THE 2018-19

Medical-Dental-Legal UPDATE

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

American Educational Institute, Inc.

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TABLE OF CONTENTS

- COURSE OBJECTIVES
- DISCLOSURES
- PRESENTATIONS

Understanding Medical Malpractice Litigation and How to Avoid It — ***Robert P. Siemion, Esq.***

Robert P. Siemion, Esq. - Biography 6
Presentation Outline 7
Self Evaluation 13

Alzheimer's Disease Update — ***Allan A. Anderson, MD, MMM, CMD, DFAPA***

Allan A. Anderson, MD, MMM, CMD, DFAPA - Biography 14
Presentation Outline 15
Self Evaluation 23

The Unreasonable Patient: Ethical and Legal Pitfalls — ***Joseph W. Shannon, Ph.D.***

Joseph W. Shannon, Ph.D. - Biography 24
Presentation Outline 25
Self Evaluation 27

Radiology Update: What to Order and Why — ***Cullen Ruff, MD***

Cullen Ruff, MD - Biography 28
Presentation Outline 29
Self Evaluation 31

Things I Wish I Knew Last Year — ***Louis Kuritzky, MD***

Louis Kuritzky, MD - Biography 32
Presentation Outline 33
Self Evaluation 50

Protecting Your Assets: Preventive Legal Medicine — ***Ike Z. Devji, Esq.***

Ike Z. Devji, Esq. - Biography 51
Presentation Outline 52
Self Evaluation 62

Cannabis and Cannabinoids in Pain Treatment — ***Daniel J. Clauw, MD***

Daniel J. Clauw, MD - Biography 63
Presentation Outline 64
Self Evaluation 69

Malpractice Litigation Stress: The Underlying Reasons — ***Thomas P. Cox, ARM***

Thomas P. Cox, ARM - Biography 70
Presentation Outline 71
Self Evaluation 78

New Directions in Diabetes — ***Louis Kuritzky, MD***

Presentation Outline 79
Self Evaluation 88

Reducing Professional Financial Stress Through More Effective Benefit Planning — ***David B. Mandell, JD, MBA***

David B. Mandell, JD, MBA - Biography 89
Presentation Outline 90
Self Evaluation 96

TABLE OF CONTENTS

Medication Adherence: A Major and Curable Medical Problem ***C. Wayne Weart, PharmD, FASHP, BCPS***

C. Wayne Weart, PharmD, FASHP, BCPS - Biography 97

Presentation Outline 98

Self Evaluation 109

Healthcare Practice Risk: A Survey ***Richard A. Honaker, MD, FAAFP***

Richard A. Honaker, MD, FAAFP - Biography 110

Presentation Outline 111

Self Evaluation 115

Aspirin as an Agent of Primary Prevention ***Louis Kuritzky, MD***

Presentation Outline 116

Self Evaluation 129

Non-pharmacologic Techniques for Managing Chronic Stress ***Rabbi Elimelech Goldberg***

Rabbi Elimelech Goldberg - Biography 130

Presentation Outline 131

Self Evaluation 138

Chest X-Ray Review ***Cullen Ruff, MD***

Presentation Outline 139

Self Evaluation 140

Mastering Patient Flow in the Healthcare Practice ***Elizabeth W. Woodcock, MBA, FACMPE, CPC***

Elizabeth W. Woodcock, MBA, FACMPE, CPC - Biography 141

Presentation Outline 142

Self Evaluation 148

The Longevity Diet ***Joel Kahn, MD, FACC***

Joel Kahn, MD, FACC - Biography 149

Presentation Outline 150

Self Evaluation 157

Malpractice Litigation Stress: Its Nature and Its Management ***Thomas P. Cox, ARM***

Presentation Outline 158

Self Evaluation 165

Diabetes and Its Relationship to Oral Health ***Daniel G. Pompa, DDS***

Daniel G. Pompa, DDS - Biography 166

Presentation Outline 167

Self Evaluation 179

Starting and Growing a Direct Patient Care Practice ***Josh Umbehr, MD***

Josh Umbehr, MD - Biography 180

Presentation Outline 181

Self Evaluation 188

COURSE OBJECTIVES

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After completing ***The 2018-19 Medical-Dental-Legal Update*** you should have acquired the knowledge that will better enable you to:

- Understand and avoid **malpractice litigation**.
- Identify and reduce **healthcare office risk**.
- Understand and start a **direct patient care** practice.
- **Protect professional and personal assets**.
- Utilize non-pharmacologic techniques for **managing chronic stress**.
- Utilize a variety of clinically **relevant but relatively unknown treatments**.
- Consult patients on the benefits of a **longevity diet**.
- Utilize **aspirin as a primary prevention agent** for CVD, stroke and colon cancer.
- Understand risks and benefits of **cannabis and cannabinoids** in pain management.
- Understand and utilize common **imaging modalities and techniques**.
- Identify and avoid legal and ethical pitfalls of treating **unreasonable patients**.
- Implement **new type 2 diabetes practice guidelines** aimed at cardiovascular risk reduction.
- Interpret **chest X-rays** for common clinical conditions.
- Improve practice profitability through more efficient **patient flow**.
- Reduce professional financial stress by better **benefit planning**.
- Understand and reduce **medication nonadherence**.
- Understand **Alzheimer's disease** and better interact with afflicted patients.
- Understand and manage **malpractice litigation stress**.
- Incorporate the **relationship between diabetes and oral health** into patient care.

All learning objectives above address IOM/ACGME core competencies.

FACULTY DISCLOSURES

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The individuals listed below have control over the content of ***The 2018-19 Medical-Dental-Legal Update***. None of them have a financial relationship with a commercial interest whose products or services are discussed in the presentation(s) over which they have control:

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Louis Kuritzky, MD, consultant for AstraZeneca, Boehringer Ingelheim, Sanofi, and Novo Nordisk

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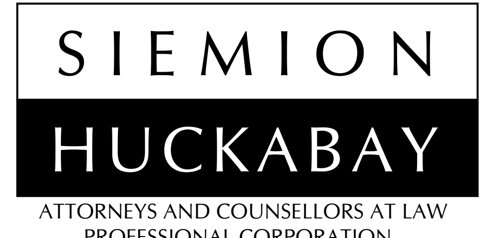

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Understanding Medical Malpractice Litigation and How to Avoid It

Robert P. Siemion, Esq.

I. Introduction and Overview

A. Litigation experience. 44 years of defending physicians and hospitals.

B. Recent trends in litigation volume, quality of cases, and costs of pursuing medical malpractice actions. Litigation volume has drastically decreased, though public believes there are more lawsuits.

II. Pre-Suit Issues

A. Effective record-keeping. Your best friend or worst enemy.

B. Be aware of the noncompliant patient and the need to decline care, if appropriate.

C. “Defensively chart” history and problems of patient before you commence care.

D. Never amend or alter chart after event unless it is clearly noted and dated and the amendment is initialed by treater.

III. Pre-Suit Investigation by Plaintiff Attorney or Medical Representative

A. Good documentation discourages lawsuits.

B. Lawyers and their medical consultants comb through medical records looking for issues to exploit.

C. After suspecting patient dissatisfaction, place chart of patient in secure, safe place.

D. Never turn over your original chart to the patient (original chart may be produced during litigation, but should be turned over to counsel). Give your lawyer <u>all</u> records.

E. Do not contact Plaintiff/patient after patient has attorney.

F. Chart everything, including profanity and threats made by patient or family.

G. If patient or family is refusing important medical treatment being offered, specifically chart the refusal. If possible, have the patient sign the chart.

H. The reviewer of your chart is looking for "holes" in your record-keeping system.

I. Do you want your records to be your best friend in the courtroom, or your enemy that could lead to a verdict for the patient?

IV. Legal Elements of Medical Malpractice Case

A. Derived from British system in 19th Century and common law – basically a negligence action.

B. Elements.

1. Duty – Was there a physician-patient relationship? Does the law recognize a legal duty? Generally, a duty exists to provide patients care and treatment within your standard of care.

2. Breach of Duty – Was the care and treatment beneath the standard of care of a physician of ordinary learning, judgment and skill? Remember: "average physician," "ordinary skill."

3. Proximate Causation – Did the breach of duty (care and treatment falling beneath the standard of care) cause damages to Plaintiff that were a natural and probable consequence of the breach of duty? There can be several causes, but the law only requires that the violation of the standard of care be a proximate cause of the patient's damages, not the only proximate cause.

   Example: If we assume there were lawsuits following the sinking of the Titanic, the law would require that the plaintiff prove that there was **A** proximate cause between the alleged negligence and the death of a passenger. There can be more than one proximate cause, such as the failure to properly see and avoid the iceberg, negligence in charting a course in the northern Atlantic in April, the failure to have sufficient lifeboats, the failure of the shipping line employees to properly evacuate the ship, brittle fracture of the hull steel, failure of the rivets, flaws in the water-tight compartments, etc., etc. There can be many proximate causes, but the law requires that the negligent act be only **A** proximate cause.

C. Damages. Plaintiff must have damages recognized as compensable under the law. It can be emotional, physical, economic, non-economic, etc. Plaintiff should not be able to recover for "almost" suffering an injury, or having an injury so slight and trivial that it is not compensable. (Law firms that represent plaintiffs do not wish to invest money in litigation where the damages are slight.)

V. Standard of Care a/k/a S.O.C.

A. Judges instruct juries: "When I use the words 'professional negligence' or 'malpractice' with respect to the defendant's conduct, I mean the failure to do something which a physician of ordinary learning, judgment or skill in this community or a similar one would do, or the doing of something which a physician of ordinary learning, judgment or skill would not do, under the same or similar circumstances you find to exist in this case." It is the function of the jury, or the judge

sitting without a jury, to be the "finder of fact" and determine whether the defendant met that legal standard or not.

1. Easy way to remember this key legal doctrine. You need to be aware of only two things:

   (a) The "average physician."

   (b) "Same or similar circumstances."

   To understand what has to be proven and how the claims can be defended, you must think through whether what you did or didn't do would be something that an average physician would or would not do under the same or similar circumstances.

VI. <u>Stages of Litigation (What will Happen is a Claim is Made?)</u>

The basic stages of litigation are as follows:

A. You receive a Notice of Intent or lawsuit and contact your insurance carrier, or employer, or insurance agent, if applicable. (Occasionally, letters are sent by a claimant's attorney trying to settle their case before any official claim is filed.)

B. You meet your defense attorney along with the insurance representative, if applicable. Consider this meeting very, very important.

C. Your defense is planned and records that are not already obtained will be subpoenaed. Your records and any later records in your possession are carefully reviewed.

D. Defense experts are discussed and retained and are given pertinent medical records and data as it comes in.

E. The defendant physician should already be <u>completely familiar</u> with the facts of the case and the medicine. A careful study of the chart should continue. Every time you look at the chart, you will see a different nuance or aspect of how to best defend the case, or where there could be serious difficulties.

F. The plaintiff's deposition is important. The defendant physician, if requested by counsel, should be present and assist the defense attorney.

G. The all-important deposition of the defendant now takes place. (See later, "Common Mistakes Made by Physicians".) Know and follow the <u>Three Golden Rules</u>.

H. Expert medical witnesses on both sides assess the testimony and the written evidence. Can your reviewing expert still support the case in light of your testimony?

I. Malpractice cases are usually evaluated by an attorney panel, and recommendations are made regarding settlement value from $0.00 to whatever the panel believes is a reasonable number.

J. Decisions are formulated on both sides with regard to whether the case will continue to proceed, what the plaintiff believes it may be worth, and whether the defense feels the case is defensible or is one that should be compromised.

K. For the defendant, after obtaining all data from reviewing experts and reviewing important medical records, such a decision is a joint decision involving the defendant physician, the defense attorney, and the insurance carrier.

L. If a decision is made to defend a case, and a trial is scheduled, there will be necessary intensive preparation which will involve the defendant physician. It is always helpful if the defendant physician is put through a "mock" deposition, which will be placed on videotape for later viewing. This is especially true if the defendant physician is perceived as being weak or non-sympathetic. (Many courtroom employees and judges state that the single most important factor in a medical malpractice lawsuit against an individual physician is the demeanor and likability of the defendant. If a defendant exhibits anger, sarcasm, bitterness, and is overly aggressive, it will be very difficult for a jury to return a verdict in that physician's favor.)

VII. Common Mistakes Made by Physicians

A. Common Mistakes Made by Physicians **Prior to Suit**

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

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

3. Failing to follow recommendations of consultants.

4. Perpetuating inaccurate or misleading history given by patient.

5. Failing to obtain prior or concurrent medical records (review EKG=s in prior records).

6. Proper triage of patient's phone calls or e-mails.

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

8. Committing to a plan with the patient and failing to follow charted plan.

9. Failing to refer.

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

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

12. Failing to make addition to records in the proper manner.

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

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

15. Write legibly.

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

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

B. Common Mistakes Made by Physicians as **a Defendant**

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

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

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

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

5. Being constantly paged or interrupted during deposition.

6. Having the deposition in your own office rather than at the attorney's office; plaintiff attorney can see textbooks, pamphlets and things that could lead to further questions.

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

8. Contacting plaintiff-patient after patient has attorney.

9. Not being totally familiar with the medical issues involved in the litigation.

10. Filing your attorney's correspondence with patient records. Unsophisticated office personnel, in response to a records subpoena, could send your chart and your attorney's privileged thoughts on to other attorneys in the case. This has happened. The chart of

a patient litigation should be separate from all other charts and locked away in a secure location.

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

12. Failing to recognize the importance of your deposition as a defendant. (The deposition cannot be approached as an inconvenience that must be squeezed into an already busy schedule. The deposition can make or break the defense of your case.)

VIII. Why Are Medical Malpractice Claims/Lawsuits Filed?

- Bad result and/or angry patient.
- Obviously, an attempt to obtain money.
- Criticism of later treaters that gives patient the idea to sue previous treaters.
- Sometimes, although very rarely, claims are filed to learn information about why something happened.

IX. Helpful Jury Instruction

Bad results in and of themselves are not evidence of medical malpractice. If a patient sues, they have to find an attorney to agree to take their case, and generally it is the attorney that finances the case which can easily run into many thousands of dollars before suit is filed. The plaintiffs also have the "burden of proof" where they must prevail on the existence of a duty, the breach of said duty, and proximate causation, which was covered earlier in this presentation. They also have the burden of proof to prove damages. A patient who is filing suit must prevail on all of these issues with a preponderance of evidence. In other words, with evidence that is more likely than not.

Medical malpractice lawsuits are far more rare than they were in the past. With a proper attitude and excellent records, along with an experienced defense trial lawyer, you should be able to successfully defend your case.

SELF EVALUATION

Understanding Medical Malpractice Litigation and How to Avoid It

True/False

1. If a record is corrected by a healthcare provider, any portion that is stricken should have a light line drawn through it which will allow what is being stricken to still be readable.

2. If you obtain a patient's prior records from a previous healthcare provider, you are not responsible for knowing important items that are contained in that record.

3. The chart is property of the physician or hospital and the patient can only obtain it in limited circumstances.

4. The two main reasons a patient requests a copy of their chart are (1) curiosity, and (2) to assist them in a billing dispute with the insurer.

5. A chart that contains less detailed information can turn out to be helpful if you are sued since there are fewer items that can be attacked by Plaintiff's counsel.

6. It is appropriate to aggressively confront the attorney for the patient who is taking your deposition if they provoke you.

7. A jury can find that a defendant physician has been negligent and did not provide the appropriate standard of care, but the defendant physician can still prevail if there is no finding that this negligence was a proximate cause of injury.

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

FACULTY

Allan A. Anderson, MD, MMM, CMD, DFAPA

Allan A. Anderson, MD, MMM, CMD, DFAPA, of Cambridge, Maryland, is a board-certified psychiatrist with subspecialty certification in geriatric psychiatry. He is also a Certified Medical Director as well as Assistant Professor in Psychiatry at Johns Hopkins University School of Medicine. Dr. Anderson served as President of the American Association for Geriatric Psychiatry and in 2014 received the “Clinician of the Year” award from AAGP.

His practice centers around the evaluation and treatment of individuals with cognitive dysfunction including Alzheimer’s disease and other dementias. Dr. Anderson has researched, written, and spoken extensively on topics associated with geriatric psychiatry, Alzheimer’s disease in particular. He is also a speaker for Assurex Health.

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GERIATRIC AND FORENSIC PSYCHIATRY

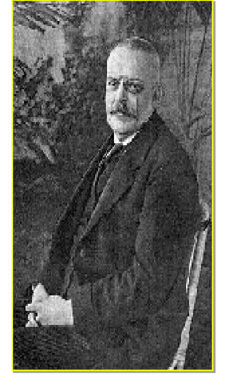
Alzheimer's Disease Update

Alzheimer's Disease

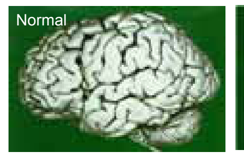
First described by Alois Alzheimer, a German psychiatrist, in 1907

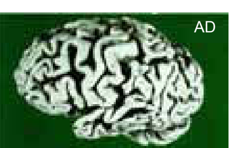
Observed in a 51-year-old female patient with memory loss, paranoid thoughts, disorientation, and hallucinations

Postmortem studies characterized senile plaques and neurofibrillary tangles (NFTs) in the cerebral cortex



Neuropathologic Changes Characteristic of Alzheimer's Disease





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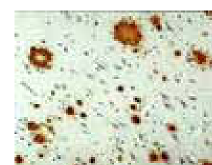


NFT

Are we experiencing an epidemic?

5.7 Million Americans are living with Alzheimer's

This number will escalate rapidly in coming years and by 2050 this number could rise as high as 14 million

About one-third of people age 85 and older have Alzheimer's disease. 1 in 3 Seniors dies with AD or other dementia.

Alzheimer's Disease is the 6th Leading Cause of death in the US

Alzheimer's Association 2018 Alzheimer's Disease Facts and Figures

AD is a very costly disease

In 2018 Alzheimer's and other dementias will cost the nation $277 billion and by 2050 this could rise to 1.1 trillion

18.4 billion hours of care by family and unpaid caregivers valued at $232 billion

35% of caregivers for people with Alzheimer's report their health has gotten worse due to care duties

Early and accurate diagnosis could save up to 7.9 trillion in medical and care costs

Alzheimer's Association 2018 Alzheimer's Disease Facts and Figures

Differential Diagnosis of Dementia

- Alzheimer's Disease (AD)
- Vascular Dementia (VaD)
- Lewy Body Dementia (LBD)
- Parkinson's Disease Dementia (PDD)

Differential Diagnosis of Dementia

- Frontotemporal Dementia (FTD)
- Normal Pressure Hydrocephalus (NPH)
- Dementia due to a Medical Condition
- Dementia of Depression

- **Decline in memory and learning and at least one other cognitive domain**
- **Insidious onset and steady progressive decline in cognition without extended plateaus**
- **No evidence of mixed pathology**

Alzheimer's Dementia

Benefits of Early Diagnosis

- Early treatment can delay end-points and create financial savings
- More likely patients will have capacity to discuss advance care planning
- Early institution of safety issues including safety in the home, managing behavioral issues, and the more difficult issue of capacity to safely operate a motor vehicle

Diagnostic Studies

- Complete Blood Count
- Basic or Comprehensive Metabolic Panel
- Vitamin B12, Folate, Vitamin D
- TSH
- RPR (FTA-Abs)
- Non contrast CT or MRI of brain

Laboratory Medicine in Psychiatry an Behavioral Science, 2012
APA Textbook of Alzheimer Disease and Other Dementias, 2009

Additional diagnostic tests

- Toxicology screen
- Heavy metal screen
- HIV testing
- Lyme's Antibody
- Parathyroid function, adrenal function
- Homocysteine
- C-reactive Protein

APA Textbook of Alzheimer Disease and Other Dementias, 2009

Additional Tests

- FDG PET Scan (FTD vs. AD, corroborate LBD)
- Neuroquantitative MRI
- SPECT (Lewy Body Dementia)
- Amyloid PET Imaging (not covered by MC)
- LP - Measure amyloid beta and P-Tau
- LP - to rule out infection, CNS Lyme's
- Neuropsychological testing
- Genetic Testing

Laboratory Medicine in Psychiatry an Behavioral Science, 2012
APA Textbook of Alzheimer Disease and Other Dementias, 2009

Please, please, please:

Do not be afraid to provide the diagnosis to the patient and family

And, when making a diagnosis of AD, discuss treatment options

Treatment

Medications:

Acetylcholinesterase inhibitors:
donepezil, rivastigmine, galantamine

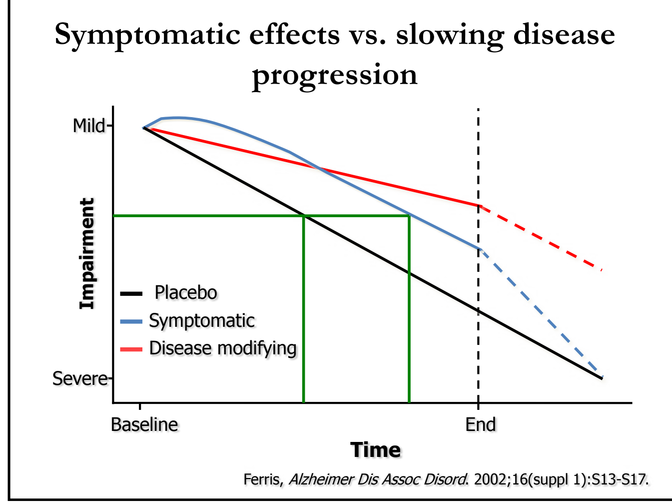
NMDA receptor antagonist:
memantine

Role of neurocognitive rehabilitation?

Cognitive training and rehabilitation

Kasper E, Ochmann S, Hoffmann W et al. Journal of the Prevention of Alzheimer's Disease. Vol 2, No 2, 2015

Symptomatic effects vs. slowing disease progression



What do we mean by:

Behavioral or
Neuropsychiatric Symptoms
of Dementia

Current trend - NPS

Inappropriate verbal, vocal, or motor activity that is unexplained by apparent needs or confusion

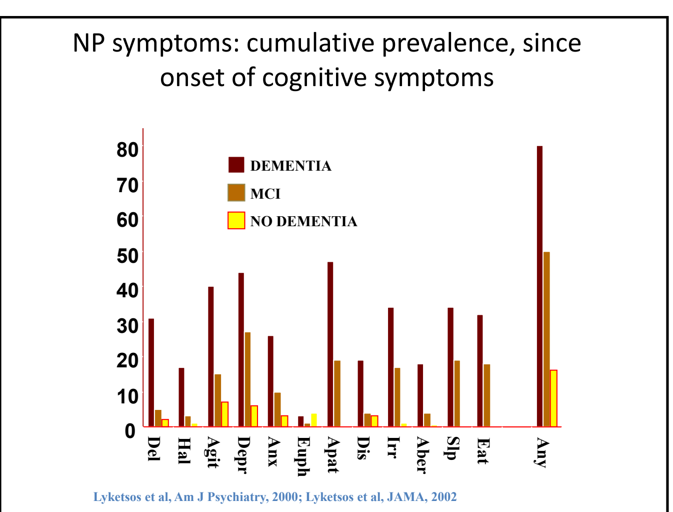
Jiska Cohen-Mansfield (1986)

Reviews of the literature

Up to 90% of patients with dementia will develop significant neuropsychiatric symptoms some time in the course of their disease

Neuropsychiatric symptoms include:

- Agitation
- Verbal and physical aggression
- Nighttime wakefulness
- Paranoia
- Hallucinations
- Anxiety
- Depression
- Shadowing
- Disinhibition
- Resistance to care
- Apathy
- Repetitive vocalizations
- Wandering
- Aberrant motor behaviors



NPS are "bad" for patients & caregivers

* Greater ADL impairment
* Worse quality of life
* Earlier institutionalization
* Major source of caregiver burden
* $10,000/year additional care costs
* Shorter time to severe dementia
* Accelerated mortality

Lyketsos et al, 1999; Murman et al, 2002; Peters et al, 2015

Common causes

Medical problem
UTI, other infections, pain, constipation, dehydration
Medication
Anticholinergic, disinhibiting rxn, stimulation, drug toxicity
Psychiatric syndrome
Recurrence of prior illness (depression, bipolar disorder)
Caused by dementing disease
Environment or change in environment
Unsophisticated care-giving

Are behaviors:

Due to general medical condition or medication?
Treat the cause, provide supportive care

Due to environmental stressor or precipitant?
Modify the environment

Due to difficulties in patient caregiver relationship or unsophisticated care?

Evaluate, educate, support and if necessary treat the caregiver

Interventions for Neuropsychiatric Symptoms of Dementia

Non-pharmacologic strategies

- Caregiver respite
- Caregiver education on skills of caregiving
- Caregiver support groups
- Treatment of the caregiver

Non-pharmacologic strategies

- Communication Strategies
- Exercise/Physical Activities
- Learn about a patient's past in order to understand how to engage and motivate patients
- Use humor and play
- Use short verbal and visual cues and repetition

Two Excellent Reviews

Nonpharmacological Management of Behavioral Symptoms in Dementia
Gitlin LN, Kales HC, and Lyketsos CG
JAMA, November 21, 2012 , Vol. 308, No. 19: 2020-2029

Meta-Analysis of Nonpharmacological Interventions for Neuropsychiatric Symptoms of Dementia
Brodaty H and Arasaratnam C
Am J Psychiatry, Sept. 2012, Vol 169, No. 9: 946-953

Physician's Knowledge of Non-pharmacological Interventions

Physicians in favor of use of NP interventions

Knowledge of NP interventions is variable and often lacking

Increasing knowledge would increase the use of NP interventions

Cohen-Mansfield J and Jenson B
JAMDA. Vol 9, No. 7, Sept., 2008: pp 491-498

Prevention is vital

Many behavioral problems can be avoided

Use of appropriate communication strategies is key

Benefits of culture change

- Lower incidence in decline of ADL's
- Less feelings of boredom and helplessness in residents
- Greater satisfaction of residents and families
- Improved staff perceptions of working conditions and ability to meet resident needs
- Greater job satisfaction of staff
- Reduction in staff turnover

Kane RA et al. JAGS 2007; Lum TY et al. Health Care Financ Rev, 2008; Bergman-Evans B. J Gerontol Nurs, 2004;Bishop CE et al. Gerontologist, 2009; Anderson RA. Gerontologist 2009; Chenoweth L. Lancet Neurol, 2009; Shier V et al. Gerontologist, 2014

Why avoid psychotropic medications?

Many elderly on multiple Rx and OTC medications

No medication is without side effects

Any additional medication increases costs to patient, family, and society

Nonpharmacological interventions are available and have demonstrated efficacy

Medications often have limited efficacy

Modern Pharmacologic Treatments

Psycho-behavioral metaphors

Phenomenological Approach

Clinically resemble?

