists can come from compiled sources, associations, partners or publications
• Outreach should be specific to specialty


KEY REFERRER PROGRAM
•Prioritize "A" thru "C" categories of referrers based upon volume of referrals and opportunity
•Create a database; continually update
•Communicate and reward referral sources according to category
•Build *relationships*


THE POWER OF FOOD
•Can be lunch or dinner or breakfast
•People bond over food
•Pick a nice place
•Keep the conversation light
•Do leave them with something they can use – a "golden nugget"


GIFTS
•Holiday gifts: something special
•Thanksgiving week vs. Christmas
-Find out personal interests
-Magazines and newsletters
-Memorable and unusual
-Staff too
•Birthdays and/or unusual holidays
•Usually less than $100


FOR YOUR "A" LIST
Group events
•Golf scramble
•Fishing trip
•Cultural night
Sporting events
•Get great seats
•Host a box
Continuing Ed Symposium


DON'T FORGET STAFF
•Treat them with respect and appreciation
•They make lots of the *real* decisions
•Your brochures will make it easy for them to refer
•Get to know them

FOR STAFF…

- Deliver lunch – front office meets front office
- Food, coffee, every 8 weeks
- Event cakes – make it fun
- Flower of the month
- Professional concessions

EXACTLY WHO IS GOING TO DO ALL THESE THINGS?

Doctors?
Existing staff?
Physician liaisons?

PHYSICIAN LIAISONS

- AKA Physician Relations, Business Development, Marketing/PR Person, Practice Representative, etc.
- Growing trend due to competition
- Hospitals, groups and solo practices use
- Can outsource or hire
- Sales is objective, not "creative marketing"
- Consider what referrers are worth to you when budgeting

PHYSICIAN LIAISON BEST PRACTICES

- Naturally good at establishing relationships
- Always has a goal for each meeting
- Advances agenda
- Goal driven with performance bonuses
- Self-starting
- Does reconnaissance
- Not afraid to talk to doctors

MORE BEST PRACTICES

- Database
- Hire the right level for what you need
- Monitor results

AVOID THESE COMMON MISTAKES

- Combine role with marketing tasks (they should be in the field!)
- "Do this in your spare time"
- Hire before you have defined expectations, goals, etc.
- Hire the wrong person (job description, role, experience, personality, sales skills)
- Offer a noncompetitive compensation package (remember, good ones are desirable for corporate America - and your competitors)
- Fail to manage them
- No database or system to measure results and activity
- Fail to train them

CULTIVATE NEW REFERRAL SOURCES

- Add new referrers to your list
- Goal is to convince
  - Non-referrers to try you
  - "Splitters" to become loyalists
  - Defectors to come back

PROCESS

LIST all potential referrers– PCPs, specialists, nurse practitioners.

BUILD your **VISIBILITY** and **CREDIBILITY** with consistent exposures to your practice.

COMMIT to a consistent continuous contact strategy.

DON'T GO INTO BATTLE UNARMED

How good are you? How good do you look?

Compelling materials

- Support your presentation
- Communicate differentiating brand value
- Demonstrate your expertise
- "Leave behind" for physician

BRANDED MARKETING KIT

- Professional image and packaging
- Include all your core marketing materials

FOLLOW UP!

- Call, build rapport
- Meet with Office Manager and "engage"
  - "Do you see patients with…?"
  - "Whom do you refer to for…?"
- Present services
- Suggest meeting with their physician
- Arrange Doctor-to-Doctor lunch
- Reason for follow up

REVERSE ENGINEER REFERRALS

- Ask “un-referred” patient for permission to speak with her primary care provider
- Use an excuse to start a dialogue with the new doctor
- Also, remember to “talk up” PCP to his/her patient

SPEAKING ENGAGEMENT TIPS

SPEAKING ENGAGEMENT TIPS

- Subject should be helpful to referral value – not just promotional
- Distribute your brochure as you start speaking for great impression and take-away recall
- End with 1 minute promo about you
- Invite them to use you as a resource

NEW PRACTICES IN TOWN

- Arrange to meet, take to lunch
- Discuss their practice, problems they are having
- Be a resource, mentor
- Introduce to key people
- Drop off your practice kit

ADDITIONAL TACTICS

- Tell patients how WONDERFUL their referring doctor is! They will often go back to that provider and share your comment. Great reinforcement of that referral relationship!
- Diagnose each practice to determine how the would like to communicate with you.
- Identify WHO is actually making the referral – Doctor, Staff, Referral Coordinator
- Don’t forget staff
- Timeline follow up and reporting
- Marketing Automation
- Develop compelling content deploy through email campaign

SELF EVALUATION

Building Physician and Patient Referral Relationships

1. T/F - Is it appropriate to ask patients directly for referrals?

2. T/F - Is it important to develop a strong patient word of mouth referral network?

3. Which of the following encourages Patient Ambassadors?

a. Offering Saturday hours
b. Thank you note and phone call
c. Online appointments

4. What is not included in the Key Referral Development Program?

a. Prioritize “A” thru “C” categories of referrers based upon volume of referrals and opportunity
b. Communicate and reward referral sources according to category
c. Communicate with all referrals prospects the same way

5. What is Reverse Engineering?

a. Having staff learn other job responsibilities
b. Ask “un-referred” patient for permission to speak with her primary care provider
c. Utilize your EMR to market to your patients

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