- Depression
- Apathy
- Mania
- Anxiety states
- Psychotic disturbance
- Impulse control disturbance
- Sleep disorders

Clinically resemble?

- Depression – Antidepressants?
- Apathy – Psychostimulants, good studies with methylphenidate
- Mania – mood stabilizers but remember this syndrome is rare
- Anxiety states – anxiolytic medications: benzos?? Antidepressants (not TCAs) buspirone, gaba agonists

Clinically resemble?

- Psychotic disturbance – 2nd generation antipsychotics, antidepressants? In PD, LBD and PDD – pimavanserin
- Impulse control disturbance – mood stabilizers, anticonvulsant meds?
- Sleep disorders –melatonin may benefit sleep disorders in dementia including REM behavioral sleep disorder. Avoid benzos and Z drugs (zolpidem, zaleplon)

Medications for managing neuropsychiatric symptoms

First optimize medications that may positively impact cognition:

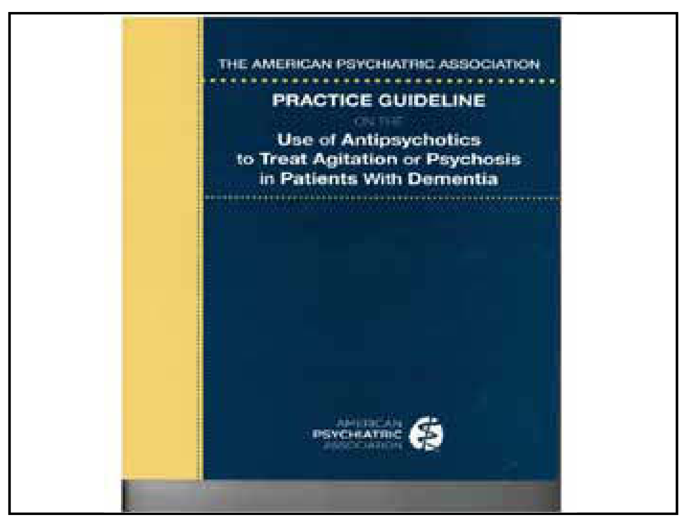
Acetylcholinesterase inhibitors (donepezil, rivastigmine, galantamine)

NMDA receptor antagonist (memantine)

Issues with use of antipsychotics

- Psychotic syndromes may be time limited
- Document need for continued use
- Consider reduction in dose after some reasonable time frame (1- 4 months)
- Document discussion of black box warnings
- Monitor for side effects
- Recent study – acceleration of cognitive decline?

Lyketsos et al, 1997; Gonzales-Salvador et al, 1999; Steele et al, 1990; Lyketsos et al, 1999; Murman et al, 2002; Peters et al, 2015; Wolf A et al, 2017



Efficacy of SSRIs to treat Depression in the context of Dementia

- Evidence is inconclusive that efficacy is worth the risk in those with mild to moderate depression.
- Non-pharm approaches and watchful waiting for 8-12 weeks in patients with mild symptoms?

Leong, Consultant Pharmacist, 29 (4): 254-263, 2014

Off label use of SSRIs in older adults

Dementia with behavioral disturbance

- **Motor Agitation**
- **Disinhibition**
- **Irritability**
- **Psychosis?**

Article

Comparison of Citalopram, Perphenazine, and Placebo for the Acute Treatment of Psychosis and Behavioral Disturbances in Hospitalized, Demented Patients

Bruce G. Pollock, M.D., Ph.D.
Benoit H. Mulsant, M.D.
Jules Rosen, M.D.
Robert A. Sweet, M.D.
Sati Mazumdar, Ph.D.
Ashok Bharucha, M.D.
Robert Marin, M.D.
N.J. Jacob, M.D.
Kimberly A. Huber, B.A.
Kari B. Kastango, M.S.
Marci L. Chew, B.S.

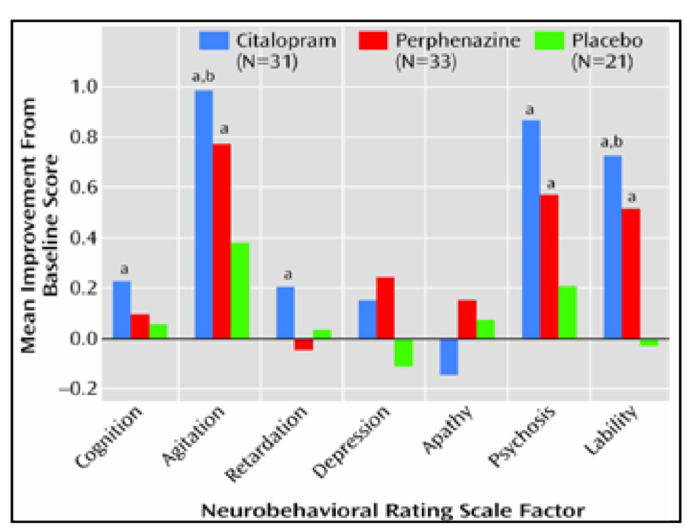
Objective: Until recently, conventional antipsychotics were the standard pharmacotherapy for psychosis and behavioral disturbances associated with dementia. This double-blind, placebo-controlled study compared the acute efficacy of the selective serotonin reuptake inhibitor citalopram and the neuroleptic perphenazine with placebo for the treatment of psychosis and behavioral disturbances in nondepressed patients with dementia.

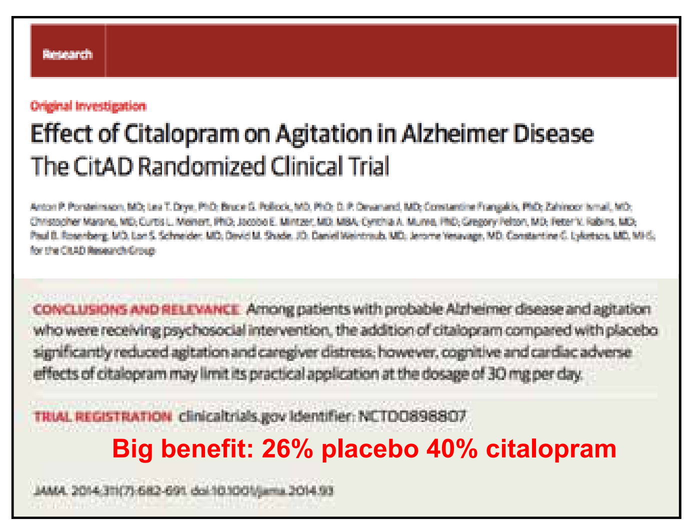
Method: Eighty-five hospitalized patients with at least one moderate to severe target symptom (aggression, agitation, hostility, suspiciousness, hallucinations, or delusions) were randomly assigned to receive either citalopram, perphenazine, or placebo under double-blind conditions for up to 17 days.

Results: Patients treated with citalopram or perphenazine showed statistically significant improvement on several Neurobehavioral Rating Scale factor scores. Compared to those receiving placebo, only patients treated with citalopram showed significantly greater improvement in their total Neurobehavioral Rating Scale score as well as in the scores for the agitation/aggression and lability/tension factors. Side effect scores were similar among the three treatment groups.

Conclusions: Citalopram was found to be more efficacious than placebo in the short-term hospital treatment of psychotic symptoms and behavioral disturbances in nondepressed, demented patients.

(Am J Psychiatry 2002; 159:460–465)




Research

Original Investigation

Effect of Citalopram on Agitation in Alzheimer Disease
The CitAD Randomized Clinical Trial

Anton P. Porsteinsson, MD; Lea T. Drye, PhD; Bruce G. Pollock, MD, PhD; D. P. Devanand, MD; Constantine Frangakis, PhD; Zahinoor Ismail, MD; Christopher Marano, MD; Curtis L. Meinert, PhD; Jacobo E. Mintzer, MD, MBA; Cynthia A. Munro, PhD; Gregory Pelton, MD; Peter V. Rabins, MD; Paul B. Rosenberg, MD; Lon S. Schneider, MD; David M. Shade, JD; Daniel Weintraub, MD; Jerome Yesavage, MD; Constantine G. Lyketsos, MD, MHS; for the CitAD Research Group

CONCLUSIONS AND RELEVANCE Among patients with probable Alzheimer disease and agitation who were receiving psychosocial intervention, the addition of citalopram compared with placebo significantly reduced agitation and caregiver distress; however, cognitive and cardiac adverse effects of citalopram may limit its practical application at the dosage of 30 mg per day.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT00898807

Big benefit: 26% placebo 40% citalopram

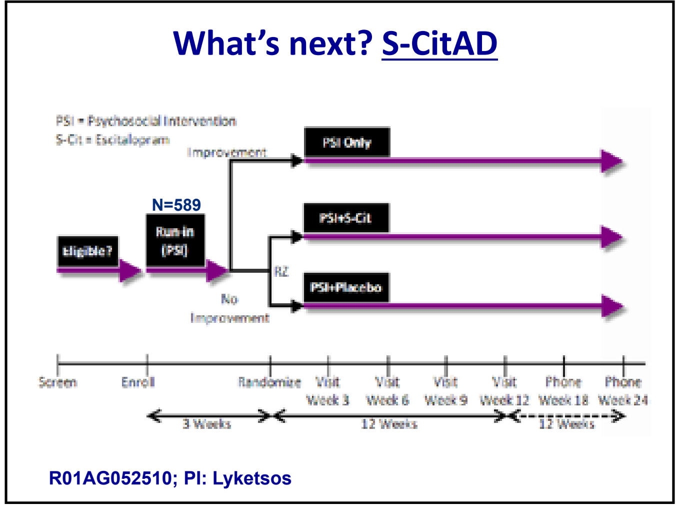
JAMA. 2014;311(7):682-691. doi:10.1001/jama.2014.93

SSRIs to treat dementia with behavioral disturbance (off label)

- Citalopram (CitAD study), N=186, mostly community dwelling
- Agitation, but no depression
- Improved agitation in patients with AD
- Reduced caregiver stress
- Higher rates of cardiac adverse effects than placebo

Porsteinsson et al, 2014

What's next? S-CitAD



R01AG052510; PI: Lyketsos

Novel medications for agitation

- Brexpiprazole (Otsuku)
- Dextromethorphan (Avanir)
- Prazosin (ADCS)
- Dronabinol (AbbVie)
- PF-05212377 (SAM-760) (Pfizer)
- ORM-12741 (Orion/Janssen)

SELF EVALUATION

Alzheimer's Disease Update

1. Providing competent evaluation and management of cognitively disordered elderly in your practice includes:

a. Performing a thorough diagnostic evaluation to rule out treatable causes of cognitive impairment
b. Screening for neuropsychiatric symptoms which might require treatment
c. Discussing treatment needs with cognitively intact family members and partners of the patient
d. Discussion of advance care planning at the initial visit
e. Answers a,b, and c above
f. All of above

2. T/F - At present there are randomized clinical trials that support a benefit for use of nutritional supplements and other over the counter remedies for Alzheimer's disease.

3. One of the most difficult safety issues to manage in patients with AD is:

a. Wandering
b. Use of stove and other appliances
c. Driving
d. Falls due to failure of making the home safe

4. T/F - Studies involving the treatment of depression in AD have shown a clinically and statistically improvement with use of antidepressant medications.

5. The most common etiology for dementia in the elderly over age 65 is:

a. Fronto-temporal dementia
b. Alzheimer's disease
c. Lewy Body Dementia
d. Parkinson's disease dementia
e. Dementia due to treatable medical disorders

6. T/F - Alzheimer's disease is the 6th most common cause of death in individuals age 65 and older.

7. Currently Medicare covers all of the following diagnostic tests for the evaluation of patients with a dementia syndrome except:

a. Tests of thyroid function and vitamin levels
b. Neuroquantitative MRI
c. FDG PET/CT when differential is between Alzheimer's disease and fronto-temporal dementia
d. Amyloid PET Imaging
e. Neuropsychological testing in select patients

8. A 72 year-old widowed white male presents to your office with his daughter with history from the daughter of insidious onset of cognitive problems that has gradually progressed over three years. He has no history of DM, HTN, or CVA. The patient has noticeable Parkinson's symptoms including a slow fenestrating gait, fixed facies, and cogwheel rigidity, but without tremor. These symptoms were present since the onset of cognitive deficits. In addition the daughter relates a history of frequent visual hallucinations and significant variation of cognitive deficits. Physical exam provides evidence of Parkinson's signs but show no other neurologic findings other than cognitive problems that include a MMSE score of 24 and significant executive function deficits with prominent slowed mental processing. The most likely diagnosis is:

a. Parkinson's disease dementia
b. Fronto-temporal dementia
c. Lewy body dementia
d. Frontal variant of Alzheimer's disease
e. Progressive Supranuclear Palsy

9. One genetic test for sporadic late-onset dementia is:

a. ApoE testing
b. Tests for trisomy 21
c. Presenillin I
d. Presenillin 2
e. BRACA gene testing

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

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.

You may contact Dr. Shannon with your questions and comments at (614) 297-0422, or by email at jshannon@insight.rr.com.

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The Unreasonable Patient: Ethical and Legal Pitfalls

Many patients in care can be "high-conflict" or "unreasonable". These individuals pose special challenges for even the most seasoned of medical and mental health professionals. Tendencies to create unnecessary conflict and drama, to avoid taking responsibility for their poor decisions and unwise behavior and to be non-compliant with treatment are but a few of these extraordinary challenges. This highly pragmatic module is designed to enhance the professional caregiver's empathy for and treatment of unreasonable patients. As a result of completing this training, participants will be able to:

1. List and describe the core characteristics of unreasonable patients;
2. Identify common legal/ethical challenges inherent in working with unreasonable patients; and
3. Generate a list of practical strategies for avoiding legal and ethical pitfalls in treatment.

AVOIDING ETHICAL AND LEGAL PITFALLS WITH UNREASONABLE PATIENTS

A. Quick Review: Core Characteristics

1. Long history of interpersonal conflict and pathological relationships.
2. Affective instability with particular difficulty in managing anxiety and anger.
3. Highly impulsive, reactive, i.e., must act on every feeling immediately without considering consequences of their behavior.
4. Lack insight and good judgement, i.e., will typically not learn from their mistakes.
5. Tendency to project blame onto others for the problems they themselves create; will not admit they are wrong; may create unnecessary "psychodramas" to avoid taking ownership of their problems.
6. Very likely to meet diagnostic criteria for one or more psychiatric disorders, most especially personality disorders.

B. Specific Recommendations: Avoiding Ethical and Legal Problems

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 behavior: "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 be 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/unreasonable patient and document this in the patient's chart.

12. Be aware of your countertransference, address it but do not share it with the patient.

    a. Anger, frustration

    b. Fear, discomfort, dread

    c. Resentment (over their not paying you in a timely fashion).

    d. Sexual attraction

    e. Disgust

    f. Feelings of inadequacy, incompetence

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SELF EVALUATION

The Unreasonable Patient: Ethical and Legal Pitfalls

1. Which of the following are characteristics of high-conflict, unreasonable patients?

a. They have a long history of interpersonal conflict.
b. They have intense emotions that over-rule rational thinking.
c. They are highly impulsive.
d. All of the above are true.

2. Unreasonable patients tend to:

a. Be highly litigious.
b. Have major problems with judgement, including moral judgement.
c. A and B are both true.
d. None of the above are true.

3. "Red flags" for spotting a potentially litigious patient include all but which of the following?

a. Prompt payment of co-payments.
b. History of treatment non-compliance
c. History of previous complaints/law suits regarding other clinicians
d. All of the above are "red flags."

4. Which of the following is not a guideline for working with high-conflict patients?

a. Avoid taking responsibility for their bad behavior.
b. Do not try to "rescue" the patient; hold them accountable.
c. Expect to do more work than the high-conflict patient; the clinician will need to take the lion's share of responsibility for the outcome of treatment.
d. All of the above are appropriate guidelines for working with these patients.

5. Appropriate/ethical reasons for termination of treatment include which of the following?

a. The patient is not appropriate for treatment.
b. The patient is clearly not benefitting from treatment.
c. Continued treatment could prove harmful to the patient.
d. All of the above are valid reasons for termination of treatment.

TRUE/FALSE:

6. Unreasonable patients typically create unnecessary conflict/drama when faced with a problem.

7. It is essential for a clinician to be clear and consistent about their role and boundaries when working with unreasonable or otherwise challenging patients.

8. It is not necessary to document peer/colleague consultations when working with unreasonable or otherwise challenging patients.

9. "Be aware of your countertransference, but keep your mouth shut."

10. It is never appropriate/ethical to terminate with a suicidal patient.

ANSWER KEY: 1. D, 2. C, 3. A, 4. C, 5. D, 6. T, 7. T, 8. F, 9. T, 10. F

Cullen Ruff, MD

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Radiology Update: What to Order and Why

Main Points:
- There is no single best test for all pathology
- Multiple ways to perform studies like CT and MRI of the same body part
- History and goals are key to optimize the study protocol
- Ordering efficiently can maximize diagnostic potential and minimize risk
- Imaging is constantly evolving
- Imaging helps result in more accurate and faster diagnoses than ever before, but there are inherent drawbacks and risk to unnecessary imaging

Imaging Cons:
- Cost
- Discomfort
- Radiation exposure (particularly with CT)
- IV contrast risk
- Interventional procedure complications

Oral Contrast:
-Iodine based vs. barium
-Complications and allergy very rare
-Barium inert
-Minimal absorption of water soluble contrast
-Requires time to drink, or inject per tube
-Water soluble better if suspect bowel perforation

Oral Contrast:
- Often used for CT A/P
- Exceptions:
  - Trauma
  - Some bowel obstructions
  - Kidney stone protocol
  - CT angiogram (CTA)
  - CT urogram
  - Different oral contrast used for enterography

IV Contrast:
-Opacifies vessels, vascular organs
-Delineates lymph nodes
-Outlines abscesses
-Enhances vascular masses

IV Contrast Complications:
Iodine based (CT, x-ray): Allergy, nephrotoxicity
Gadolinium based (MRI): Nephrogenic systemic fibrosis (NSF); allergy (rare); trace gadolinium tissue deposition even in patients with normal renal function, currently thought to be asymptomatic but longer follow up studies underway.

Contrast allergy issues:

- No one is allergic to elemental iodine—please do not list as an allergy.
- Clinically important not to group all contrast agents together, nor to permanently label patients as allergic to “Iodine”, as this may prevent them from being able to receive other contrast agents to which they may not be allergic. Best to record allergies by the name of the compound as would be done for any other drug

Allergies now considered unrelated to iodinated contrast:

- Shellfish allergy: muscle protein (tropomyosin)
- Iodine soap: other substances in solution

Resources available on line, e.g. **American College of Radiology, www.acr.org**

Iodinated Contrast:

- **Ionic**
  - Oldest, cheapest, rarely used now
  - More allergenic
- **Nonionic**
  - Most commonly used today
  - Fewer complications and reactions than ionic
- **Iso-osmolar nonionic**
  - Potentially less nephrotoxic; more expensive

Contrast Allergy Guidelines:

- List what the patient is allergic to—not “iodine”
- Shellfish allergy: no premedication if not severe
- Severe asthma, multiple allergies: may premedicate with steroids
- Ionic contrast allergy: give nonionic; may premedicate
- Nonionic contrast allergy: can premedicate and give contrast, if needed & prior reaction not severe
- <u>Severe IV contrast allergy: avoid contrast</u>
- Consult with radiology staff and resources e.g. www.acr.org

Breast imaging modalities:
Mammography
Ultrasound
MRI
Tomosynthesis (“3D mammography”)

SELF EVALUATION

Radiology Update: What to Order and Why

1. Rank the following modalities from greatest to least sensitive in detecting gallstones:

a. CT (computed tomography)
b. Abdominal radiograph
c. Ultrasound

2. The best study for visualizing acute intracranial hemorrhage is:

a. Head CT without contrast
b. Head CT with contrast
c. MRI (magnetic resonance imaging) without contrast
d. MRI with contrast
e. Cerebral angiogram

3. T/F - A small bowel follow-through requires that an upper GI study be performed in conjunction

4. T/F - Patients may be allergic to elemental iodine

5. Recent guidelines for ultrasound workup of incidentally discovered thyroid nodules on CT or MRI include:

a. Ultrasound if the nodule is at least 1 cm and the patient < 35 years old
b. Ultrasound if the nodule is at least 1.5 cm and the patient is >35 years old

6. Updated Fleischner Society 2017 Recommendations for incidental lung nodule follow up by CT include:

a. Following only nodules at least 6 mm mean diameter
b. No follow up for nodules 5mm mean diameter and smaller, even in high risk patients, as these nodules are overwhelmingly benign
c. No follow up of classically benign nodules such as calcified granulomas and normal intrapulmonary lymph nodes

7. Match the following types of chest CT studies with the corresponding disease process being investigated:

Chest CT with IV contrast	a. interstitial fibrosis evaluation
Chest CT without contrast	b. pulmonary embolism detection
Thin section high resolution, no contrast	c. previous lung nodule follow-up

8. Imaging options in patients with renal insufficiency might include which of the following:

a. Reduced iodinated-contrast dose
b. CT without contrast
c. Iso-osmolar nonionic contrast
d. MRI without contrast
e. All of the above

9. The best study to evaluate most newly discovered liver masses is:

a. Ultrasound
b. MRI
c. CT
d. Nuclear medicine scan

10. The best test to detect appendicitis in a pregnant woman is:

a. ultrasound
b. MRI without contrast
c. CT

11. In addition to digital mammography and ultrasound, other breast imaging includes:

a. MRI for women diagnosed with breast cancer
b. MRI as an additional screening test for high risk women, and to workup indeterminate abnormalities questioned on mammography
c. tomosynthesis (“3D mammography”) to improve mammogram sensitivity and specificity, improving cancer detection while also decreasing call backs from screening mammograms
d. all of the above

12. The following statements are true regarding CT (virtual) colonoscopy:

a. it is a less invasive, faster alternative to standard colonoscopy in screening asymptomatic people, requiring no sedation
b. it has similar sensitivity in detecting polyps > 5 mm
c. it is a workup alternative for patients at high risk for bleeding or anesthesia complications
d. there is negligible risk of colorectal perforation
e. detected significant lesions typically require subsequent conventional colonoscopy for biopsy or removal
f. all of the above

13. Depending on the protocol performed, pelvic MRI can be used to

a. evaluate neurological and musculoskeletal disease
b. evaluate gynecological pathology
c. detect and stage prostate cancer
d. stage rectal cancer
e. assess for pelvic floor weakness
f. all of the above

14. Match the following abdominal/pelvic CT studies with their primary indication:

Noncontrast scan	a. assess blood vessels
CT angiogram	b. detect kidney stones
CT urogram	c. assess for intestinal disease
CT enterography	d. detect stones, renal and ureteral masses

ANSWER KEY: 1. C,A,B, 2. A, 3. F, 4. F, 5. A & B, 6. D, 7. B,C,A, 8. E, 9. B, 10. B, 11. D, 12. F, 13. F, 14. B,A,D,C

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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*. He is a consultant for AstraZeneca, Boehringer Ingelheim, Sanofi, and Novo Nordisk

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Things I Wish I Knew Last Year

Alcohol in Moderation: The Fountain of Youth

Winston, an otherwise healthy 52 y.o. man is obtaining a refill of his chlorthalidone for well-controlled hypertension. He has been a life-long non-drinker, but his wife and many of his friends consistently encourage him that 'alcohol in moderation helps you live longer', suggesting he should have a couple of drinks on a regular basis. He is dubious. Who's right?

a) Winston is correct. There is no mortality benefit
b) His friends are correct, but it only applies to lifelong imbibers
c) His friends are correct, and it's never to late to start drinking
d) It goes without saying that wives are always correct

Probably Your Baseline Premise….

"A substantial body of literature suggests that moderate alcohol consumption has health benefits."

Goulden R *Am J Med* 2016;129:180-186

The Presumed Benefits?

- Vs non-drinkers, an inverse relationship between alcohol and
  - CV disease
  - All-cause mortality

Goulden R *Am J Med* 2016;129:180-186

Confounders: Abstainers

Abstainers =

- non-drinkers by choice
- Persons who sustained alcohol toxicity and then stopped

Goulden R *Am J Med* 2016;129:180-186

ETOH & Mortality: HRS
Health and Retirement Study

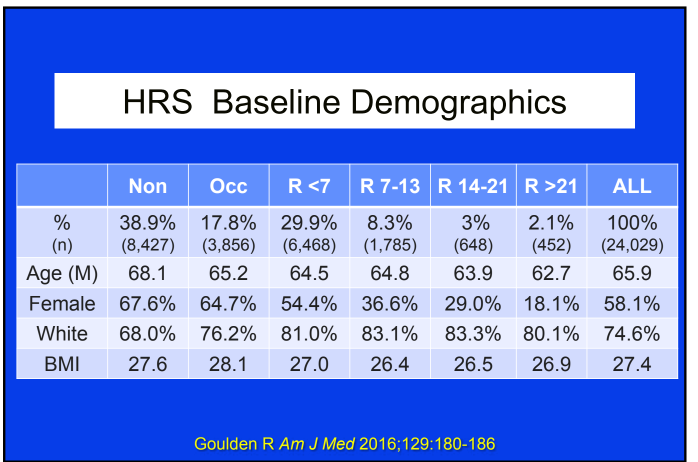
- Prospective observational study (n = 28,083)
- Inclusion: adults > 50 years
- Method: live interview q2y 1994-2012
- 6 Comparison groups

Goulden R *Am J Med* 2016;129:180-186

HRS Comparison Groups
Health and Retirement Study

Categorization	# Alcohol Drinks per week
Nondrinker	No alcohol
Occasional Drinker	1 drink ever, but always <1/week
Regular <7	1-7
Regular 7-13	7-13
Regular 14-21	14-21
Regular >21	>21

Goulden R *Am J Med* 2016;129:180-186



HRS Baseline Demographics

	Non	Occ	R <7	R 7-13	R 14-21	R >21	ALL
% (n)	38.9% (8,427)	17.8% (3,856)	29.9% (6,468)	8.3% (1,785)	3% (648)	2.1% (452)	100% (24,029)
Age (M)	68.1	65.2	64.5	64.8	63.9	62.7	65.9
Female	67.6%	64.7%	54.4%	36.6%	29.0%	18.1%	58.1%
White	68.0%	76.2%	81.0%	83.1%	83.3%	80.1%	74.6%
BMI	27.6	28.1	27.0	26.4	26.5	26.9	27.4

Goulden R *Am J Med* 2016;129:180-186

HRS Baseline Demographics

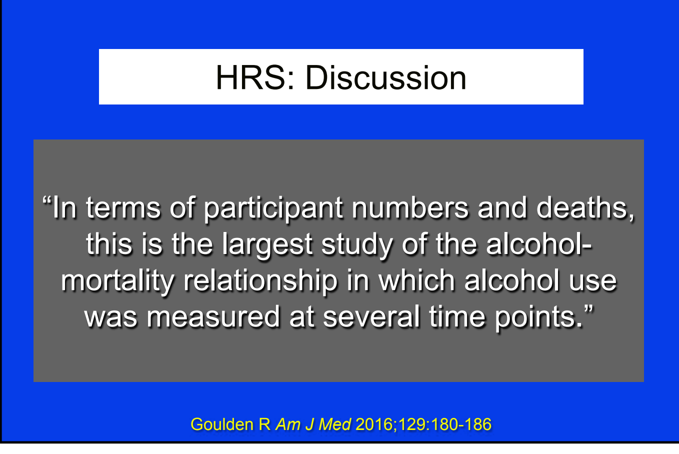
	Non	Occ	R <7	R 7-14	R 14-21	R >21	ALL
Ever Smoker (%)	42.7	51.4	58.7	73.3	81.5	84.0	53.2
Heart Disease (%)	15.2	12.7	10.3	10.8	8.2	8.9	12.6
DM (%)	15.6	10.3	7.2	5.0	4.6	7.5	10.8
CA (%)	6.8	7.2	6.6	7.6	6.9	6.6	6.9

Goulden R *Am J Med* 2016;129:180-186

HRS Outcome: Mortality Hazard Ratio

	H.R.	p
Occasional Drinker	1.00	
Lifetime Nondrinker	1.16 (0.95-1.43)	NS
Regular Alcohol Drinkers		
< 7 drinks/wk	0.99 (0.82-1.23)	NS
7-13 drinks/wk	1.21 (0.91-1.61)	NS
14-21 drinks/wk	1.30 (0.88-1.99)	NS
>21 drinks/wk	1.49 (0.97-2.29)	NS
Former Drinker Now Abstinent	1.26 (1.05-1.53)	P< 0.05

Goulden R *Am J Med* 2016;129:180-186



HRS: Discussion

"This study found no evidence* of an association between any level of regular alcohol consumption and reduced all-cause mortality."

* Emphasis added

Goulden R *Am J Med* 2016;129:180-186

HRS: Bottom Line Conclusions

"This analysis…suggests that the previously observed association between alcohol and ↓mortality does not reflect a causal relationship, and adequate adjustment for potential biases removes any association."

Goulden R *Am J Med* 2016;129:180-186

A Man with Concerning Changes in Function

Albert is a 62 y.o. Caucasian man whose wife, a neurology P.A., reports about 6 months of episodes of getting lost while driving, mismanagement of his job at the local grocery store, and dramatic variations in his attention span. His memory seems minimally impaired, if it all. He does not drink alcohol, has had no head trauma, and his only medication is loratidine for seasonal allergic rhinitis. She is suspicious that this may be early Lewy Body Dementia. An appropriate next step would be

a) Perform a CT Brain
b) Perform Lewy Body Composite Risk Score
c) Alzheimers/Schmaltzheimers: what difference does it make?
d) Obtain UDT for illicit substances

Differentiating the Dementing Disorders: Why Bother?

"One of the great challenges in differential Dx of neurodegenerative disorders is attributing clinical Sx to specific pathologies to guide Rx choices and discuss prognosis and clinical course."

Galvin JE *Alzheimer's & Dementia* 2015;1:316-324

Where Did the LBCRS Come From? (Lewy Body Composite Risk Score)

"The LBCRS was derived from clinical features in autopsy-verified cases of healthy controls, Alzheimer's disease, Lewy body dementia, and Parkinson's disease with and without dementia."

Galvin JE *Alzheimer's & Dementia* 2015;1:316-324

Lewy Body Composite Risk Score*

	Does the patient have: **(Physical findings over the past 6 months and Sx ≥ 3 times over the past 6 mo)**
1	Slowness in initiating/maintaining movement or have frequent hesitations or pauses during movement
2	Rigidity with/without cogwheeling on passive ROM
3	Postural instability with/without frequent falls
4	Tremor at rest in the 4 extremities or head
5	Excessive daytime sleepiness/lethargy when awake
6	Episodes of illogical thinking/incoherent, random thoughts
7	Frequent staring spells or periods of blank looks
8	Visual hallucinations
9	Dream enactment (eg kick, punch, thrash, scream)
10	OH or other signs of autonomic insufficiency

*adapted

Galvin JE *Alzheimer's & Dementia* 2015;1:316-324

Lewy Body Composite Risk Score*

		AD	LBD	Vasc D	FTD
	Total	2.4	6.1	2.9	2.4
1	Bradykinesia	54%	97.6%	66.7%	75%
2	Rigidity	5.7%	70.7%	0.0%	0.0%
3	Postural instability	21.8%	70.7%	0.0%	12.5%
4	Rest tremor	9.2%	36.6%	0.0%	0.0%
5	Daytime sleepiness	60.9%	92.7%	33.3%	50.0%
6	Illogical thoughts	48.3%	72.5%	66.7%	37.5%
7	Staring spells	23.0%	55.5%	33.3%	50.0%
8	Hallucinations	9.2%	53.7%	0.0%	0.0%
9	RBD	4.6%	41.5%	0.0%	0.0%
10	Autonomic insufficiency	1.2%	25.9%	0.0%	0.0%

Galvin JE *Alzheimer's & Dementia* 2015;1:316-324 *adapted

Back to "Why Should I Care?"

"One of the most critical and distinctive clinical features of the disease is hypersensitivity to neuroleptic and antiemetic medications that affect dopaminergic and cholinergic systems."

Wikipedia "Dementia with Lewy Bodies" Accessed 12/16/17

Back to "Why Should I Care?"

"In the worst cases, a patient treated with these medications could become catatonic, lose cognitive function or develop life-threatening muscle rigidity."

Wikipedia "Dementia with Lewy Bodies" Accessed 12/16/17

Lewy Body Disease: Common Meds to Be Restricted

- Chlorpromazine
- Halperidol
- Thioridiazine

Wikipedia "Dementia with Lewy Bodies" Accessed 12/16/17

Lewy Body Dementia: Medication Issues

"…traditional antipsychotic[s] (e.g., haloperidol, thioridazine)… prescribed for…Alzheimer's disease…. can cause a severe worsening of movement and a potentially fatal condition…neuroleptic malignant syndrome [which] causes severe fever, muscle rigidity and…can lead to kidney failure."

Lewy Body Dementia Association Home Page accessed 12/17/17

Heart Failure Better, But Fatigue and Joint Pain

A 62 y.o. AA man with HFrEF has been Rx X 2 yrs with simvastatin 20 mg/d, valsartan/sacubitril (Entresto), metoprolol XL, spironolactone, isosorbide/hydralazine (Bidil), and furosemide for the last 2 years. He has recently noted increased fatigue, hand/wrist joint pain, and loss of appetite. His ANA is positive (1:160), RF negative, anti-Sm negative. One of his meds is the culprit. Which one?

a) Valsartan/sacubitril (Entresto)
b) Metoprolol XL (Toprol XL)
c) Spironolactone (Aldactone)
d) Isosorbide/hydralazine (Bidil)
e) Furosemide (Lasix)

HFrEF in African Americans Pharmacologic Menu 2018

1) Valsartan/Sacubitril
2) ACE or ARB if #1 Not Accessible
3) Beta Blocker (bisoprolol, carvedilol, metoprolol)
4) Aldosterone antagonist (eplerenone, spironolactone)
5) Isosorbide dinitrate/Hydralazine (Bidil)
5) Loop diuretic (furosemide, bumetanide)

What's Goin' On with Hydralazine?

"…the use of hydralazine as an antihypertensive and HF medication has increased tremendously in the last decade since the publication of the A-HeFT trial. This was due to an overwhelming 45% reduction in mortality seen in black patients….

Iyer P et al *Case Reports in Rheumatology* 2017;Article ID5245904

Drug-Induced Lupus: How Common?

"Approximately 10.4% of patients on 200 mg or higher dose of hydralazine develop it after at least 3 months of treatment."

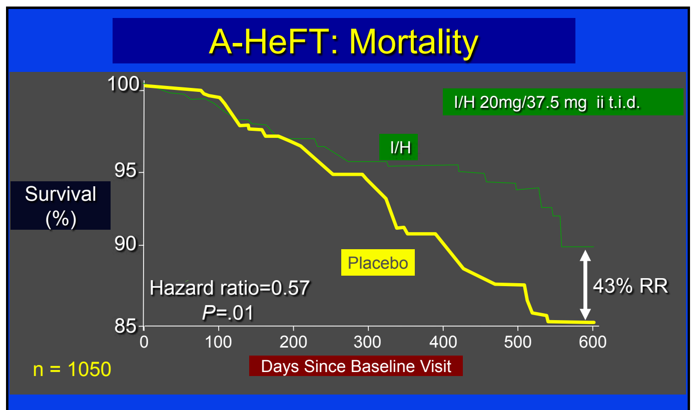
Iyer P et al *Case Reports in Rheumatology* 2017;Article ID5245904

Drug-Induced Lupus: Clinical Presentation

"…clinical manifestations include arthralgia, myalgia, fever, and serositis….renal, pulmonary, visceral, and CNS systems are usually spared."

Iyer P et al *Case Reports in Rheumatology* 2017;Article ID5245904

A-HeFT: Mortality



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

Hydralazine-Induced Lupus: Key Points

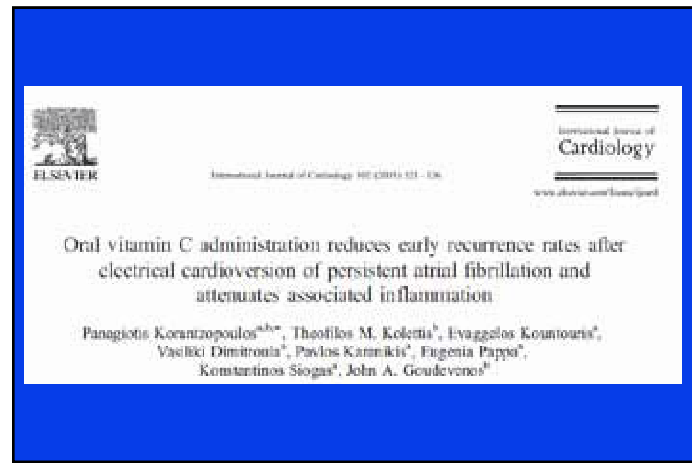
- Slow onset: ≥3-6 months, usually 9-40 months
- Potential + lab: ANA, antihistone-ab, RF
- Usually – lab: Sm antibody
- ANA at hydralazine initiation suggested
- No F/u for aSx + ANA
- D-C hydralazine if Sx or Signs of SLE
- Adverse effects remit upon D-C
- Can occur with as little as 50 mg/d

Self TH, Owens RE *Consultant* 2015;December:1046-1048

Reducing A Fib Recurrences Post Cardioversion

An 83 y.o. ♀ underwent successful electrical cardioversion for persistent atrial fibrillation. She is receiving amiodarone 200 mg t.i.d. and anticoagulation. Is there anything you, as the primary care clinician, can recommend to reduce risk of early atrial fibrillation recurrence?

a) Recommend bed rest
b) Initiate a beta blocker (e.g., metoprolol)
c) Initiate a calcium channel blocker(e.g., diltiazem)
d) Initiate Vitamin C



International Journal of Cardiology

Oral vitamin C administration reduces early recurrence rates after electrical cardioversion of persistent atrial fibrillation and attenuates associated inflammation

Panagiotis Korantzopoulos, Theofilos M. Kolettis, Evaggelos Kountouris, Vasiliki Dimitroula, Pavlos Karanikis, Eugenia Pappa, Konstantinos Siogas, John A. Goudevenos

Reducing Atrial Fib Recurrences: Why Vitamin C?

- Animal data: reduces atrial electrical remodeling
- ↓ Postop atrial fib in cardiac surgery
- Inflammation and oxidative stress believed to play a role

Korantzopoulos P, et al *Am J Cardiol* 2005;102:321-326

Reducing Atrial Fib Recurrences: Vitamin C

- Study: Atrial fib post successful cardioversion
- Rx: S.O.C. (coumadin, amiodarone)
- \+ Vit C 2 g load 12 hrs pre-Rx then 500 mg b.i.d. vs placebo X 1 week
- Outcome: atrial fib recurrence rate

Korantzopoulos P, et al *Am J Cardiol* 2005;102:321-326

Atrial Fib Recurrences & Vit C Results

	Vit C	Placebo	p
Atrial Fib Recurrence	4.5%	36.3%	0.024

Korantzopoulos P, et al *Am J Cardiol* 2005;102:321-326

Vit C for Atrial Fib Recurrences Systematic Review 2017

- Study: metaanalysis 15 trials (n = 2, 050)
- Inclusion: AF post cardiac surgery or AF cardioversion patients
- Intervention: Vit C vs placebo

Hemila H, Suonsyrja T *BMC Cardiovascular Disorders* 2017;17:49

Vit C for Atrial Fib Recurrences Systematic Review 2017

Population	Location	# Trials	RR	p
Post Op AF	US	5	1.04 (0.86-1.27)	NS
	Greece, Russia, Slovenia	4	0.71 (0.54-0.93)	0.01
	Iran	5	0.49 (0.39-0.62)	< 0.001
Cardioversion	Greece	1	0.73 (0.64-0.83)	<0.001

Hemila H, Suonsyrja T *BMC Cardiovascular Disorders* 2017;17:49

Cry-Baby

A 10-week old exclusively breastfed baby has unexplained crying episodes lasting about 3.5 hours/d on most days of the week for the last month. ROS otherwise negative. No fever, abdominal swelling. Growth normal. A safe, effective evidenced-based recommendation would be

a) Simethicone (eg, Infant's Mylicon)
b) dicyclomine (eg, Bentyl)
c) Lactobacillus reuteri probiotics DSM 17938
d) Lactobacillus reutier probiotics ATCC 55730
e) Omeprazole (Prilosec)

Colic L reuteri DSM 17938

- Study: Infant colic (Wessel's criteria) (n = 50)
- Rx: L reuteri DSM 17938 vs placebo x 21 d
- Outcomes
  - Crying time (mins/d)
  - Stool lactobacilli
  - Stool E Coli
  - Stool ammonia

Savino F et al Pediatrics;2010:e526-e533

How was the *Lactobacillus reuteri* Administered?

- Freeze-dried L reuteri DSM 17938 suspension in sunflower oil and medium chain triglceride oil mixture
- Provided in 5 ml dropper-cap bottles
- 5 gtts qd 30 mins prior to morning feed

Savino F et al Pediatrics;2010:e526-e533

Infantile Colic: Wessel Criteria (Rule of 3's)

- Episodes of fussy crying
  - ≥3 hrs/d
  - ≥ 3 days/week
  - ≥ 3 weeks

Johnson JD, Cocker K, Chang E Am Fam Phys 2015;92(7):577-582

Infantile Colic: Red Flags

- Abdominal distension
  - Mass, Hirschprung, volvulus, colitis
- Fever
  - AOM, appendicities, meningitis, UTI pneumonia, sepsis, URI
- Lethargy
  - Meningitis, sepsis, hematoma, hydrocephalus

Johnson JD, Cocker K, Chang E Am Fam Phys 2015;92(7):577-582

Infantile Colic: Simethicone SAFE, but NOT EFFECTIVE

"Although simethicone drops are readily available and often used to Rx colic a systematic review of 3 RCTs found that they are no better than placebo."

Johnson JD, Cocker K, Chang E Am Fam Phys 2015;92(7):577-582

Infantile Colic: Omeprazole Probably SAFE, but NOT EFFECTIVE

"A 4-wk RCT of 30 infants with colic Sx and GER or esophagitis found that omeprazole (Prilosec) was no better than placebo at reducing crying or fussing time."

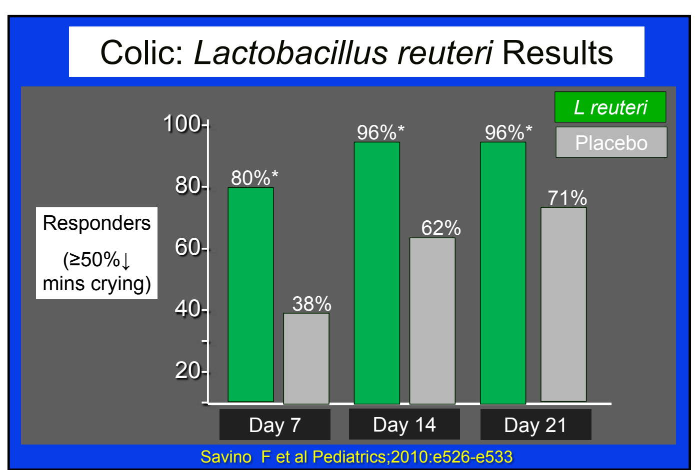
Johnson JD, Cocker K, Chang E Am Fam Phys 2015;92(7):577-582

Infantile Colic: Dicyclomine Efficacious, But NOT SAFE

"Although a systematic review of 3 RCTs found that dicyclomine was significantly better than placebo for the Rx of colic, it is contraindicated in infants < 6 months because of AEs such as drowsiness constipation, diarrhea, and apnea."

Johnson JD, Cocker K, Chang E Am Fam Phys 2015;92(7):577-582

Colic: *Lactobacillus reuteri* Results



Savino F et al Pediatrics;2010:e526-e533

L reuteri for Infantile Colic Conclusions

"…*L reuteri* 17938…in early breastfed infants improved Sx….and was well tolerated and safe….Gut microbiota changes induced by the probiotic could be involved in the observed clinical improvement."

Savino F et al Pediatrics;2010:e526-e533

Helping Folks During Opioid Discontinuation

An otherwise healthy 32 y.o. who had been taking oxycodone/acetaminophen 10 mg t.i.d. since an auto accident 3 years is ready to quit them, but says every time he stops, he gets problematic withdrawal Sx. What might help his opioid discontinuation more tolerable?

a) Baclofen (Lioresal)
b) Carisoprodol (SOMA)
c) Diazepam (Valium)
d) Assert "Tough it out, it'll make a better man of you."

Opioid Withdrawal: Baclofen VS Clonidine

- Study: ♂opioid addicts (as per DSM IV)
- Rx X 14 days (4 d titration):
  - baclofen q.d.(15 mg/d → 40 mg/d) vs
  - clonidine t.i.d.(0.3 mg/d → 0.8 mg/d)
- Outcomes:
  - Short Opiate Withdrawal Scale
  - Mental Sx

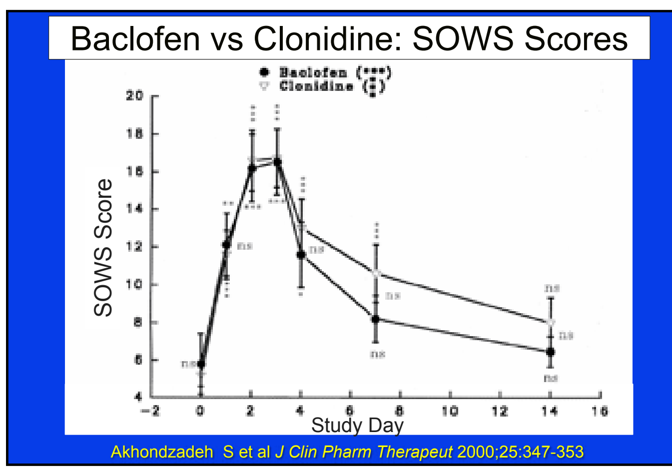
Akhondzadeh S et al *J Clin Pharm Therapeut* 2000;25:347-353

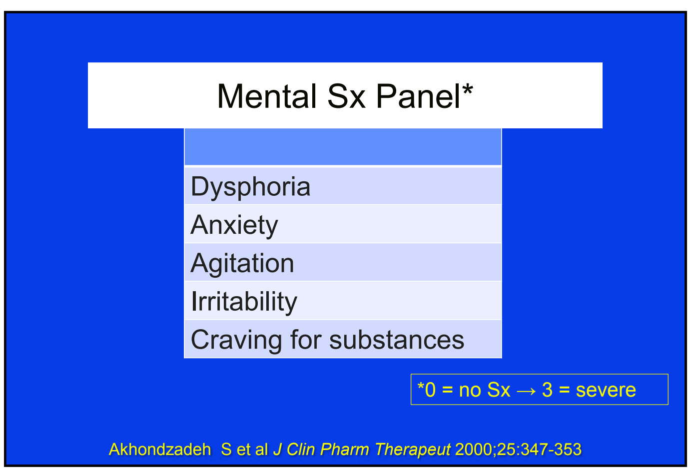
Short Opiate Withdrawal Scale*

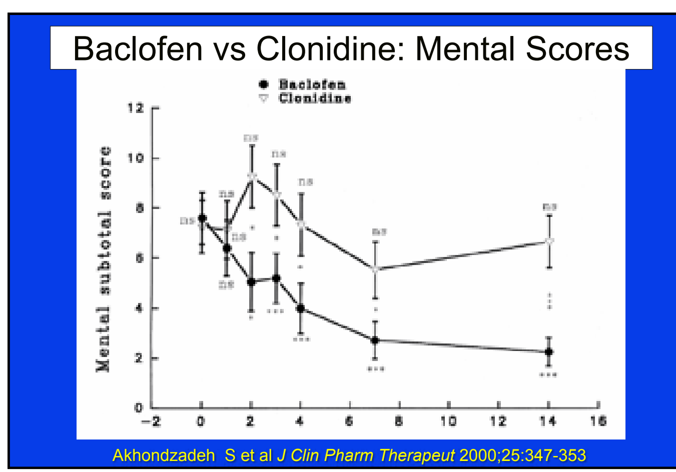
Feeling Sick	Muscle tension
Stomach cramps	Aches and pains
Muscle spasm/twitching	Yawning
Feeling cold	Runny eyes
Heart pounding	Insomnia

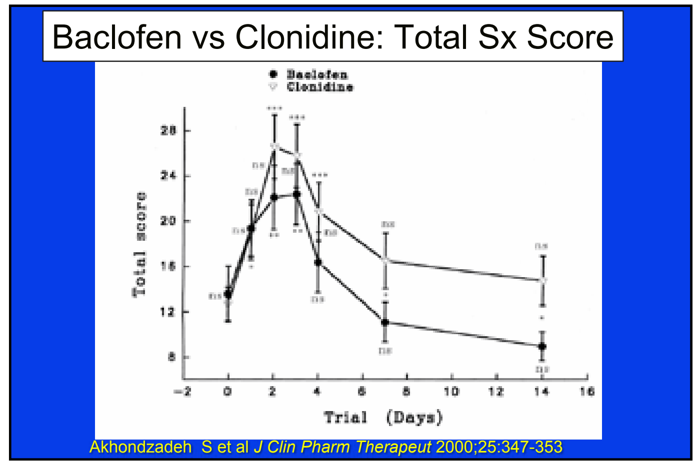
*0 = no Sx → 3 = severe

Akhondzadeh S et al *J Clin Pharm Therapeut* 2000;25:347-353





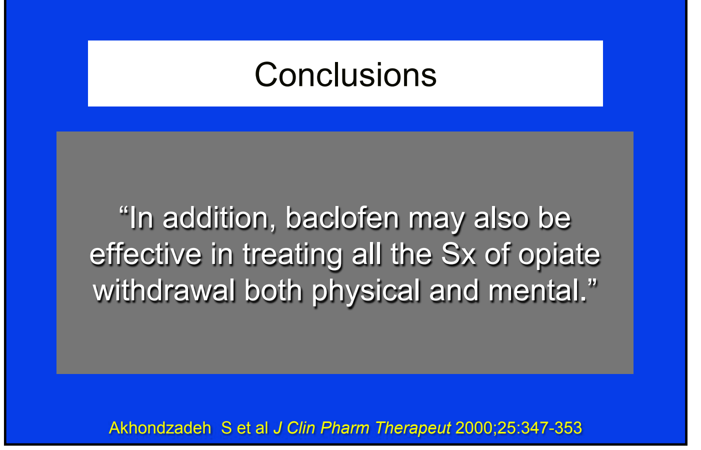




Conclusions

"Our main overall findings were that baclofen and clonidine are broadly effective in reducing physical Sx of acute opiate withdrawal syndrome."

Akhondzadeh S et al *J Clin Pharm Therapeut* 2000;25:347-353



Study Limitations

- All male enrollees
- 62 enrolled, 30 completers
  - Baclofen dropouts = 14
  - Clonidine dropouts = 18

Akhondzadeh S et al *J Clin Pharm Therapeut* 2000;25:347-353

Opioid Discontinuation: Helping Folks K.O.K.O.

An otherwise healthy 32 y.o. who had been taking oxycodone/acetaminophen 10 mg t.i.d. since an auto accident 3 years ago stopped meds 2 weeks ago. His UDT is clear. He reports 'having a hard time staying off the stuff' & is considering heroin, which is cheap and readily accessible in the community. What might be an appropriate consideration to make maintenance of his opioid discontinuation more tolerable?

a) Baclofen (Lioresal)
b) Carisoprodol (SOMA)
c) Diazepam (Valium)
d) Assert "Tough it out, it'll make a better man of you."

Low Libido in a Young Man

A 52 y.o. truck driver has declined surgical intervention for severe spinal stenosis at the L3-L4 level. He has had adequate pain control using hydrocodone 5 mg/acetaminophen (e.g., Lortab, Vicodin) b.i.d. for the last 3 months, but has begun to notice decreased libido. He also takes atorvastatin 10 mg/d and lisinopril 20 mg/d. What is the most probable cause?

a) Nerve root compression from spinal stenosis
b) Neuropathy from the statin
c) Opioid induced androgen deficiency
d) Renal insufficiency from the ACEi reducing libido

TST Replacement in OPIAD

"Clinicians need to be aware of the endocrinologic effects of opioid therapy and offer TST Rx when clinically indicated…."

Raheem OA, et al Am J Men's Health 2017;11(4):1208-1213

Commentary

PAIN

Endocrinopathies in women during opioid therapy cause loss of androgens, fatigue, listlessness, loss of libido and quality of life: stop prescribing opioids or follow the 2016 Centers for Disease Control and Prevention guidelines?

Harald Breivik, Audun Stubhaug Pain 2017;158(1):1-3

OPIAD Is Probably: More Common Than You Thought

"The reported prevalence of opioid induced hypogonadism ranges from 21% to 86%."

Reddy RG, et al BMJ 2010;341:c4462:1-6

OPIAD Is Probably: More PROMPT & INTENSE Than You Thought

"Testosterone concentrations seem to drop more than 50% within a few hours of taking an opioid…."

Reddy RG, et al BMJ 2010;341:c4462:1-6

OPIAD Is Probably: More PERSISTENT Than You Thought

"…[although] usually returning to baseline within 24-72 hours after withdrawal…depending on the dose used, it may take up to a month to recover."

Reddy RG, et al BMJ 2010;341:c4462:1-6

Low Testosterone Levels Are Associated With Increased All-Cause Mortality

VA 8-year study of 858 men

Low T <250 ng/dL or a free T <0.75 ng/dL

All-cause mortality was 34.9% in men with low and 20.1% in men with normal T

Shores MM, Matsumoto AM, Sloan KL, Kivlahan DR. *Arch Intern Med.* 2006;166:1660-1665.

OPIAD: Incidence?

"Unfortunately, PRCT data regarding the occurrence of OPIAD in humans is virtually non-existent."

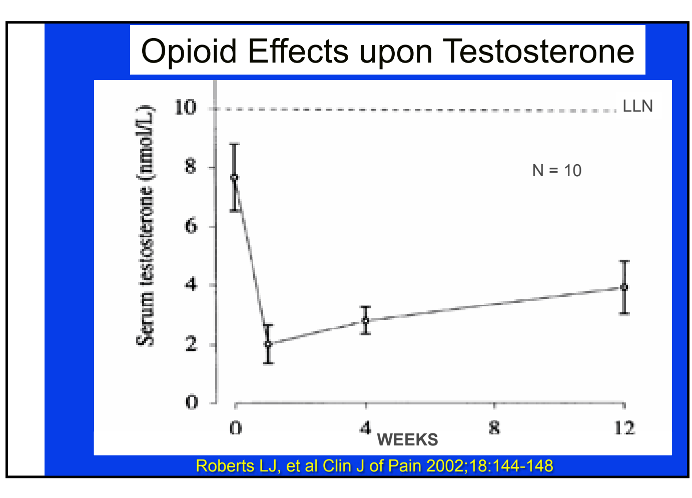
Smith HS, Elliott JA OPIAD *Pain Physician* 2012;15:ES145-ES156

Opioid Effects upon Testosterone

"…there are no studies examining the effects of oral opioids on [HPG] axis in patients with chronic noncancer pain."

Roberts LJ, et al Clin J of Pain 2002;18:144-148

Opioid Effects upon Testosterone



Roberts LJ, et al Clin J of Pain 2002;18:144-148

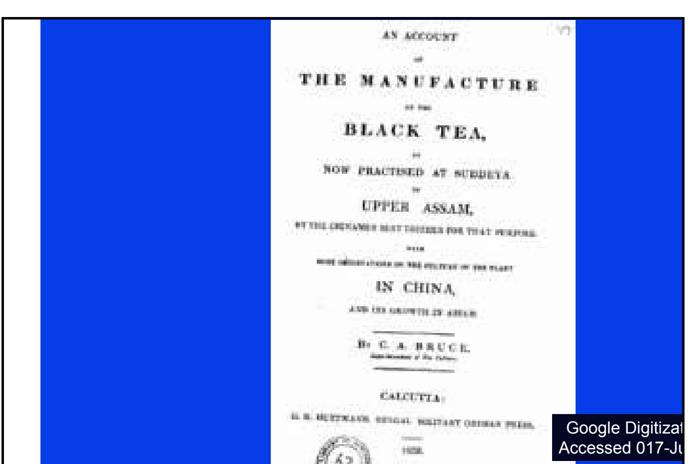
OPIAD Definitions

- Men on opioids
  - New Sx of hypogonadism (especially low libido) confirmed with subnormal testosteror
- Women on opioids
  - New Sx of hypogonadism (especially menstrual irregularity, HSDD) confirmed in the absence of another cause

Steroids
Volume 22, Issue 4, October 1973, Pages 467-472

Decreased serum testosterone concentration in male heroin and methadone addicts

Fereidoun Azizi M.D., Apostolos G. Vagenakis M.D., Christopher Longcope M.D., Sidney H. Ing M.D., Lewis E. Braverman M.D.


AN ACCOUNT
OF
THE MANUFACTURE
OF THE
BLACK TEA,
AS
NOW PRACTISED AT SUDDEYA
IN
UPPER ASSAM,
IN CHINA,
BY C. A. BRUCE,
CALCUTTA:

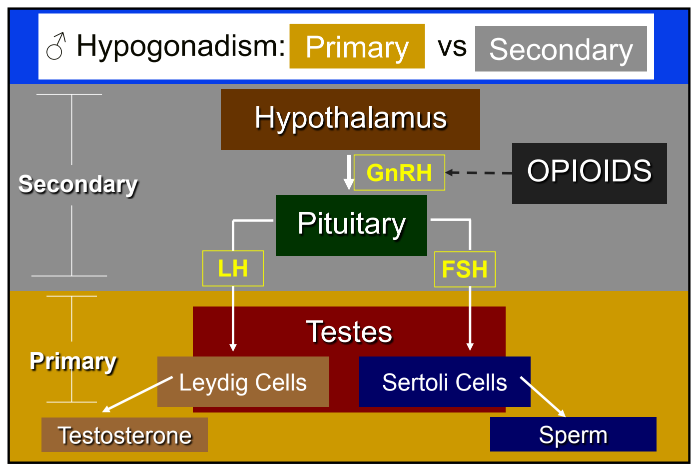
"…Opium….has kept and does now keep down the population: the women have fewer children than those of other countries….the feeble [male] opium smokers of Assam… are more effeminate than women."

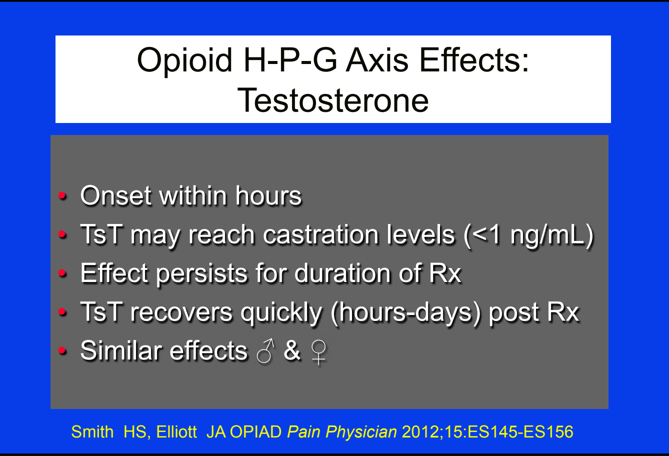
CA Bruce Superintendant of Tea Culture18
Cited in *Pursuit of Oblivion* Davenport-Hines R W.W. Norton 20

FSH Does WHAT?
LH Does WHAT?

FSH & LH

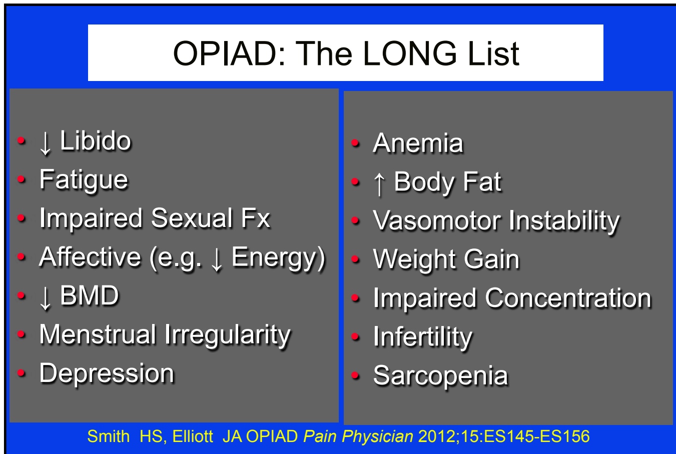
- F is for FERTILITY
  - ♂ FSH → Spermatozoa (Sertoli Cells)
  - ♀FSH → Follicle Maturation (Ovulation)
- L is for LIBIDO
  - ♂ LH → Testosterone (Leydig Cells)
  - ♀ LH → Testosterone (Theca cell)

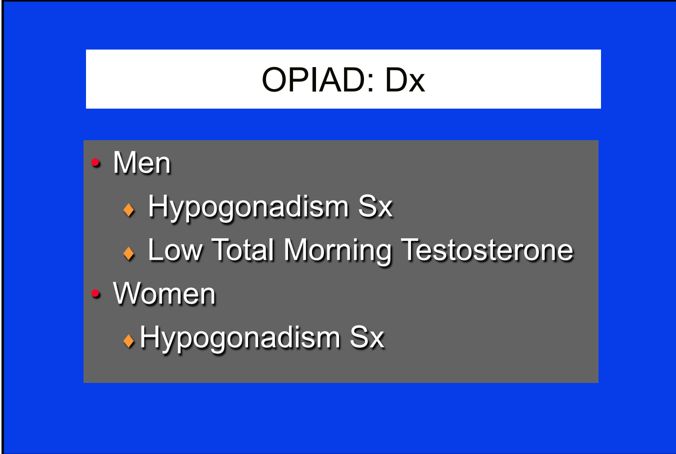


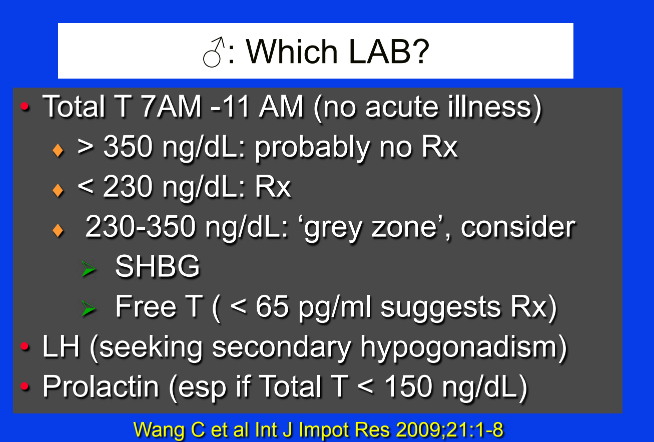


OPIAD: The Short List

- ↓Libido
- Fatigue
- Impaired Sexual Function
- Affective Changes



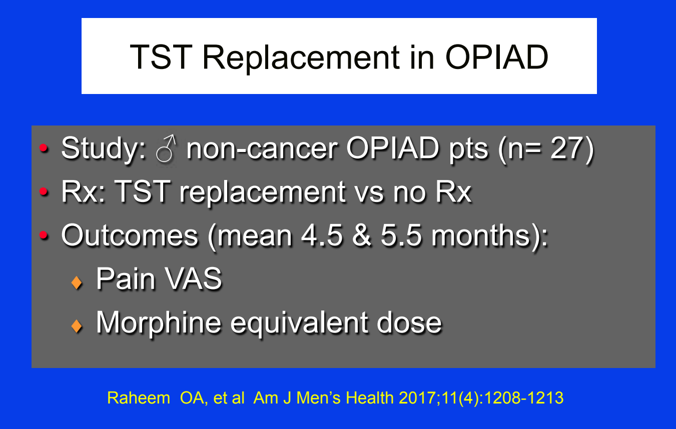


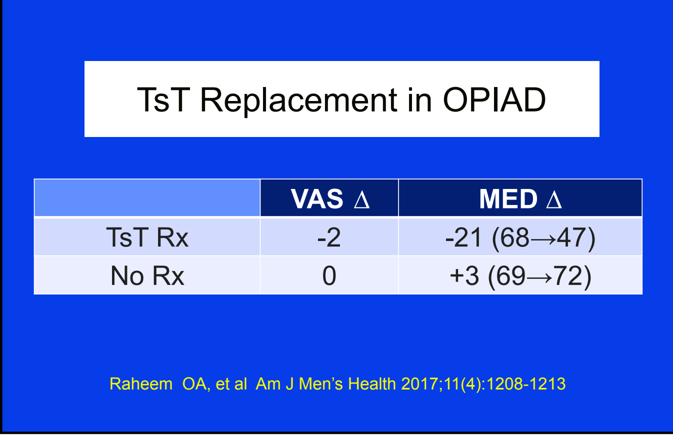


Article

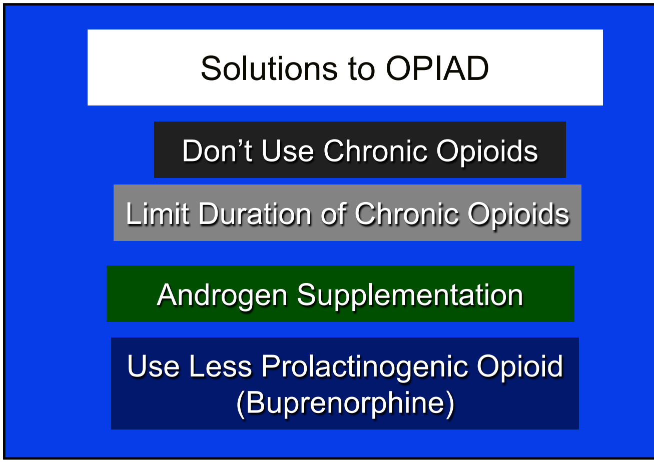
The Role of Testosterone Supplemental Therapy in Opioid-Induced Hypogonadism: A Retrospective Pilot Analysis

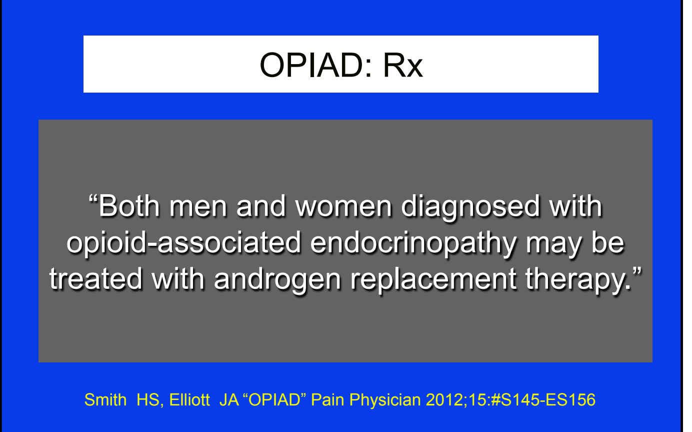
Omer A. Raheem, MD[1], Sunil H. Patel, MD[1], David Sisul, MD[1], Tim J. Furnish, MD[2], and Tung-Chin Hsieh, MD[1]





	VAS Δ	MED Δ
TsT Rx	-2	-21 (68→47)
No Rx	0	+3 (69→72)





OPIAD Rx ♀: DHEA

"It is recommended that women take a 50 mg dose of DHEA daily if this is to be used as androgen replacement therapy."

Smith HS, Elliott JA "OPIAD" Pain Physician 2012;15:#S145-ES156

Your MI Patient's 'Teachable Moment'

A 54 y.o. chronic smoker with dyslipidemia had an acute MI 6 months ago. Because he has recently remarried and has a new 9 month baby, he has decided to make "whatever changes it takes"! According to clinical trial data, which intervention provides him the greatest risk reduction?

a) Smoking cessation
b) His post-MI beta blocker
c) Statins
d) Mediterranean diet

Mediterranean Diet Preconceptions?

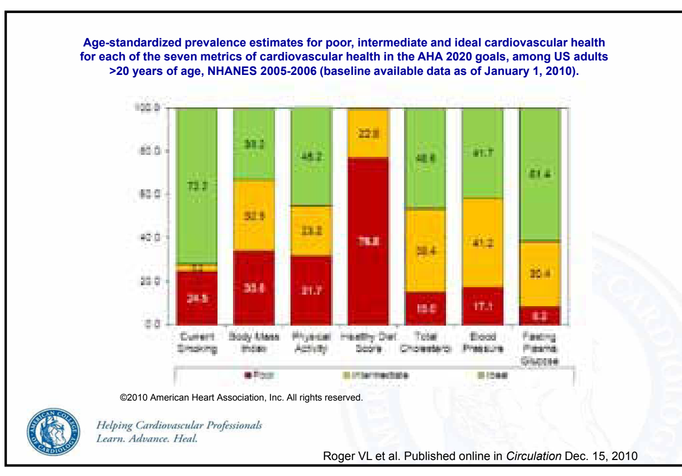
- Why
  - It must not be all that effective, or else we'd all be doing it already
  - Even if it is effective, other stuff (statins, BP control, smoking cessation) must be much better
- How
  - I'm not a dietician, and not about to become one: NEXT TOPIC
  - Messing with diet is too complicated and time consuming: NEXT TOPIC

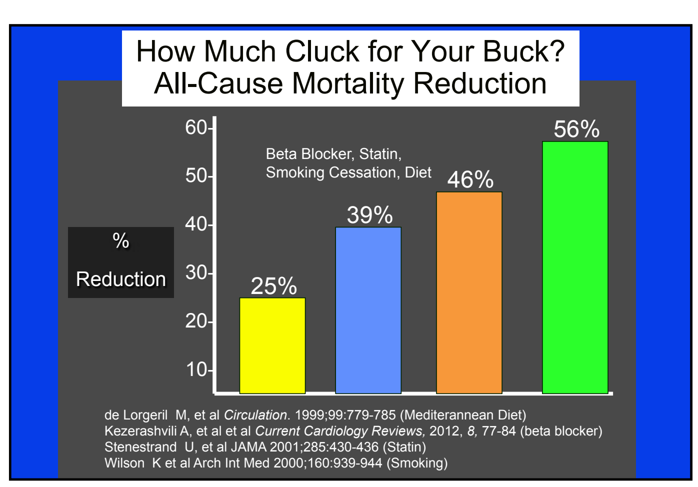
Nutrition, physical activity and NCD prevention

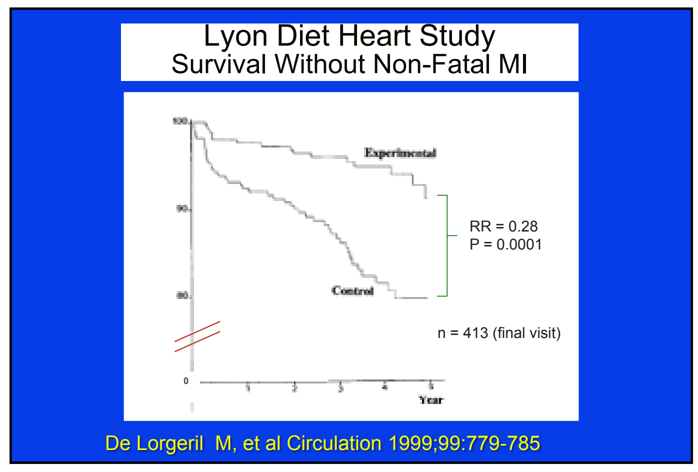
- Up to **80% of heart disease, stroke and type 2 diabetes** and over a third of the most common cancers **could be prevented** by eliminating obesity, unhealthy diets and physical inactivity

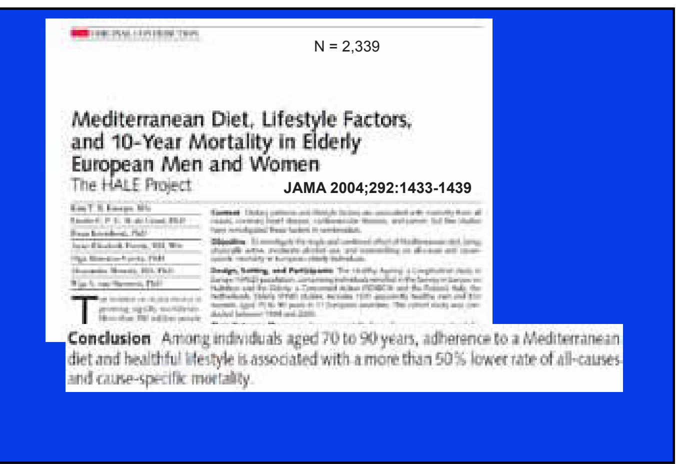
- Call for commitments at the global and national level to address these risk factors including:
  - Control food supply, food information and marketing and promotion of energy-dense, nutrient-poor foods that are **high in saturated, trans-fat, salt or refined sugars**

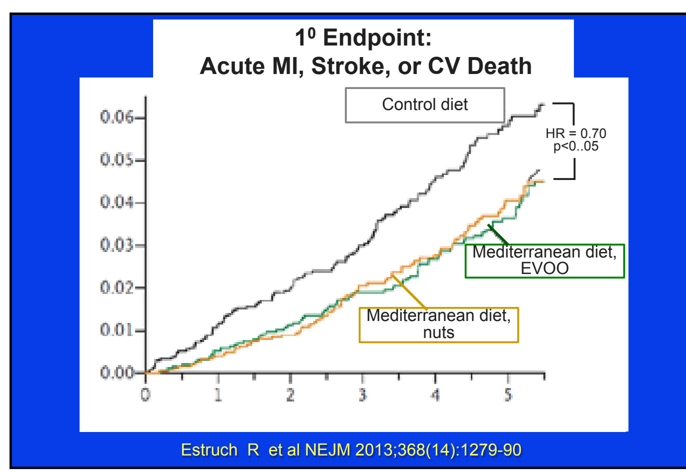
Helping Cardiovascular Professionals
Learn. Advance. Heal.



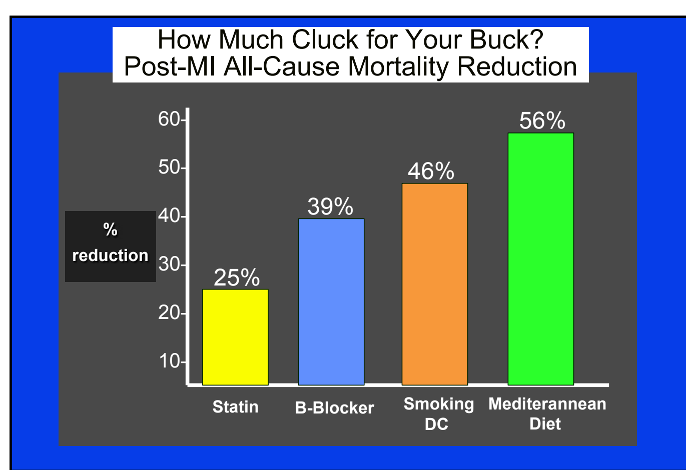


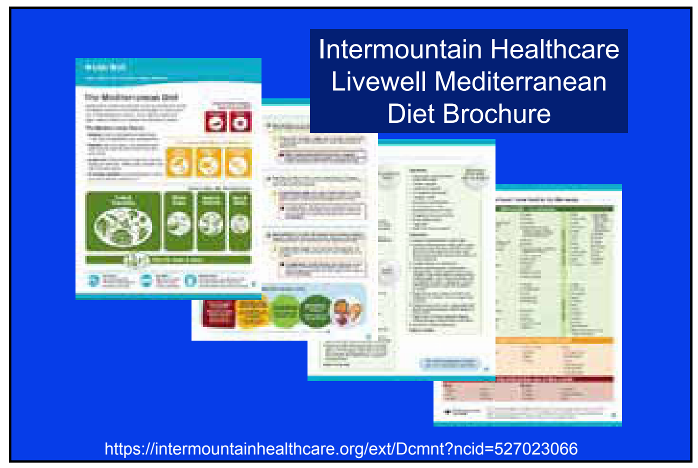

Lyon Diet Heart Study
Survival Without Non-Fatal MI
Experimental
Control
RR = 0.28
P = 0.0001
n = 413 (final visit)
Year
De Lorgeril M, et al Circulation 1999;99:779-785

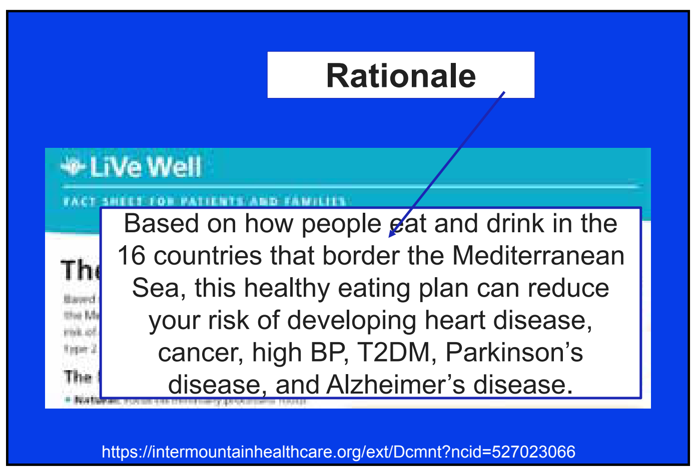

N = 2,339
Mediterranean Diet, Lifestyle Factors, and 10-Year Mortality in Elderly European Men and Women
The HALE Project
JAMA 2004;292:1433-1439
Conclusion Among individuals aged 70 to 90 years, adherence to a Mediterranean diet and healthful lifestyle is associated with a more than 50% lower rate of all-causes and cause-specific mortality.


1⁰ Endpoint:
Acute MI, Stroke, or CV Death
Control diet
HR = 0.70
p<0..05
Mediterranean diet, EVOO
Mediterranean diet, nuts
Estruch R et al NEJM 2013;368(14):1279-90

Research
N = 447
Mean age = 67 years
JAMA Intern Med 2015;175(7):1094-1103
Original Investigation
Mediterranean Diet and Age-Related Cognitive Decline
A Randomized Clinical Trial
CONCLUSIONS AND RELEVANCE In an older population, a Mediterranean diet supplemented with olive oil or nuts is associated with improved cognitive function.

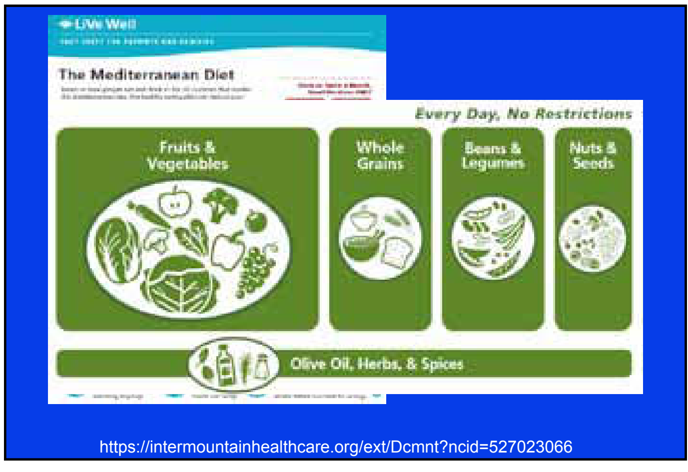

How Much Cluck for Your Buck?
Post-MI All-Cause Mortality Reduction
% reduction
25%
39%
46%
56%
Statin
B-Blocker
Smoking DC
Mediterannean Diet


Intermountain Healthcare Livewell Mediterranean Diet Brochure
https://intermountainhealthcare.org/ext/Dcmnt?ncid=527023066


Rationale
LiVe Well
FACT SHEET FOR PATIENTS AND FAMILIES
Based on how people eat and drink in the 16 countries that border the Mediterranean Sea, this healthy eating plan can reduce your risk of developing heart disease, cancer, high BP, T2DM, Parkinson's disease, and Alzheimer's disease.
https://intermountainhealthcare.org/ext/Dcmnt?ncid=527023066

LiVe Well
The Mediterranean Diet
Once or Twice a Month, Small Portions ONLY
Red Meat
Sweets
https://intermountainhealthcare.org/ext/Dcmnt?ncid=527023066

LiVe Well
The Mediterranean Diet
Throughout the Week, In Moderation
Fish & Seafood
Poultry & Eggs
Low-fat Cheese & Yogurt
https://intermountainhealthcare.org/ext/Dcmnt?ncid=527023066


LiVe Well
The Mediterranean Diet
Every Day, No Restrictions
Fruits & Vegetables
Whole Grains
Beans & Legumes
Nuts & Seeds
Olive Oil, Herbs, & Spices
https://intermountainhealthcare.org/ext/Dcmnt?ncid=527023066

Shopping List: Select at least 1 new food to try this week.
Go! Eat daily — no restrictions
Vegetables
Fruits
Herbs, Spices, and Oils
Whole Grains
https://intermountainhealthcare.org/ext/Dcmnt?ncid=527023066

LiVe Well
The Mediterranean Diet
Slow! Enjoy in moderation throughout the week
Fish & Seafood
Poultry & Eggs
Dairy
https://intermountainhealthcare.org/ext/Dcmnt?ncid=527023066

How to Locate the Intermountain Healthcare LiveWell Mediterranean Diet Brochure

https://intermountainhealthcare.org/ext/Dcmnt?ncid=527023066

SELF EVALUATION

Things I Wish I Knew Last Year

1. Your patient inquires about the health effects of social drinking. You should explain

a. Alcohol abstinence is always the best path
b. Alcohol in moderation is beneficial to health
c. The effects of alcohol in moderation upon health are essentially neutral
d. Alcohol in moderation is detrimental to health

2. An important reason to valuable to identify Lewy Body Dementia (LBD) is?

a. LBP is fully reversible with anticholergic treatment
b. Magnetic ablation of Lewy Bodies slows LBD progression
c. Antipsychotics (eg, haloperidol) can prevent catatonia in LBD
d. Antipsychotics (eg, haloperidol) can induce neuroleptic malignant syndrome in LBD

3. You have added isosorbide 20 mg/hydralazine 37.5 mg (Bidil) two tabs t.i.d. to your patients GDMT for HFrEF. Could this treatment produce drug-induced lupus?

a. No, because the isosorbide is protective
b. No, because the dose is insufficient to cause concern
c. Yes, but drug-induced lupus is limited to cutaneous signs
d. Yes, typical signs and symptoms of lupus can emerge at this dose

4. Which treatment for infant colic has demonstrated safety & efficacy in a RDBPCT?

a. Simethicone
b. Dicyclomine
c. Probiotic *Lactobacillus reuteri*
d. Omeprazole

5. Which of the following adverse effects of chronic opioid treatment is commonly persistent?

a. Nausea
b. Sedation
c. Opioid Induced Androgen Deficiency
d. Opioid Induced Xerophthalmia

6. Which oral treatment might be considered for treatment of female hypoandrogenic hypogonadism?

a. DHEA 50 mg/d
b. Medroxyprogesterone 20 mg/d
c. Finasteride 5 mg/d
d. Methyltestosterone 10 mg/d

7. The primary mechanism of action of SLIT (Sublingual Immunotherapy) is?

a. Blockade of interleukin-13
b. IgE immobilization
c. Generation of IgG
d. Augmentation of allergen-specific complement

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

Ike Z. Devji, Esq.

Ike Z. Devji, Esq., of Phoenix, Arizona, has been solely focused on asset protection and wealth preservation planning for the last 14 years. He and his colleagues have protected over $5 billion in personal assets for a national client base that includes thousands of successful physicians, as well as business owners and entrepreneurs. Mr. Devji is a noted national educator (CME, CLE and CE) and author with over 300 nationally published bylines and a frequent speaker having taught thousands of doctors, lawyers and advisors on asset protection and risk management in addition to being a contributing author to multiple books and a dozen medical journals. He is AVVO rated “10.0 Superb” for seven years in a row and is included in Arizona’s Finest Lawyers among other distinctions.

You may contact Mr. Devji with your questions or comments at (602) 808–5540, by email at ID@thewealthy100.com or through his website at www.ProAssetProtection.com.

Protecting Your Assets: Preventive Legal Medicine

What Exactly is "Asset Protection"?

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

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

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

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

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

TIMING IS EVERYTHING

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

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

Traditional Estate Planning is **"death planning"** that provides details and controls who gets your assets when you pass, how they are administered, who is appointed to manage your estate, and in many cases helps mitigate your estate tax exposure. This year, a married couple can pass roughly the first $10.9 Million dollars of their estate (or roughly $5.45 million each) to anyone they like free of federal estate tax. There is no estate tax on assets passed between spouses.

- **ASSET PROTECTION is LIFE PLANNING**; how you can help ensure that you and your family get to safely and predictably keep and enjoy your wealth **DURING** your life and that it will ultimately be there to go to your estate plan and protect your heirs at the end of your life as well
- Most People omit a good LIFE PLAN

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

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

Asset Protection Is a System of Layers

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

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

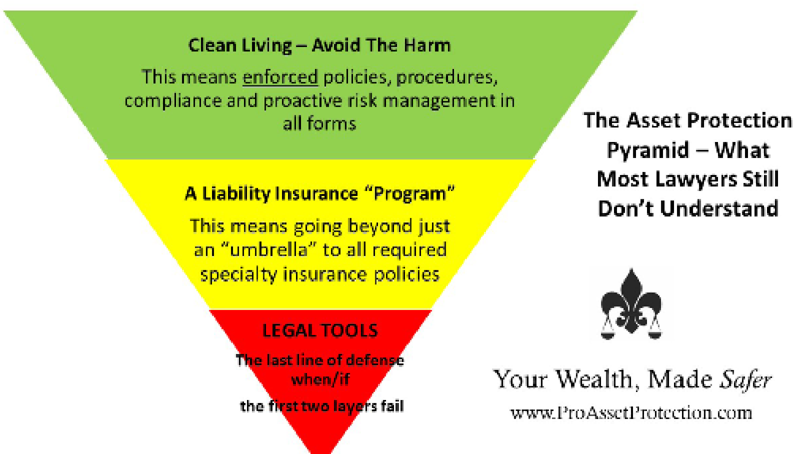
• **Proactively managing all your predictable risks, not just those related to medial malpractice.** We won't dwell on this issue beyond this; medical malpractice lawsuits are a real threat and no matter what various experts tell you about statistics, how many actually go trial, and etc. we have seen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

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

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

and experienced professional. **In other words, the familiar pattern of exam, diagnosis and then personalized treatment.** There may be a reasonable and proven course of treatment for any particular problem, but your advisors should always know what the problems are before they start proposing specific solutions.

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



What Does Asset Protection Achieve?

- Removes the economic incentive to sue, or aggressively pursue you
- Creates an incentive to settle within limits of applicable liability coverage if there is real liability – MAKES THE INSURANCE WORK
- Controls what is exposed in the event of a lawsuit judgment
- Legally separates personal and business assets and exposures
- Protects you from the internally generated liability of certain assets, like real estate
- Add additional surety and control to assets that will be distributed at your death by your estate

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

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

What Are The Risks You Need To Protect Yourself Against?

- The U.S. has the world's most litigious legal system, up to 70,000 lawsuits filed per day
- Cost of defending a frivolous lawsuit can exceed $91,000
- **A total of $3.6 billion was paid out for medical malpractice lawsuits in 2012,** and 48% of those payouts occurred in just five states, according to Diederich Healthcare's 2013 Medical Malpractice Payout Analysis.
- In 2012, there were a total of 12,142 medical malpractice payouts in the United States – accounting for

one about every 43 minutes. The medical malpractice insurance company based its analysis on 2012 data from the U.S. Department of Health and Human Services' National Practitioner Data Bank.

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

RISK FACTORS OF THOSE NEEDING ASSET PROTECTION

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

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

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

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

Don't fall for the trap of "**self insuring**" against risks – this really means "un-insured" – transfer the risk to someone else.

- Even the affluent must examine **disability** and **long term care insurance** – 40% of American bankruptcies are related to medical bills
- **Is your family, lifestyle and overhead based on your income? How long could you go without it?**
- Don't take **BIG** risks to avoid *small* expenses
- Just because you are doctors does not mean that you can not get sick or hurt, just like everyone else

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

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

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

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

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

2. Protecting Your Practice Against The Loss of Your Income Production With *Disability Overhead Expense Insurance*

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

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

Add Up These and Any Other Significant Recurring Costs
Rent
Utilities
Professional dues and license fees
Maintenance *(including repairs, cleaning services, etc.)*
Loan Payments
Taxes *(including real estate, property, payroll)*
Interest on business loans
Insurance premiums *(including liability, casualty, malpractice)*
Legal and professional fees *(including accounting, legal, billing, etc.)*
Employee salaries and benefits

The total is the exposure that must be considered in protecting your business and personal financial solvency. If you're uncomfortable with the exposure that either scenario above presents, the time to act is today, proactively, we see too many doctors looking for heroic solutions to simple problems only after problems arise, including several physicians I've already had to personally pass on helping because of their pre-existing exposure so far this year.

Protect Yourself Against Divorce

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

Protect Your Practice Against Your Automobile Accident Exposure

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

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

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

This one of several areas where a **personal liability umbrella policy** is vital. You should have a minimum of $1 Million in umbrella coverage on your home and automobile and that coverage should ideally include "UIM and UM" which stands for underinsured and uninsured driver protection for you in case the person who hits you is underinsured or uninsured.

It's also vital that you don't rely on your umbrella as a one step asset protection, it isn't. It covers some very specific risks, mainly issues related to your **home and autos only** and typically will not help you with any business related risks.

OTHER COMMON RISKS

Employee Related Liability
Data Breach Exposure
RAC Audits
Executive Liability
Drug Based Treatment Liability

A recent case that made national headlines involved the unknowing use of infected epidural steroid compounds by pain management practices across the country. Over 200 patients across more than twelve states came suffered meningitis infection and a variety of other serious ailments with nearly 50 causalities.

Premises Liability Risk

How Great is The Risk?

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

Whose Injuries Are You Responsible For?

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

Invitees are generally defined as those on the property by express or implied invitation for a business purpose. Licensees or guests are persons on the property at the express or implied invitation for a social purpose. A higher degree of care is typically due to a child guest. Trespassers are defined as persons on the property without actual or implied permission. A higher degree of care may be owed to trespassing children under the attractive nuisance doctrine.

ADA Compliance Liability – Is your facility "Accessible"?

Equipment Disposal Liability

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

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

WHAT ARE THE "BEST" LEGAL TOOLS?

- There is no good general answer to this question as these plans should all be tailored to your specific assets, age liability, net worth and liquidity needs and implemented with experienced professional guidance.
- Certain legal tools, like a limited partnership may be perfectly suited for a particular asset like an investment account *and outright failures at protecting others*, like the house you live in. Make sure your planner knows the difference, many lawyers do not.

There are however tools that you should almost never use for asset protection:

Revocable Living Trusts – Be clear, I love and use this as an ESTATE PLANNING tool and regularly recommend them for that purpose, but using them for asset protection is like using Aspirin for Cancer; simply the wrong tool for the job.

Anything "Secret" -This means your planner is relying on the hope that no one will ever find it, and even more ridiculous from a legal standpoint, that no one will put you under oath and ask you – also

known as the crime of PERJURY – many plans by amateurs and non-lawyer promoters are set up this way and are the legal equivalent of psychic surgery

Anything that is "Tax Free" – the best asset protection is typically tax neutral and does not rely on secret planning that only really important, smart and special people know about or opinion letters or private letter rulings of questionable origin. We've seen these plans, structured to appeal to tax sensitive doctors, cause both massive monetary and even criminal penalties

USE THE LAW – EXEMPTION PLANNING

- Do you know what percentage of your wealth is exposed?
- Where are your *non-qualified* (cash, stocks, bonds, securities, etc.) assets? i.e. in your own name or your "trust" or actually somewhere safe?
- Do you know how much of your home equity is exposed? What is your states' Homestead Protection? It is different in every state.
- Are you maximizing the use of tools like "qualified retirement plans" that may be protected in your state?
- Life Insurance and Annuities are well protected in many states, in some cases 100% with little or no "waiting period"
- Life Insurance can be a creditor protected cash alternative <u>because the law says so</u>
- Some advanced forms of life insurance are also completely liquid and have strong legitimate business purpose – many advisors don't even know this exists – some do and don't care because it pays them less commission

What Are the Most Common Mistakes Doctors (and their Advisors) Make With Asset Protection?

1. Doing Nothing. Asset Protection can be described as "net worth insurance" and like insurance you have the best, most effective and legally supportable options available to you when you implement the planning before a crisis exists. You cannot insure the car after the accident occurs and similarly you must act proactively on the issues covered below. We regularly get calls from doctors and other successful individuals only after something bad has happened and hear the same story about how they always meant to take care of this, just didn't have the time and worked too many hours to get it done. My advice, if you work that hard and are not acting to protect the results of that labor for yourself and your family you need to put a greater value on your own efforts and act now, especially given the changes in physician compensation and profitability over the last ten years. Most doctors I talk to say that the money they made the last decade was harder earned and lower margin than what they made the decade before. Imagine having to replace that effort with the next ten years of earnings.

2. Thinking That You Aren't Rich Enough To Worry About It. It's amazing how important what ever you have becomes when you face the prospect of losing it. This is a common mistake I see made both doctors and more surprisingly, by other professionals like lawyers, CPAs, and financial advisors. These advisors often tell clients that they are "not rich enough" to worry about asset protection planning and that that only those with a net worth north of $5 million or even $10 million need to worry about. This advice is dangerous if not malpractice especially for those in the "fall" of their careers. What you have earned is important to you and there are basic defensive and risk management moves that should be made at nearly any net worth level.

3. Relying on Traditional Estate Planning, a.k.a. The Emperor's New Trust. "I've already taken care of this. My home, cars and investments are all titled in my trust," is something asset protection planners hear often. A transfer of these assets to a vehicle like an estate planning trust, or more specifically a Revocable Living Trust, is not effective asset protection and leaves assets exposed to your creditors during your lifetime. I distinguish estate planning, as important as it is, as death planning. What has been done about your life planning and the exposures you face every day as a practicing physician, employer, executive, driving a car, a parent (with kids driving your car), or property owner?

4. Using Any Particular Tool As A Catch-All. Correctly implementing a tool like an LLC as a barrier between yourself and your investments, but failing to adequately segregate and subdivide assets so that they are protected from both the owner and each other is self-defeating. A common example is the case of the physician property owner who has a single LLC that is legally and financially responsible for multiple properties that have different levels of liability, equity, and use. As an example, if you have $10,000 down on 3 properties in a single LLC, it's probably OK, because your total exposure is theoretically limited to $30,000, the value of the LLC's assets. On the other hand, if you have five pieces of real estate with a total equity position of six or seven figures, some paid for, some all debt, including an office condo, a rental home, a triplex, a lot, and a commercial strip mall, grouping them that way can be fatal. Any exposure at a new, zero equity property could wipe out your entire portfolio of paid for or partially paid for properties. Assets should always be divided based on risk, use and equity among many other factors.

5. Not Using the Right Tool for the Job. Certain vehicles have great use for specific business functions supported by statute, tax law, and case history. You and your planner must have a good handle on these issues and know what pros and cons each entity presents, how it will affect access to your liquidity and future options, and what it will take to maintain and support that stated business purpose as a start to the detail required. One specific example is the common misuse of what is commonly referred to as a Family Limited Partnerships (FLP) to own the client's personal residence. What is the legitimate business purpose of using a vehicle that is most often created (and which can be very effectively used for) for "family investment management and wealth transfer" to own your personally occupied residence? If you're not paying commercially reasonable rent and maintaining some legitimate business purpose, you don't have one. In litigation, expect the adverse party (or worse, the IRS) to successfully argue that you are using the FLP as personal piggy bank in way that is not legally distinct and immune from your personal assets and liabilities.

6. Infecting Your Plan And Assets With Unnecessary And Unrelated Liability. I routinely see doctors and their advisors move liability generating property and activities like personal vehicles moved into structures like an LLC or S-Corp. that is your primary business or into an entity like an FLP that is holding safe and attractive assets like cash, stocks, bonds, and other assets. If you lease or own your vehicle through your business, your CPA has likely told you that it's a good tax deduction, he's probably right. From a liability perspective however it's penny-wise and pound-foolish. You have linked the liability of the most dangerous thing you likely do on a repeated daily basis, driving a car, to either the source of your wealth (your practice) or in the example of your FLP, the place you stored your liquid wealth.

7. Relying on "Gifting" to Spouse and Relatives. In another common example of too little to late, transferring significant assets to your spouse and/or children, especially after something has happened, will not protect your assets from a lawsuit and simply opens up another level of liability. As popular as this method is with doctors do to it's relatively low cost and DIY ethos, it simply exchanges one person's liability for another's and when done right, makes a real, binding and permanent legal transfer of the title to that property to someone else. We've seen disastrous results from this strategy at divorce, when the person gifted the assets is estranged, has a substance abuse issue, dies or has their own significant liability.

Consider this scenario: Let's suppose that you transfer all of your assets to your 18-year-old daughter who causes an auto accident. Several other cars are involved in the accident and multiple injuries, a fatality and significant property damage are incurred. Chances are high that the other parties will come looking for the driver with the deepest pockets. If your daughter "owns" your house and business, a sympathetic jury will undoubtedly take the possession away from her in order to teach her a lesson about reckless driving. The same holds true for spouses, parents, and even friends. Also, gifting is limited to about $14,500 annually, per spouse, per donee. Gifts over that amount must be documented with a gift tax return. Failing to do so will result in you having to answer the

question: "Are you lying about the date and validity of this transfer or did you commit tax fraud by making the transfer and not filing the return?" Clearly a bad place to be in a time of need, and often under oath in litigation discovery proceedings.

8. Using Amateur Tools Like "Friendly Liens". Another common play I see that targets doctors is when promoters of LLC mills set up LLCs that you or a friendly party own and that entity records a "lien" against some valuable asset, most typically real estate. While validly recorded and executed liens can provide a great deterrent against creditors, they have to be backed by a legitimate exchange of value. Your brother's Nevada LLC that holds a lien on your home for most of its value should have included some exchange or "consideration" roughly equal to the amount of the lien. "Your brother has a $400,000 lien against the $500,000 home you live in? OK…then where is the record of the $400,000 (or some other equivalent value) he gave you, as a bank would have in a real secured loan? He didn't actually give you anything in return? He doesn't actually have $400,000 in the bank to give you for that alleged secured line of credit? Great, we'll take the house."

9. Working With Inexperienced Counsel, No Counsel, Or Promoters. There are some common issues with DIY plans and those created by promoters; mainly that they are often based on some of the faulty logic and planning outlined above and often combine a variety of the mistakes that we've warned you about. Non-attorney promoters of DIY LLC kits, abusive or outright fraudulent trust structures (pure trusts, constitutional trusts, admiralty trusts and abusive private charitable foundations are just a few of many examples) have **no real professional liability or oversight, nor do they have an attorney-client privileged relationship with you as a consumer**. In plain English, that means every letter and email you exchange during their "consultation" as these sales presentations are euphemistically referred to, should be expected to be fully discoverable by any 3rd party. Adding a final layer of risk, many of these plans are abusive from the perspective of the I.R.S. and you cannot rely upon sales materials, false (or forged) letters of opinion, or their marketing materials as a defense. You will be all alone and out-of-pocket if these issues are challenged by the I.R.S.. The worst of these plans we've seen were not only defective from a creditor protection standpoint, they actually created six and seven figure liabilities for the clients who were taken by them, and in some cases, *criminal charges*.

10. Relying On Insurance Alone Or Failing To Adequately Insure. Why Can't We "Just" Insure Our Way To Safety? This is a reasonable and common question we get from clients and advisors alike. In the most egregious cases of arm-chair quarterback misinformation, we actually see uninformed advisors telling their clients that the only Asset Protection they need is a good umbrella policy – THIS IS FLAT OUT WRONG for the kind of successful people we protect. Why? Because they are successful, visible and typically have assets above and beyond just the insurance policy itself, they are good targets from a net-worth perspective.

We've just scratched the surface here, so use this an as outline to get individualized, expert counsel on your own needs now, before an exposure prevents you from implementing the most predictable and cost. Nothing in a general educational setting like this is a substitute for individual advice, nor should it be construed as legal advice of any kind.

SELF EVALUATION

Protecting Your Assets: Preventive Legal Medicine

1. Asset Protection requires attention to which of the following:

a. Legal tools
b. Insurance
c. Best practices
d. Understanding all your risks
e. All of the above

2. Your medical malpractice policy adequately protects you from which of the following issues?

a. Data Breach
b. Actions of Your Employees
c. Audits from Payors
d. All of the above
e. None of the above

3. Transferring assets to a lower risk relative often fails because:

a. The gift is not legally completed
b. Your spouse can divorce you and take the assets AND half of the rest of the estate
c. The assets then become subject their liability
d. All of the above

4. T/F - Automobile leasing through your practice is a good idea because the corporation protects you from liability *and* you get a huge tax deduction:

5. The most important element in asset protection planning is:

a. Using the right legal tools
b. Having all the right insurance
c. When you do it
d. What state your LLC is in
e. Keeping it a secret

6. Transferring real estate and non-qualified assets to your Revocable Living Trust will automatically protect them from:

a. Professional lawsuits and liability
b. Probate
c. Personal Lawsuits and Liability
d. Bankruptcy
e. All of the above

ANSWER KEY: 1. E, 2. E, 3. D, 4. F, 5. C, 6. B

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Cannabis and Cannabinoids in Pain Treatment

Benefits and Risks of Cannabinoids

- Definitions and Background
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Definitions

- Cannabis – A genus of flowering plants with three different species: indica, sativa, and ruderalis
  - Can be bred to have low amounts of psychoactive compounds (e.g. THC) that are used to make hemp, or high amounts that are used for recreational/medicinal purposes
  - Sativex is a oral spray that is a cannabis extract
- Cannabinoid – Compounds that act at cannabinoid receptors
  - Endocannabinoids – endogenous ligands produced naturally that bind to CB1 and CB2 receptors
  - Phytocannabinoids – plant origin (cannabis/marijuana)
    - At least 80 different cannabinoids in cannabis
  - Synthetic cannabinoids

CB, cannabinoid receptor; THC, tetrahydrocannabinol

Pertwee RG. Handb Exp Pharmacol. 2005;(168):1-51.

Endocannabinoid system - I

A set of receptors and their naturally occurring ligands and enzymes regulating control

- **Receptors** – G-coupled protein receptors (the most abundant in CNS in man) on presynaptic membrane of cells in peripheral and central nervous system
  - CB1 – Primarily in central nervous system (but not in medulla in man) these act primarily to inhibit release of neurotransmitters
  - CB2 – Largely found in periphery on immune and nerve cells (although some in CNS on microglia and DRG)
  - Other receptors can bind these ligands because there is activity in CB1/CB2 knockouts (TRPV1, GPR55)

CB, cannabinoid receptor; CNS, central nervous system, DRG, dorsal root ganglion

Pertwee RG. Handb Exp Pharmacol. 2005;(168):1-51.

Endocannabinoid system - II

- **Ligands** – Endocannabinoids are eicosanoid lipid messengers that are the physiological ligands for the cannabinoid receptors:
  - ananamide (N-arachidonoylethanolamide, AEA)
  - 2-arachidonoylglycerol (2-AG)
  - PEA, virodamine, OAE
- **Enzymes** that synthesize and degrade the lipids endocannabinoids, such as fatty acid amide hydroxylase or monoacylglycerol lipase
  - Drugs being developed for pain that inhibit these enzymes

AEA, arachidonoylethanolamine PEA, palmitoylethanolamide; OAE, oleoylethanolamine

Pertwee RG. Handb Exp Pharmacol. 2005;(168):1-51.

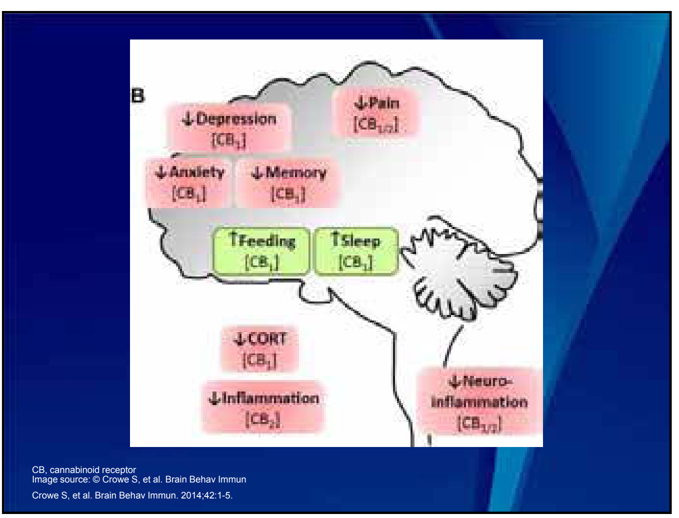
Endocannabinoid system - III

Some known functions of the endocannabinoid system in humans:

- **Memory** – Generally affect short term memory, may play adaptive role in extinction of old memories in hippocampus
- **Neurogenesis**
- **Appetite** – Act in hypothalamus to increase appetite, inversely related to leptin levels
- **Analgesia**
- **Immune function** – Generally inhibit immune function, generally mediated via CB2[1] but some evidence CB1 might play role in T-cell responses. May be upregulation of CB2 receptors in some inflammatory disorders
- **Stress** – Help habituate/reduce HPA axis activity during repeated stress[2]

CB, cannabinoid receptor; HPA, hypothalamic-pituitary-adrenal

1. Rom S, Persidsky Y. J Neuroimmune Pharmacol. 2013; 8:608-20. 2. Hill MN, et al. Proc Natl Acad Sci U S A. 2010;107:9406-11.



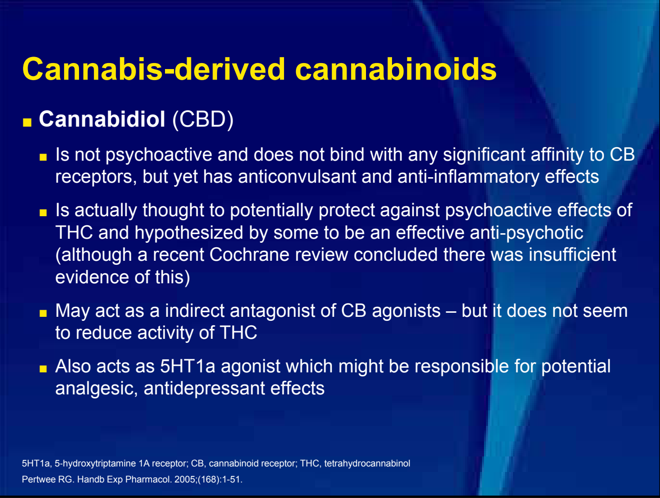
Cannabis-derived cannabinoids

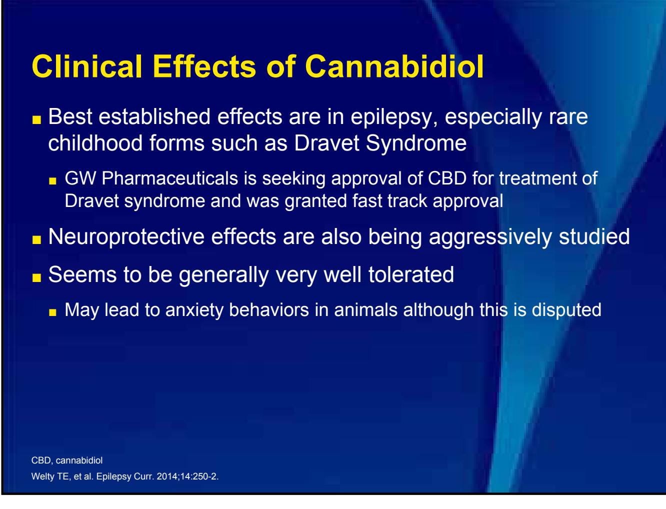
More than 80 known, with different strains having different relative concentrations

- **THC** (Synthetic forms include Dronabinol, Marinol, Nabilone)
  - The primary psychoactive cannabinoid in cannabis, and its metabolites are those assayed for in drug tests
  - Although it binds relatively equally to both the CB1 and CB2 receptors, most of its effects are associated with CB1 activity in brain

CB, cannabinoid receptor; THC, Tetrahydrocannabinol

Pertwee RG. Handb Exp Pharmacol. 2005;(168):1-51.





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Potential Benefits of Cannabinoids

- Antiemetic[1] – Marinol is FDA-approved (Schedule III) for use in post-chemotherapy nausea/vomiting
- Anorexia – Marinol is FDA-approved for this use in AIDS-induced anorexia in US
- Anti-spasticity agent[2]
- Anticonvulsant[3] – Focus on CBD effects
- Neuroprotective
  - Being studied in Alzheimer's[4] because preclinical models show CB1/2 activation leads to reduction in beta-amyloid
  - Retrospective study of patients admitted with severe TBI showed significant reduction in death in those who had a positive drug screen for THC[5]
- Anti-tumor effects[6]

AIDS, acquired immune deficiency syndrome; CB, cannabinoid receptor; CBD, cannabidiol; FDA, Food and Drug Administration; TBI, traumatic brain injury; THC, tetrahydrocannabinol

1. Sharkey K, et al. Eur J Pharm. 2014; 722:134-46. 2. Koppel, et al. Neurology. 2014;82:1556-63. 3. Devinsky O. Epilepsia;2014:55:791-802. 4. Aso E, et. al. Front Pharmacol. 2014;5:37. 5. Nguyen BN. Am Surg. 2014;80:979-83. 6. Cridge B, Rosengren RJ. Cancer Manag Res. 2013;5:301-13.

Anti-inflammatory effects of CBD

- There are many animal models where CBD has been demonstrated to have potent anti-inflammatory effects in a variety of models (including murine collagen arthritis and carrageenan models) but it is much less clear how those anti-inflammatory effects are being mediated
- Some evidence that anti-inflammatory effects might be occurring via CB2 (very high doses needed), adenosine receptors, arachidonic acid release (causes shift from cyclooxygenase to lipoxygenase pathway), via direct inhibition of cytokine production, or via binding to the GPR55 receptor (which has both inflammatory and nociceptive properties)

CB, cannabinoid receptor; CBD, cannabidiol; GPR55, G protein-coupled receptor 55

Burstein S. Bioorg Med Chem. 2015;23:1377-85.

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Risks of Cannabinoids

- Almost all available data is from long term recreational users so we probably have good “worst case” data
- Partly related to route of administration
  - Smoking cannabis may lead to chronic bronchitis and potentially cancer of the mouth, throat, lung
  - This is likely reduced or eliminated with use of vaporizers or e-cigarettes
  - Oral administration causes less “likability” than inhalation or smoking and presumably no risk of bronchitis or cancer
  - *Individuals using cannabis for medicinal purposes should probably be using an oral formulation but dosing is problematic*
- The few deaths associated with cannabis are generally due to severe paranoia or tachycardia associated with overdose via oral administration

Degenhardt L, Hall WD. CMAJ. 2008;178:1685-6.

Long Term Risks of Cannabinoids[1]

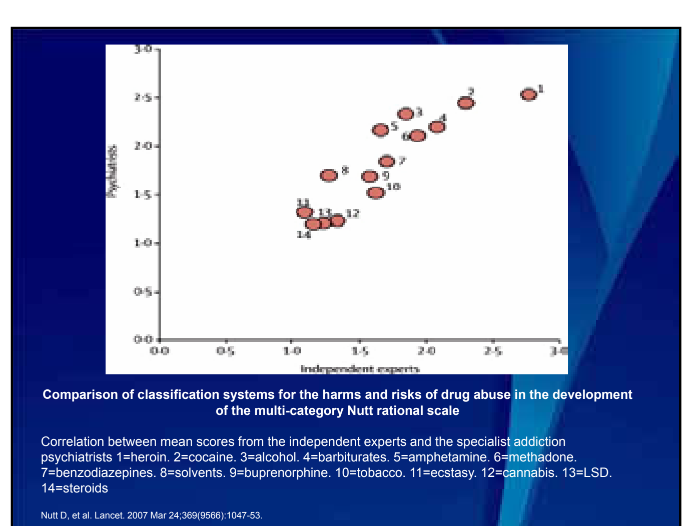
- Psychotic illnesses
  - It is now generally accepted that individuals who begin smoking cannabis prior to age 25 have 1.5 – 2.4X the rate of developing a psychotic illness[2]
  - This risk is modified by childhood trauma, family history of a psychotic illness, and perhaps genetic polymorphisms
- Long term effects on memory and brain structure
  - Both neuropsychological testing, and functional and structural neuroimaging studies, have suggested that individuals who use cannabis recreationally beginning in adolescence have decreased cognitive performance[1,3]
  - These studies have significant methodological issues because of other common exposures (e.g. alcohol or other illicit drugs) and behavioral issues in these individuals[3]

1. Hall W. Drug Test Analysis 2014:6:39-45 2. Radhakrishnan R. Front Pharmacol. 2014:5:1-6. 3. James A, et al. Psychiatry Res. 2013;214:181-9. 3. Batalla A. PLOSone 2013;8:e55821.

Risks of Cannabinoids[1]

- Respiratory
- Dependence
  - Occurs in approximately 9% of individuals who use cannabis, but is about double in those who begin using in adolescence
  - This is lower than almost all other drugs of abuse (nicotine 32%, opioids 23%, alcohol 15%)
  - Highest risk in those with poor academic achievement, deviant behavior in childhood, poor parental relationships, family history of substance abuse
  - Physical addiction and withdrawal are much less common/severe than other drugs of abuse

1. Hall W. Drug Test Analysis 2014:6:39-45 2. Radhakrishnan R. Front Pharmacol. 2014:5:1-6. 3. James A, et al. Psychiatry Res. 2013;214:181-9.



Comparison of classification systems for the harms and risks of drug abuse in the development of the multi-category Nutt rational scale

Correlation between mean scores from the independent experts and the specialist addiction psychiatrists 1=heroin. 2=cocaine. 3=alcohol. 4=barbiturates. 5=amphetamine. 6=methadone. 7=benzodiazepines. 8=solvents. 9=buprenorphine. 10=tobacco. 11=ecstasy. 12=cannabis. 13=LSD. 14=steroids

Nutt D, et al. Lancet. 2007 Mar 24;369(9566):1047-53.

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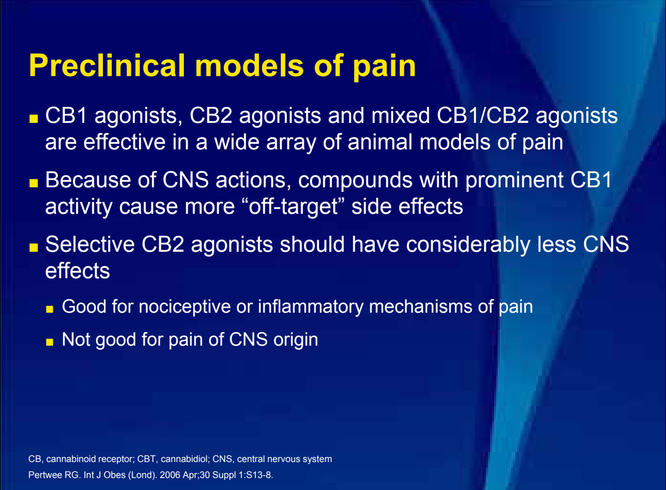
Role of Cannabinoids in Treating Chronic Pain

- Preclinical models
- Mechanisms of action
- Clinical trials in chronic pain states
  - Underlying mechanisms of pain
  - Efficacy
  - Toxicity



Mechanisms of analgesic action of cannabinoids

- In periphery, CB2 activation leads to fairly pronounced anti-inflammatory effect
  - May have less effect on nociceptive pain that is not of inflammatory origin
- In CNS, cannabis (presumably mainly via CB1 effects) has a dissociative effect of reducing connectivity between limbic and sensory brain regions and reduces the unpleasantness of pain[1]
  - This is likely also the mechanism of action of cannabinoids for treating nausea

CB, cannabinoid receptor; CNS, central nervous system

1. Lee MC, et al. Pain. 2013;154:124-4.

Cannabinoids for the Treatment of Non-Cancer Pain: A Systematic Review

- Cannabinoids studied included smoked cannabis, oromucosal extracts of cannabis based medicine, nabilone, dronabinol and a novel THC analogue
- Chronic non-cancer pain conditions included neuropathic pain, fibromyalgia, rheumatoid arthritis, and mixed chronic pain.
- ***Fifteen of the eighteen trials that met the inclusion criteria demonstrated a significant analgesic effect of cannabinoid as compared with placebo*** and several reported significant improvements in sleep
- There were no serious adverse effects. Adverse effects most commonly reported were generally well tolerated, mild to moderate in severity and led to withdrawal from the studies in only a few cases

THC, tetrahydrocannabinol
Lynch ME, et al. Br J Clin Pharmacol. 2011;72:735-44.

Mechanistic Characterization of Pain
Variable degrees of any mechanism can contribute in any disease

	Nociceptive	Neuropathic	Centralized
Cause	Inflammation or damage	Nerve damage or entrapment	CNS or systemic problem
Clinical features	Pain is well localized, consistent effect of activity on pain	Follows distribution of peripheral nerves (i.e. dermatome or stocking/glove), episodic, lancinating, numbness, tingling	Pain is widespread and accompanied by fatigue, sleep, memory and/or mood difficulties as well as history of previous pain elsewhere in body
Screening tools		PainDETECT	Body map or FM Survey
Treatment	NSAIDs, injections, surgery, ? opioids	Local treatments aimed at nerve (surgery, injections, topical) or CNS-acting drugs	CNS-acting drugs, non-pharmacological therapies
Classic examples	Osteoarthritis Autoimmune disorders Cancer pain	Diabetic painful neuropathy Post-herpetic neuralgia Sciatica, carpal tunnel syndrome	Fibromyalgia Functional GI disorders Temporomandibular disorder Tension headache Interstitial cystitis, bladder pain syndrome

CNS, central nervous system; FM, fibromyalgia; GI, gastrointestinal
Clauw DJ. The taxonomy of chronic pain: Moving towards more mechanistic classification. In: Wallace DJ & Clauw DJ, editors. Fibromyalgia and other central pain syndromes. Philadelphia: Lippincott, Williams & Wilkins; 2005. p.10-16.

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Summary

- The endocannabinoid system is widely distributed in the human body and there is strong biological plausibility that these can be effective and safe analgesics at the right dose and in the right person
- Cannabinoids can exert analgesic effects in the periphery (mainly anti-inflammatory) and CNS (dissociate individuals from the sensory experience of pain)
- For treatment of clinical pain with cannabinoids there is best evidence that they are effective in neuropathic and centralized pain, and little current evidence that they are effective in nociceptive/inflammatory pain states

CNS, central nervous system

Pragmatic Advice for Using Cannabinoids in 2018

- Where possible use a cannabinoid or cannabinoid extract of consistent and known potency
- Start with CBD alone and then go to low dose of low THC:high CBD strain and go up slowly
- Emerging evidence of U-shaped curve
- Oral dosing better once stable dose and strain identified
- The strongest recommendation based on current benefit: risk data is for the use of cannabinoids instead of opioids for neuropathic or centralized pain states
  - Data from US suggest that legalizing cannabis in a state leads to fairly dramatic reductions in opioid overdoses[1]
- Use with caution in individuals under age 25

CBD, cannabidiol; THC, tetrahydrocannabinol
1. Bachhuber MA, et. al. JAMA Int Med 2014;174:1668-73.

SELF EVALUATION

Cannabis and Cannabinoids in Pain Treatment

1. **T/F -** The body produces several endocannabinoids that bind to either CB1 or CB2 receptors that are widely distributed within the nervous system and immune system.

2. Which of these statements is false:

a. THC is potentially addictive although much less so than other drugs of abuse
b. High doses of THC work better than low doses to treat pain
c. Cannabinoids have generally not been shown to be effective for treating acute pain
d. There are several forms of synthetic THC approved in the US for treating nausea and anorexia associated with AIDS

3. Which of the following statements is false regarding cannabidiol (CBD):

a. It is not psychoactive and in fact when co-administered with THC actually protects against the "high" individuals get from THC alone
b. It can be extracted from hemp as well as cannabis
c. It is extremely well tolerated and generally is devoid of any side effects
d. It has no beneficial effect unless co-administered with THC or other cannabinoids

4. Which of the following statements are true regarding states that have passed medical marijuana laws or legalized marijuana:?

a. In general there is a decrease in opioid overdoses in states following passage of these laws
b. There has not been an increase in adolescent use of cannabis in these states
c. There has not been an increase in motor vehicle accidents in these states
d. Many chronic pain patients find that they can decrease or reduce opioid use once they begin using cannabis
e. All of the above are true

ANSWER KEY: 1. T, 2. B, 3. D, 4. E

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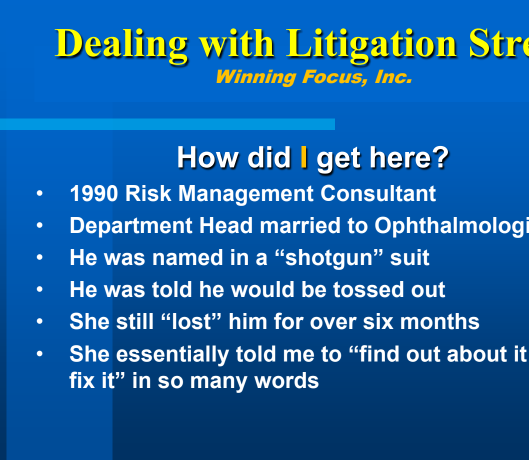
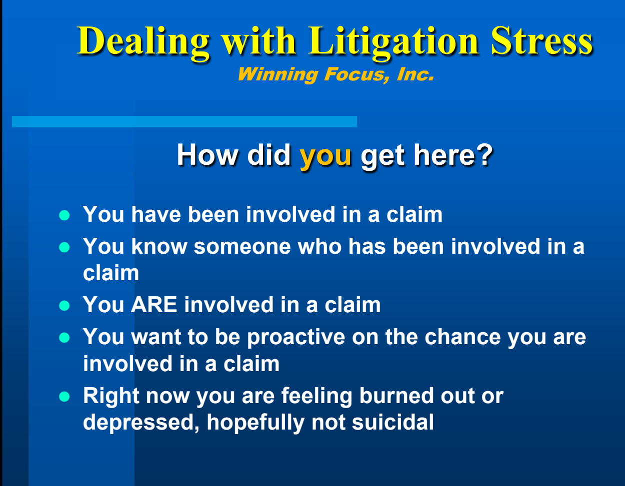
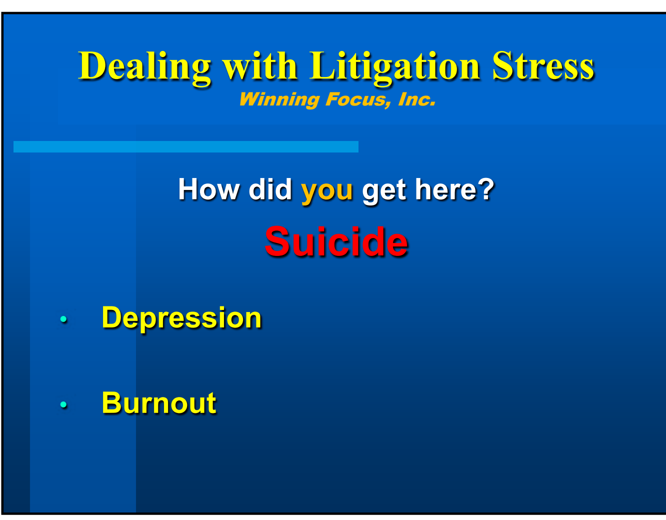
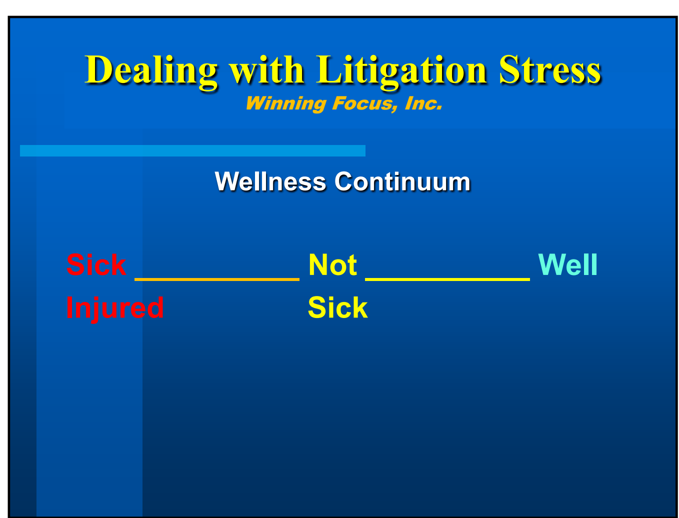
Malpractice Litigation Stress: The Underlying Reasons









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Dealing with Litigation Stress
Winning Focus, Inc.

Peace is a choice; you can choose peace and you can do so now.

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Winning Focus, Inc.

Knowledge helps increase feelings of control, so what is a malpractice claim and who is to "blame?"

- A civil wrong
- A claim of negligence
- A desire to make things "even"
- A business transaction

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Knowledge helps increase feelings of control, so what is a malpractice claim and who is to "blame?"

- Plaintiff's attorneys
- Defense attorneys
- Patients
- Healthcare Providers
- Society
- Our civil legal system
- Modern healthcare

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Pop Quiz

What is meant by "tort reform?

A. Make it harder to file a malpractice suit

B. Make it easier to file a malpractice suit

C. Make it quicker, easier, less expensive, more equitable, and less adversarial for a person to be made "even" who has genuinely been injured due to the negligence of another person.

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Question?

Putting aside Amendment VII of the Constitution for a moment, if medical or dental malpractice claims were completely banned by law, would acts of malpractice cease occurring?

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Prevention

- Risk Avoidance
- Informed Consent
- "MDeity" Syndrome
- Voluntarily restoring losses
- Sound policies and procedures
- Documentation
- Good faith medicine

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12 Rs of Malpractice Prevention

1. Rapport
2. Rational
3. Records
4. Remarks
5. Rx habits
6. Res Ipsa Loquitur
7. Respect
8. Results
9. Risks
10. Review
11. Report
12. Responsibility

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What precipitates a claim?

- Bad outcome?
- Unexpected bad outcome?
- Large bill ?
- Large bill after a bad outcome?
- Staff?
- Other providers?

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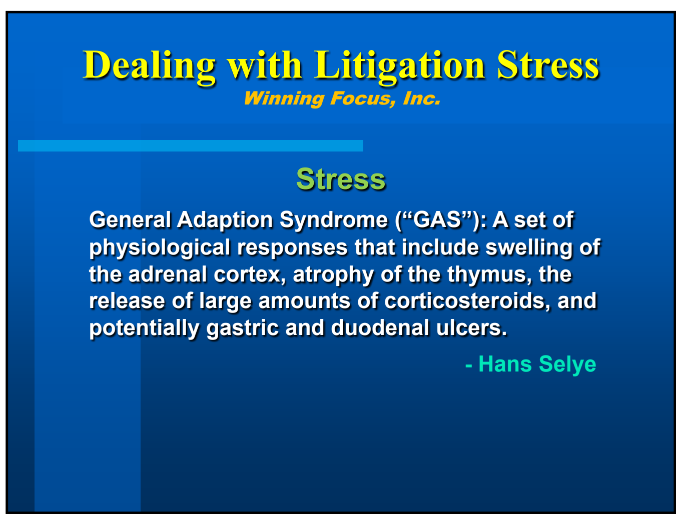
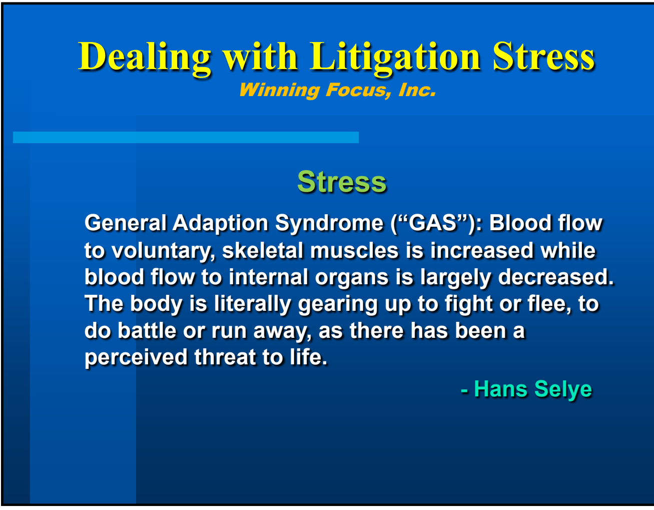
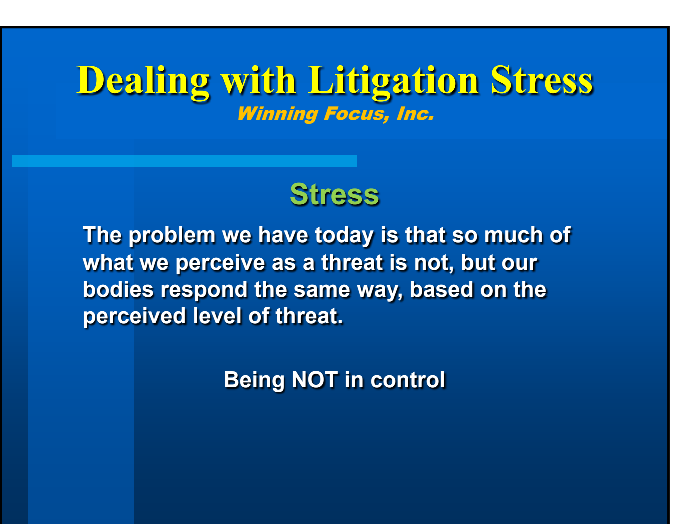
Stress

The "father" of modern stress research, Hans Selye, developed what is called the General Adaption Syndrome. It can be summarized as "everything bothers us to some degree and we react." A Canadian internist who died in 1982, his work eventually evolved into an understanding that the problem we have today is that so much of what we perceive as a threat is not, but our bodies respond the same way, based on the perceived level of threat.







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Stress

Further refinement of terms:

- **Stress**: Responding to the world around you
- **Stressor**: An event that causes a stress response
- **Distress**: Extreme stress reaction, either in severity, frequency, or duration
- **Eustress**: A "good" form of stress that elicits much the same "fight or flight" response, but helps us in our performance or functioning.

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Stress

The problem we have today is that so much of what we perceive as a threat is not, but our bodies respond the same way, based on the perceived level of threat. We are like an automobile with the gas pedal and the brake pedal both jammed to the floor with the transmission in "Drive."

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Basic Concepts

A stress response, the "fight or flight" mechanism, is designed to protect us in life or death situations. The challenge today is that if you make everything life or death, you will "die" a lot.

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Stress Summary

Stress is our response to the world around us. There is a stressor, there is our response to the stressor based on our perception of it, it can be bad (distress) or good (eustress), followed by our management of the response.

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Stress Summary

The biggest challenges are an inappropriate response to the stressor or a lack of control over the stressor.

How you deal with stress now will help determine how well you deal with the stress of litigation.

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Litigation and HealthCare Professionals

- First do no harm
- Regardless of the origin of that phrase, you did not enter into this profession to harm people
- Healthcare providers are scientists; a malpractice claim is mostly NOT a scientific inquiry

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Litigation and HealthCare Professionals

Pioneering work done by psychiatrist Sara Charles and her husband, Eugene Kennedy, out of the natural curiosity most health care providers have: she was sued, had a horrendous emotional reaction to it, wondered if other physicians reacted the same way, and then set out to find out why?

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Litigation and HealthCare Professionals

1. Personality
2. Training
3. Nature of the healing arts
4. Injury
5. The legal system

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Litigation and HealthCare Professionals

1. Personality

- Intelligent
- Driven
- Independent thinkers
- Strong tendency towards self-criticism, which leaves you vulnerable to feelings of doubt
- Exaggerated sense of responsibility
- Lack of loyalty

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Litigation and HealthCare Professionals

2. Training

- Self-Discipline
- Sacrifice
- High E.Q.
- Survival mentality which rewards those with independent, driven, self-critical personalities who want to be or feel in control
- Changes in health care system

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2. Training

Changes in health care system

- "Things Fall Apart" by Chinua Achebe
- Then v. Now: Health care, insurance, communication
- Outcome-based medicine and Yogi Berra
- Health insurance companies
- Hospitals
- Kaiser
- Lack of control

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Litigation and HealthCare Professionals

3. Nature of the Healing Arts

- School and training foster independence
- Success predicated on guilt and competition
- Result is often isolation
- Who you are v. What you do = workaholism
- Ongoing stress = fatigue = burnout = depression
- "Sin Eater"

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Litigation and HealthCare Professionals

3. Nature of the Healing Arts

Serving yourself up

When you envisioned your career in health care you always "won," you always saved the day by doing good work. You were always perfect and striving for perfection gets in the way of excellence. Striving for perfection every day in every way can eat you up, can keep you in a low level of "fight or flight" arousal continually.

Then you have a bad outcome or malpractice claim.

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When confronted with a malpractice claim…

- Isolation
- Negative self-worth
- Negative self-image
- Severe emotional response
- Emotional volatility
- Insecurity
- Anxiety
- Suicide ideation

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How are these reactions expressed?

Depression	Frustration
Insomnia	Irritability
Anger	Fatigue
Alcohol/drug abuse	Eating Disorders
Family and/or marital problems	
Health complications	

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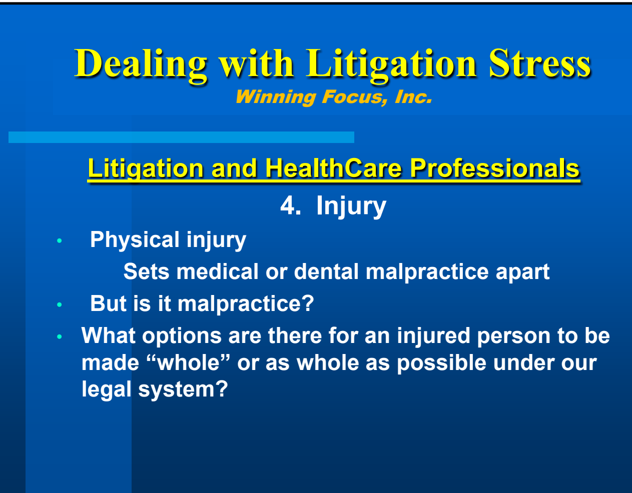
Organizations report being impacted by…

- An increase in accidents
- Increased errors
- Increased absenteeism
- Unpreparedness
- Increased use of sick leave
- Premature retirement
- Increased job dissatisfaction
- Impaired decision-making



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5. Our Legal System

"*Principle of Legitimacy*"

In his book "David and Goliath" Malcolm Gladwell discusses "*Principle of Legitimacy*" and that the principle is based on three things.

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Litigation and HealthCare Professionals

5. Our Legal System

"Principle of Legitimacy"

1) People who are asked to obey authority must feel as if they have a voice, that if they speak up they will be heard.
2) The law at issue must be predictable, there must be reasonable expectations that the rules today are going to roughly be the same rules tomorrow
3) The authority must be fair; it cannot treat one group differently from another.

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5. Our Legal System

Compare and contrast attempts at tort reform with the impacts of tort reform, with the results claimed by malpractice insurance companies, but also with studies of closed medical records, and you end up with…sausage.

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5. Our Legal System

The Harvard Studies

- 1991
- 2006
- Researchers analyzed past malpractice claims and closed medical records
- Meritless claims that received compensation were outnumbered by meritorious claims that did not receive compensation

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5. Our Legal System

The civil legal system only infrequently compensates injured patients, and rarely identifies and holds healthcare providers accountable for substandard care. Although malpractice litigation may fulfill its social objectives, the current system endures because of the perception that no adequate replacement has been found.

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5. Our Legal System

The "Fix?"

- Creditable systems and procedures…
- Accepted by the public…
- That guarantee professional accountability to the public

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5. Our Legal System

"Tort reform is needed to lower the cost of healthcare."

No.

"It would be helpful if doctors could learn to separate the alleged act of malpractice from the malpractice claim; one is an issue of medical competence, the other is a business/legal transaction, an exchange of money in return for alleged negligence." -Sara Charles, M.D.

SELF EVALUATION

Malpractice Litigation Stress: The Underlying Reasons

1. T/F - Litigation stress is unique to health care providers.

2. T/F - All health care providers will have a uniformly strong emotional response to a malpractice claim.

3. A malpractice claim is:

a. A civil wrong
b. A claim of negligence
c. A desire on the part of the patient to make things "even"
d. A business transaction
e. All of the above

4. T/F - One solution to high health care costs would be tort reform.

5. T/F - The "fight or flight" mechanism serves us well today as so many perceived threats are genuine threats to our life.

6. The litigation response of many healthcare professionals is due in part to:

a. Their personality before or after training
b. The nature of their training
c. The nature of practicing the healing arts
d. Physical injury
e. The legal system
f. All of the above

7. T/F - Changes in the health care delivery system over the last 20 years has not contributed to any ongoing, low-level stress in providers.

8. T/F - Healthcare providers in general are able to separate who they are from what they do.

9. The goal of many hospitals today is to:

a. Move physicians towards independent practice models
b. Help decrease the use of electronic medical records
c. Embrace the Kaiser model of total ownership of the healthcare system
d. Return to a vibrant coalition of independent, community hospitals

10. Which of the following is **NOT** a part of Malcolm Gladwell's *Principle of Legitimacy?*

a. People who are asked to obey authority must feel as if they a voice, that if they speak up they will be heard.
b. The law at issue must be predictable, there must be reasonable expectations that the rules today are going to roughly be the same rules tomorrow.
c. The authority must prioritize which groups or individual deserve special treatment.
d. The authority must be fair; it cannot treat one group differently from another.

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

LOUIS KURITZKY, MD
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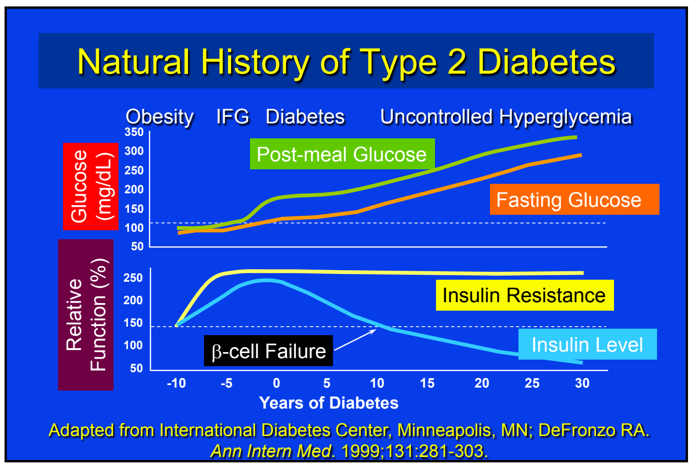
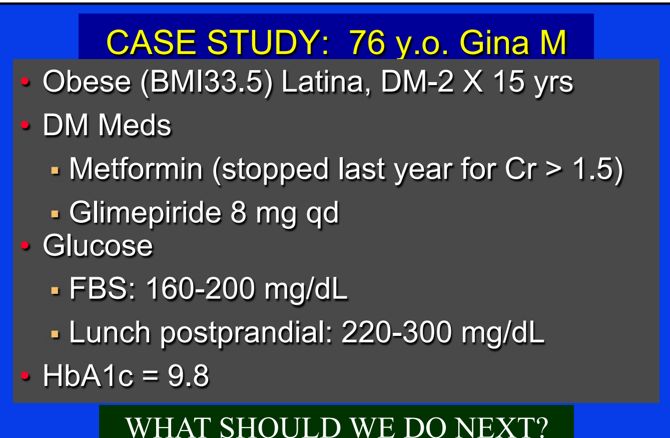
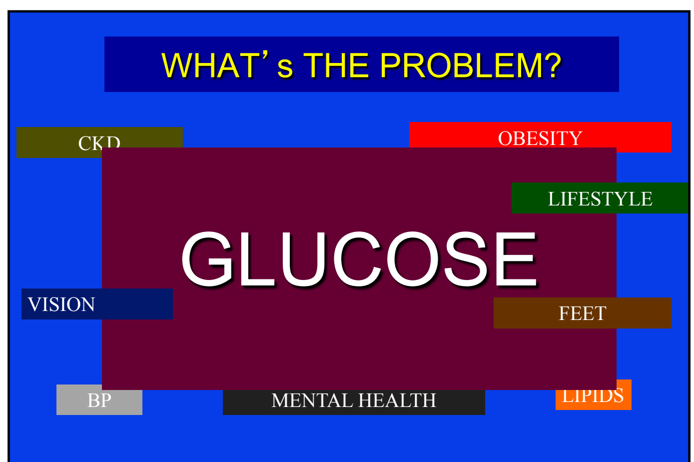
New Directions in Diabetes







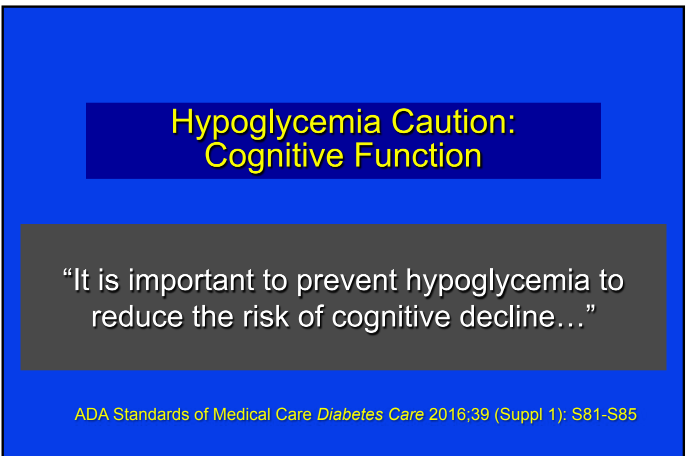
Goals for Our Senior Patients

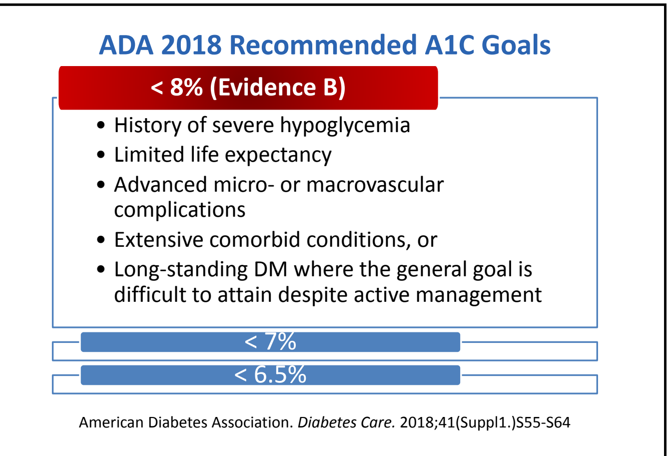
- MACROvascular Risk Reduction
  - MACE (stroke, MI, CHF, ACS)
- MICROvascular Risk Reduction
  - Nephropathy, neuropathy, retinopathy
- Avoidance of hypoglycemia
- Improved QOL
- Minimization of polypharmacy
- Cost-consciousness

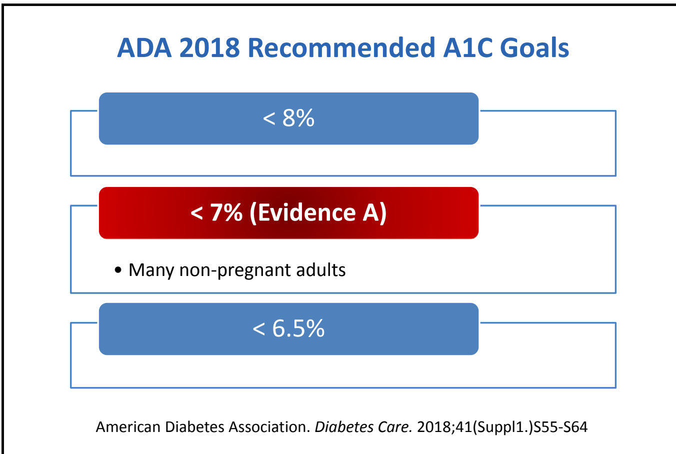
DM in Older Adults
ADA Recommendations 2016

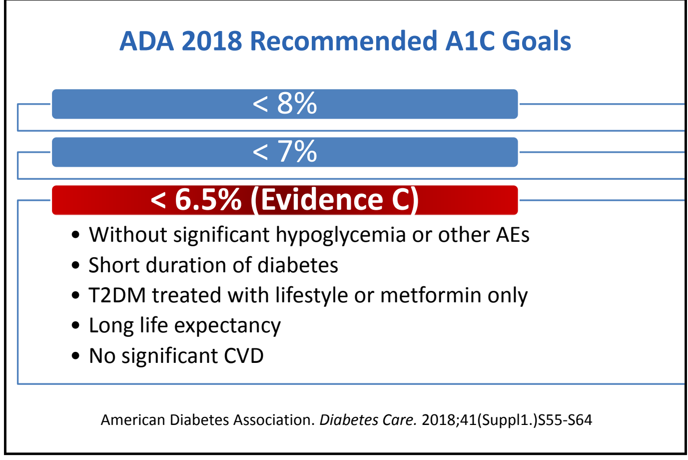
"Consider the assessment of medical, functional, mental, and social geriatric domains for DM management in older adults to provide a framework to determine targets and therapeutic approaches."

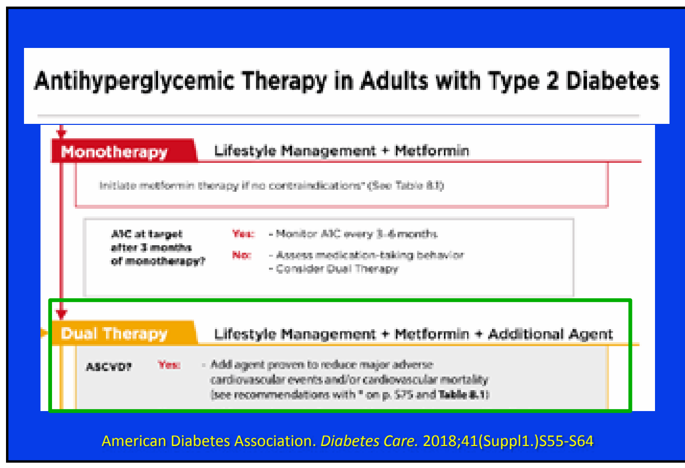
ADA Standards of Medical Care *Diabetes Care* 2016;39 (Suppl 1): S81-S85

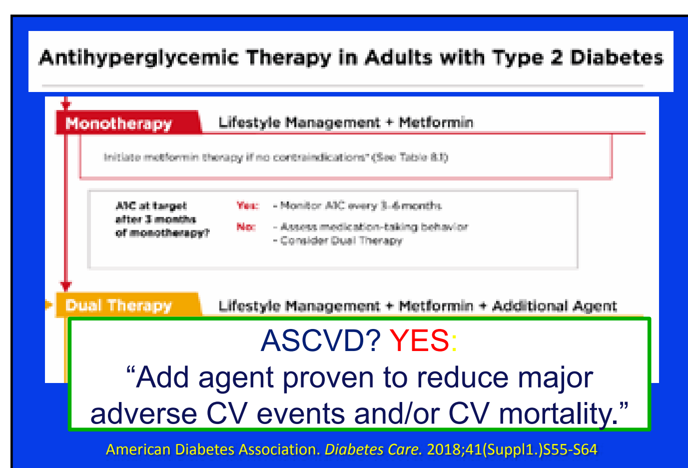

Hypoglycemia Caution:
Cognitive Function
"It is important to prevent hypoglycemia to reduce the risk of cognitive decline…"
ADA Standards of Medical Care Diabetes Care 2016;39 (Suppl 1): S81-S85

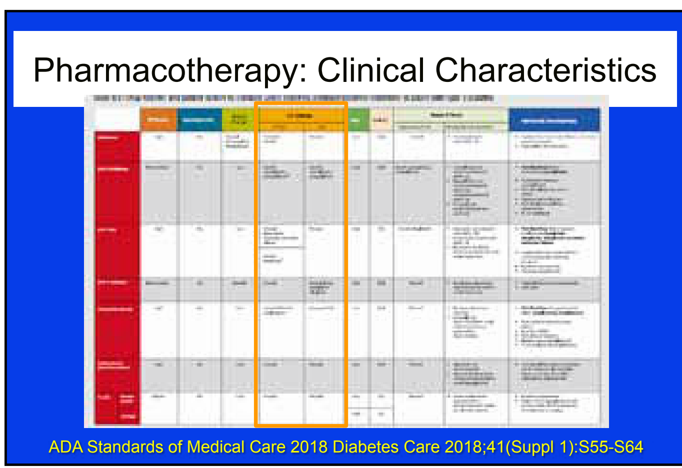

ADA 2018 Recommended A1C Goals
< 8% (Evidence B)
• History of severe hypoglycemia
• Limited life expectancy
• Advanced micro- or macrovascular complications
• Extensive comorbid conditions, or
• Long-standing DM where the general goal is difficult to attain despite active management
< 7%
< 6.5%
American Diabetes Association. Diabetes Care. 2018;41(Suppl1.)S55-S64

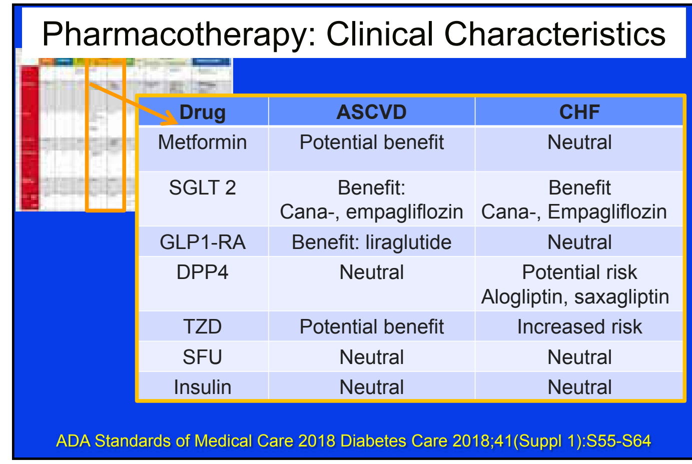

ADA 2018 Recommended A1C Goals
< 8%
< 7% (Evidence A)
• Many non-pregnant adults
< 6.5%
American Diabetes Association. Diabetes Care. 2018;41(Suppl1.)S55-S64


ADA 2018 Recommended A1C Goals
< 8%
< 7%
< 6.5% (Evidence C)
• Without significant hypoglycemia or other AEs
• Short duration of diabetes
• T2DM treated with lifestyle or metformin only
• Long life expectancy
• No significant CVD
American Diabetes Association. Diabetes Care. 2018;41(Suppl1.)S55-S64


Antihyperglycemic Therapy in Adults with Type 2 Diabetes
Monotherapy
Lifestyle Management + Metformin
Dual Therapy
Lifestyle Management + Metformin + Additional Agent
American Diabetes Association. Diabetes Care. 2018;41(Suppl1.)S55-S64


Antihyperglycemic Therapy in Adults with Type 2 Diabetes
Monotherapy
Lifestyle Management + Metformin
Dual Therapy
Lifestyle Management + Metformin + Additional Agent
ASCVD? YES:
"Add agent proven to reduce major adverse CV events and/or CV mortality."
American Diabetes Association. Diabetes Care. 2018;41(Suppl1.)S55-S64

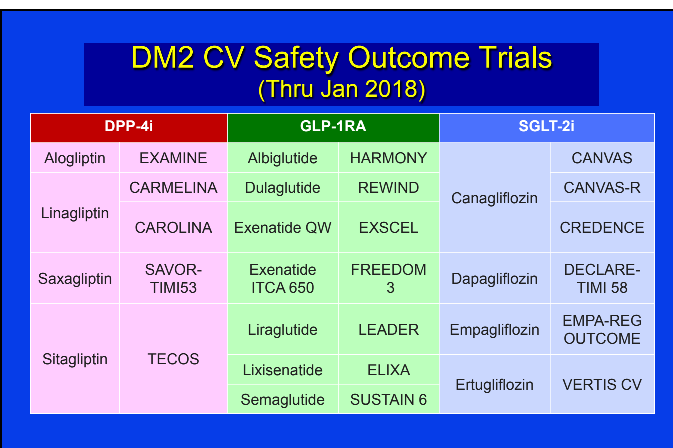




Pharmacotherapy: Clinical Characteristics

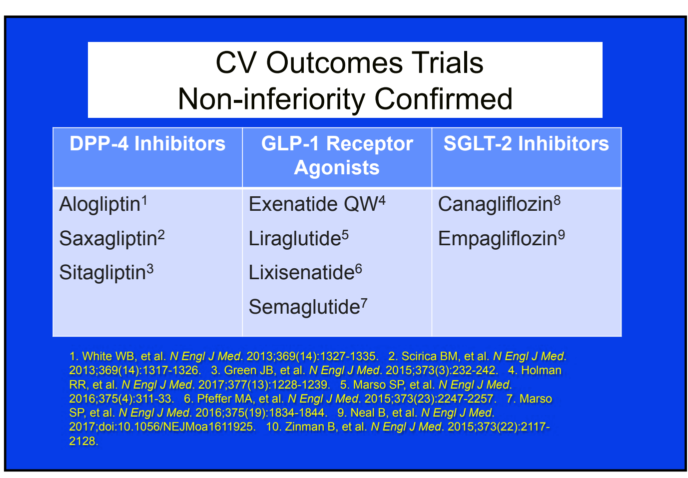
Drug	ASCVD	CHF
Metformin	Potential benefit	Neutral
SGLT 2	Benefit: Cana-, empagliflozin	Benefit Cana-, Empagliflozin
GLP1-RA	Benefit: liraglutide	Neutral
DPP4	Neutral	Potential risk Alogliptin, saxagliptin
TZD	Potential benefit	Increased risk
SFU	Neutral	Neutral
Insulin	Neutral	Neutral

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	Canagliflozin	CANVAS-R
Linagliptin	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 Outcomes Trials
Non-inferiority Confirmed

DPP-4 Inhibitors	GLP-1 Receptor Agonists	SGLT-2 Inhibitors
Alogliptin[1]	Exenatide QW[4]	Canagliflozin[8]
Saxagliptin[2]	Liraglutide[5]	Empagliflozin[9]
Sitagliptin[3]	Lixisenatide[6]	
	Semaglutide[7]	

1. White WB, et al. *N Engl J Med.* 2013;369(14):1327-1335. 2. Scirica BM, et al. *N Engl J Med.* 2013;369(14):1317-1326. 3. Green JB, et al. *N Engl J Med.* 2015;373(3):232-242. 4. Holman RR, et al. *N Engl J Med.* 2017;377(13):1228-1239. 5. Marso SP, et al. *N Engl J Med.* 2016;375(4):311-33. 6. Pfeffer MA, et al. *N Engl J Med.* 2015;373(23):2247-2257. 7. Marso SP, et al. *N Engl J Med.* 2016;375(19):1834-1844. 9. Neal B, et al. *N Engl J Med.* 2017;doi:10.1056/NEJMoa1611925. 10. Zinman B, et al. *N Engl J Med.* 2015;373(22):2117-2128.

CV Safety Trial Showing CV Risk REDUCTION Canagliflozin

Endpoint [a] = primary endpoint * = all p < 0.05	Rate/100 pt-years Cana	Rate/100 pt-years Pbo	Hazard Ratio* (95% CI)
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 Empa	Rate/100 pt-years Pbo	Hazard Ratio * (95% CI)
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

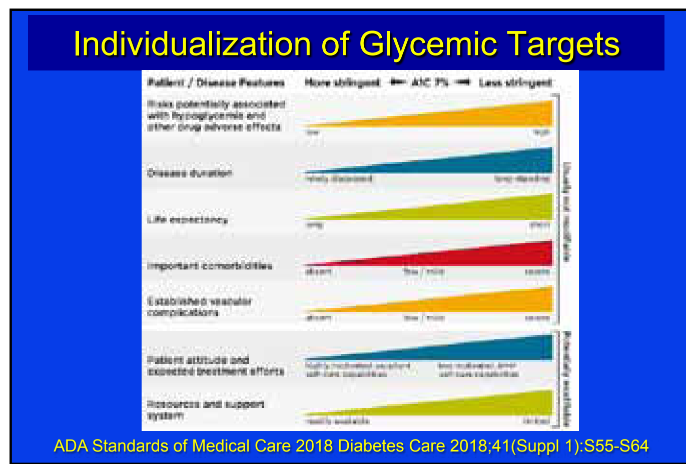
Endpoint a = primary endpoint * = all p < 0.05	Rate/100 pt-years Lira	Rate/100 pt-years Pbo	Hazard Ratio (95% CI) *
CV death, nonfatal MI & stroke[a]	3.4	3.9	0.87 (0.78-0.97)
1^0 + revascularization, unstable angina, or HF hospitalization	5.3	6.0	0.88 (0.81-0.96)
All cause mortality	2.1	2.5	0.85 (0.74-0.97)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

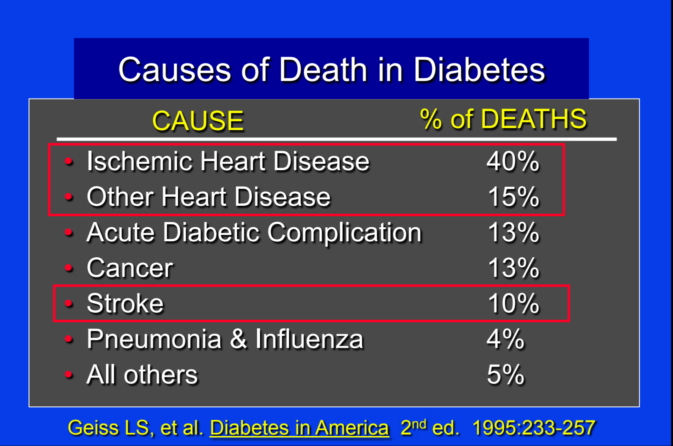
Marso SP, et al. *N Engl J Med*. 2016;375(4):311-322.

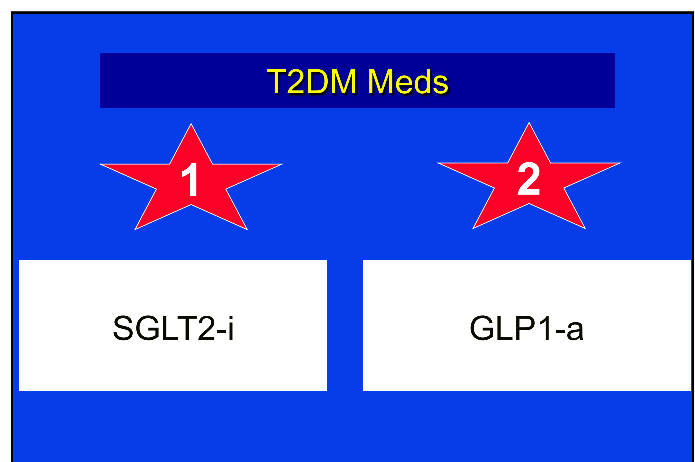
CV Safety Trial Showing CV Risk REDUCTION Semaglutide

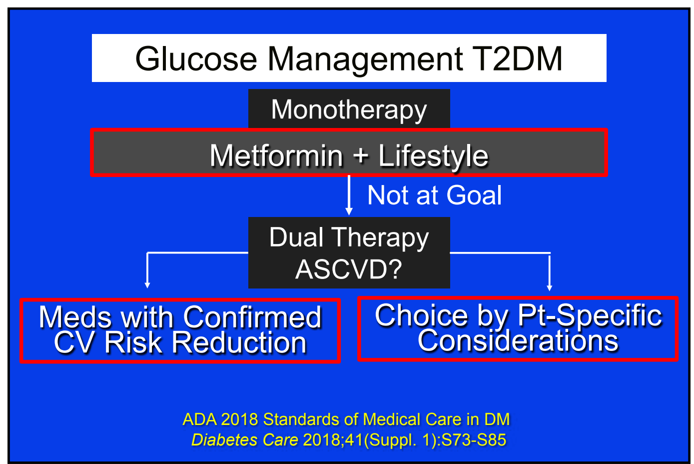
Endpoint a = primary endpoint * p < 0.05	Rate/100 pt-years Sema	Rate/100 pt-years Pbo	Hazard Ratio (95% CI)
CV death, nonfatal MI & stroke[a]	3.24	4.44	0.74 (0.58-0.95)*
1^0 + revascularization, unstable angina, or HF hospitalization	6.17	8.36	0.74 (0.62-0.89)*
All cause mortality	1.82	1.76	1.05 (0.61-0.97)
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)*

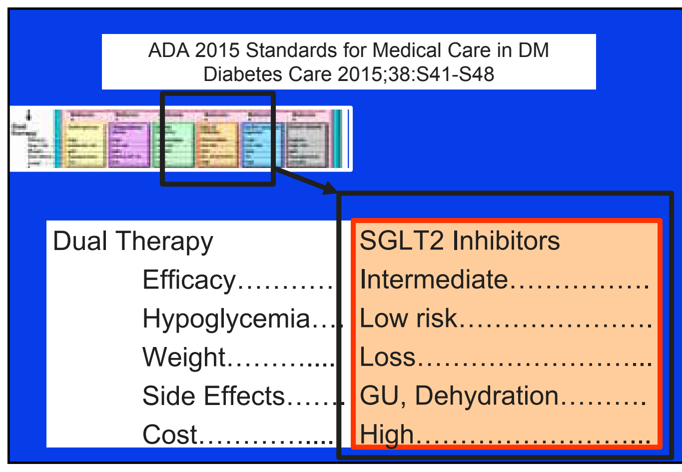
Marso SP, et al. *N Engl J Med*. 2016;375(19):1834-1844.







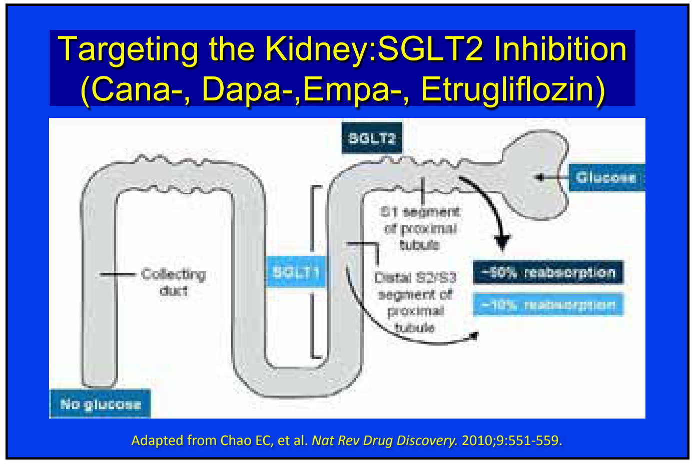


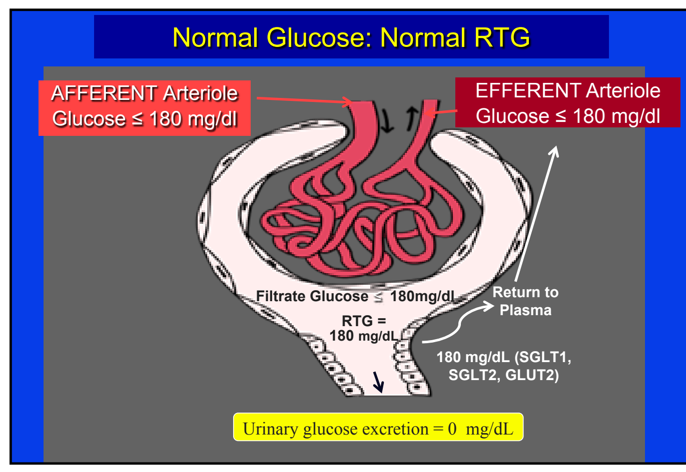


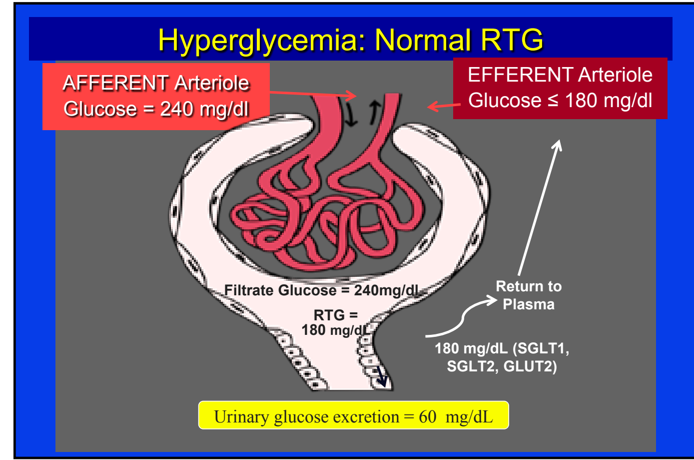
Glucose Metabolism: Role of Healthy Kidneys

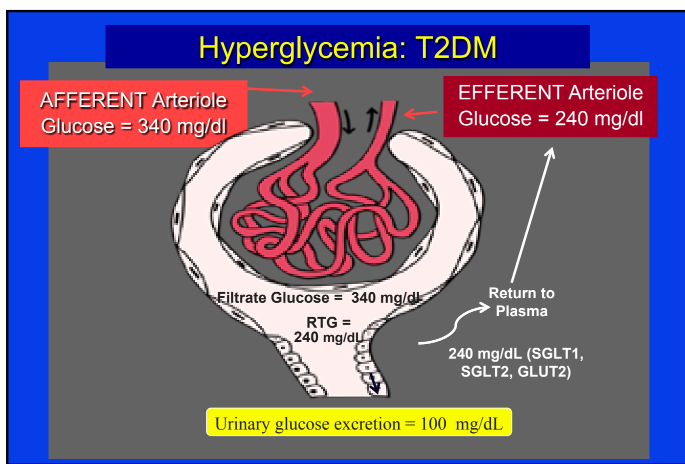
- 180 g/d glucose filtered
- ≥99% glomerular glucose reabsorbed into circulation
  - 90% by SGLT2
  - 10% by SGLT1

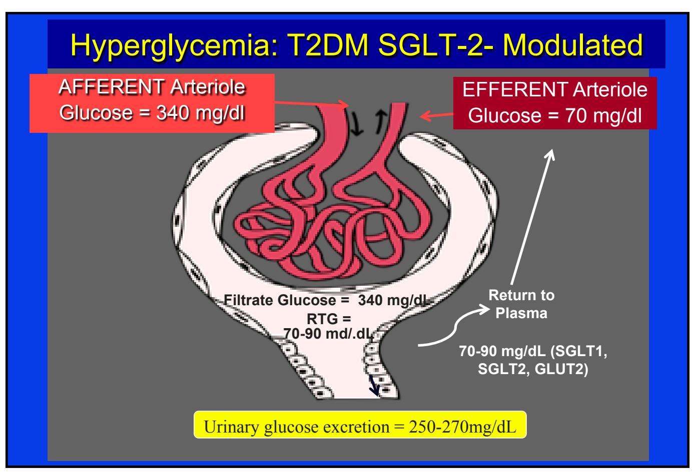
Mather, A & Pollock, C. *Kidney International*. 2011;79:S1-S6.

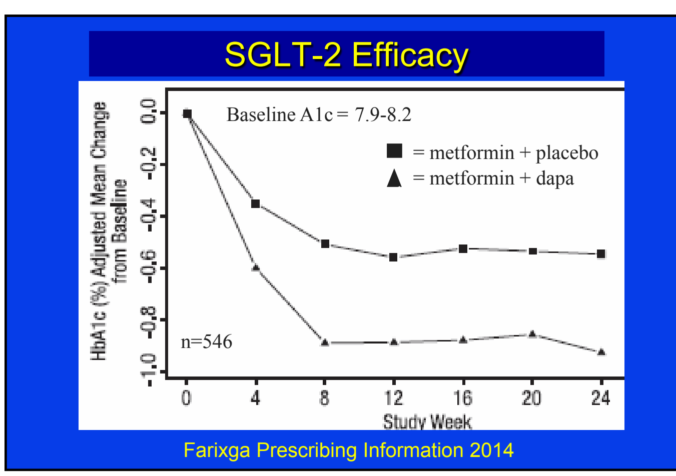


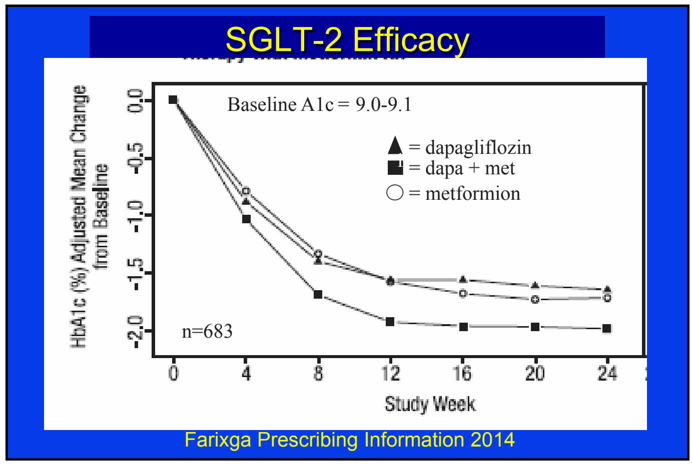


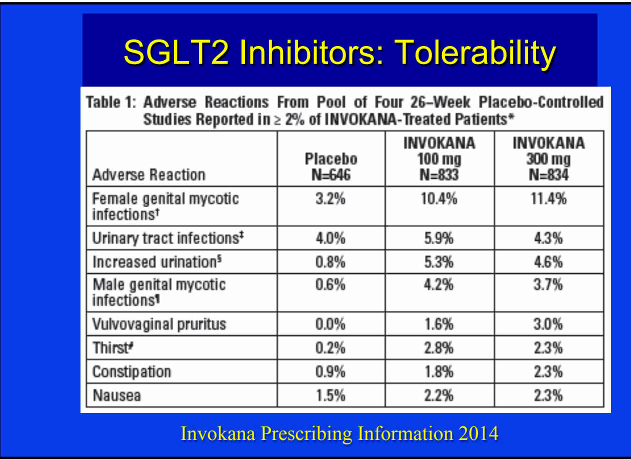












SGLT2 Inhibitors: Tolerability

Table 1: Adverse Reactions From Pool of Four 26-Week Placebo-Controlled Studies Reported in ≥ 2% of INVOKANA-Treated Patients*

Adverse Reaction	Placebo N=646	INVOKANA 100 mg N=833	INVOKANA 300 mg N=834
Female genital mycotic infections†	3.2%	10.4%	11.4%
Urinary tract infections‡	4.0%	5.9%	4.3%
Increased urination§	0.8%	5.3%	4.6%
Male genital mycotic infections¶	0.6%	4.2%	3.7%
Vulvovaginal pruritus	0.0%	1.6%	3.0%
Thirst#	0.2%	2.8%	2.3%
Constipation	0.9%	1.8%	2.3%
Nausea	1.5%	2.2%	2.3%

Invokana Prescribing Information 2014

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

+

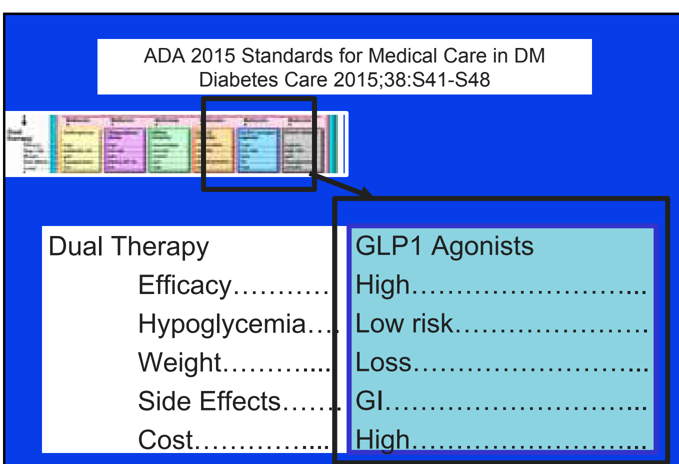
- Hydrocortisone cream if inflammation problematic

Why SGLT2 Inhibition?

- Efficacy: Intermediate
- Weight: Loss
- Tolerability: Excellent (UTI/Volume/Fungal)
- Serious AE: rare euglycemic DKA, amputations (cana, etruva)
- Compatibility: all other classes of Rx
- Hypoglycemia: Minimum
- BP: Reduced
- Dosing: Oral QD
- Limitations: CKD (*NOT* because of toxicity)

GLP1 Agonists

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



ADA 2015 Standards for Medical Care in DM
Diabetes Care 2015;38:S41-S48

Dual Therapy	GLP1 Agonists
Efficacy……….	High……………………..
Hypoglycemia…	Low risk…………………
Weight………....	Loss……………………..
Side Effects……	GI………………………...
Cost…………....	High……………………..

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

- Blunted 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]

[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 DPP4

Property/Effect	GLP-1R Agonists	DPP-4 Inhibitors
Mechanism of action	Pharmacologic agonist of GLP-1R	Inhibitor of incretin degradation
Route of administration	Subcutaneous	Oral
A1C lowering (dose dependent)	Up to 1.5%	Up to 1%
Slows gastric emptying	Yes	No
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.

ASPIRIN
SECONDARY Prevention

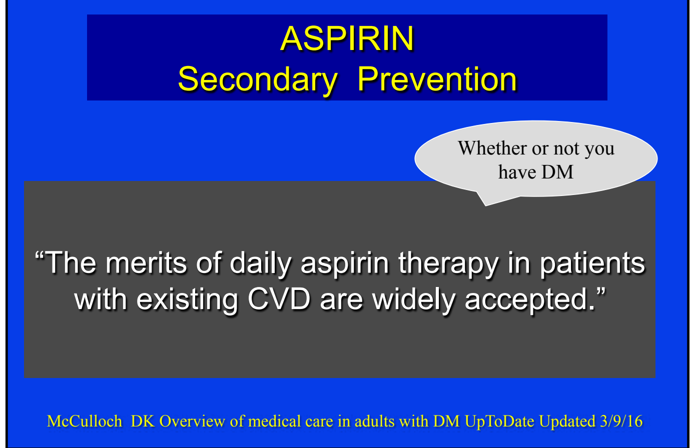
"For 2^0 prevention of CVD in patients with DM, we recommend aspirin 75-162 mg/d"

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

ASPIRIN PRIMARY Prevention

"For 1^0 prevention of CVD in patients with DM at ↑ CVD risk (10 yr risk >10%) we suggest aspirin (75-162 mg/d), although the evidence supporting this approach is weak."

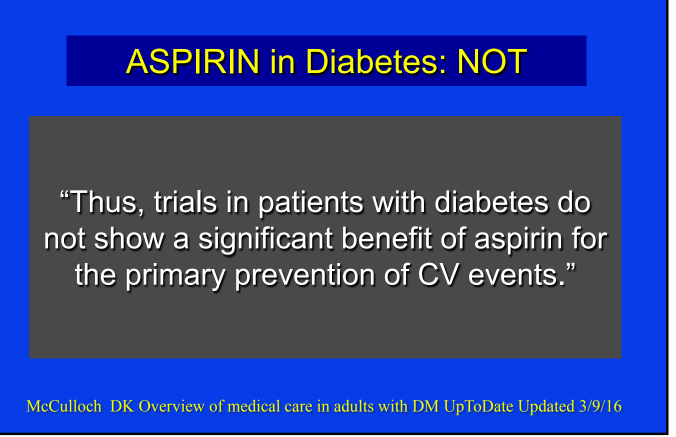
McCulloch DK Overview of medical care in adults with DM UpToDate Updated 3/9/16



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



Summary: New Directions

- ADA Flexible A1c Goals
- ASCVD prioritization for Step 2 drug Rx
- SGLT2 and GLP1 have confirmed ASCVD outcomes improvements
  - liraglutide*, semaglutide
  - canagliflozin, empagliflozin*

SELF EVALUATION

New Directions in Diabetes

1. Hypoglycemia as a consequence of DM treatment has been associated with?

a. Hypercompensatory glucose ingestion leading to prolonged hyperglycemia
b. Cognitive decline
c. Blunting of glucagon secretion
d. Improved CV outcomes in the ACCORD trial

2. According to the 2018 ADA treatment guidelines, an A1c goal of <8% is appropriate for?

a. Patients with newly diagnosed T2DM
b. Patients with limited life expectancy
c. Patients who say they feel better when A1c is about 8%
d. Patients with hemoglobinopathy (e.g., hemoglobin C, hemoglobin S)

3. According the 2018 ADA treatment guidelines, an A1c goal of <7% is appropriate for?

a. Most non-pregnant adults
b. Patients with multiple microvascular and macrovascular complications
c. Patients experiencing multiple hypoglycemic episodes
d. Pregnant women

4. Which agents have shown cardiovascular risk reduction in the treatment of T2DM?

a. Liraglutide, semiglutide
b. Sitagliptin, algogliptin
c. Repaglinide, nateglinide
d. Acarbose, miglitol

5. Which agents have shown cardiovascular risk reduction in the treatment of T2DM?

a. Basal insulin, prandial insulin
b. Pramlintide, Bromocriptine
c. Canagliflozin, empagliflozin
d. Glipizide, Glimepiride

6. Which class of agents is associated with balanitis in uncircumcised men?

a. GLP1-RA
b. SGLT2i
c. Sulfonylureas
d. Thiazolidinediones

7. GLP1-RA may reduce postprandial hyperglycemia by?

a. Blunting glucagon secretion
b. Increased intestinal motility
c. CNS satiety effects
d. Glucose-dependent insulin secretion

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

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David B. Mandell, JD, MBA, of Ft. Lauderdale, Florida, is a practicing attorney and a principal of the financial consulting firm OJM Group. He specializes in risk management, asset protection and financial planning and has authored a number of books for doctors including, *For Doctors Only: A Guide to Working Less and Building More*. 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 Professional Financial Stress Through More Effective Benefit Planning

David B. Mandell, JD, MBA

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OJM MATERIALS: FREE TO ATTENDEES

TODAY'S PRESENTATION

1. Background on physician financial stress
2. Financial efficiency in benefit planning for physicians in private practice
3. Considerations for employed physicians
4. Efficiency in retirement planning

PHYSICIAN DEMAND: FINANCIAL STRESS*

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

PHYSICIAN STRESS: FINANCIAL PREPAREDNESS*

- Providing a comfortable retirement for themselves and spouse/partner is the #1 financial goal – having enough to retire is their #1 personal financial concern (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.

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

WHAT IS A RETIREMENT PLAN?

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

Retirement

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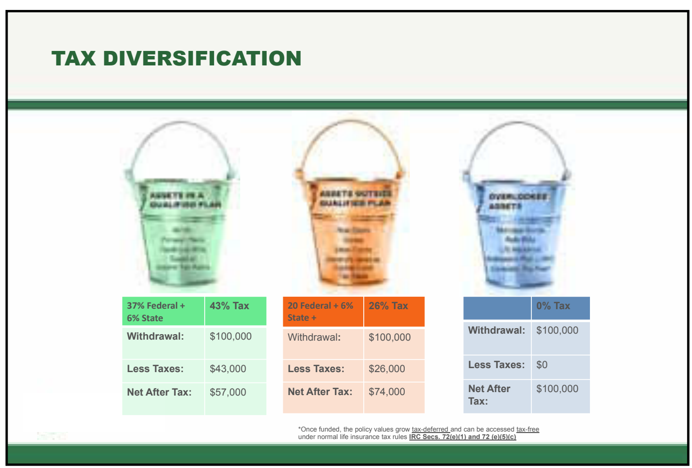
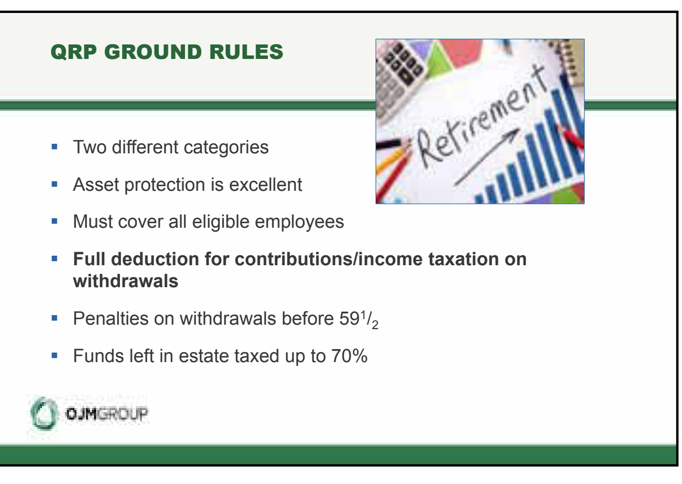
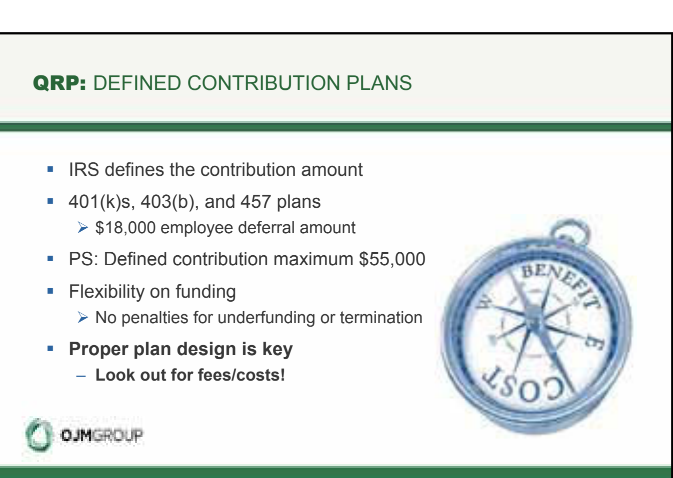
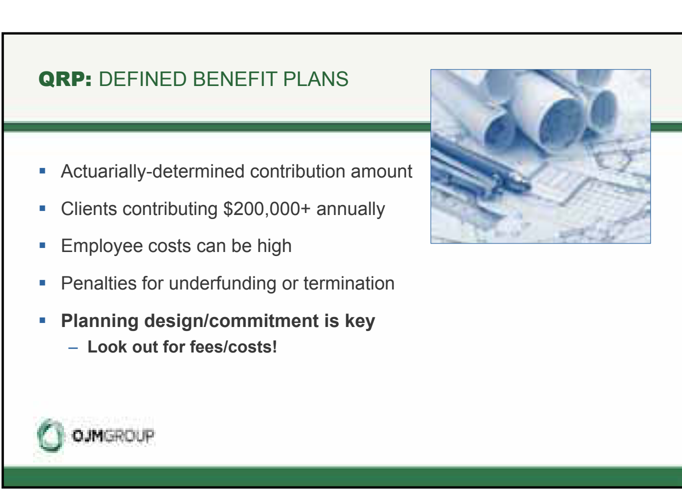
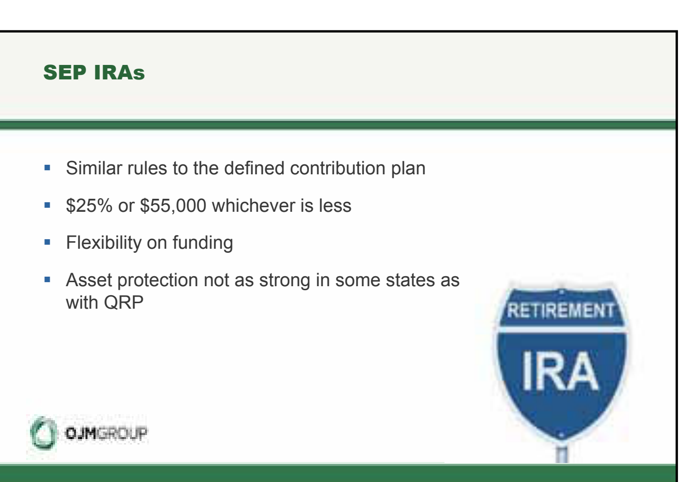




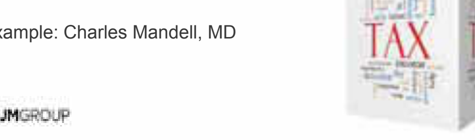




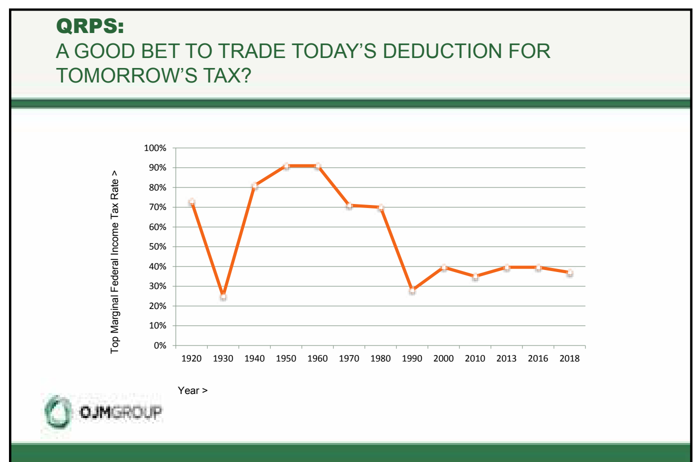


QRP GROUND RULES: REVISITED

- **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



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

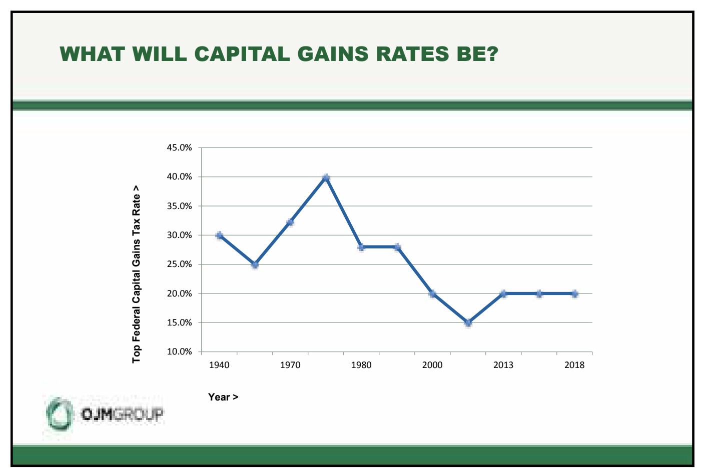


TRADING ORDINARY INCOME FOR CAPITAL GAINS TAXES

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

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

WHAT WILL CAPITAL GAINS RATES BE?



USING BENEFIT PLANS TO HEDGE YOUR LONG-TERM TAX BET

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

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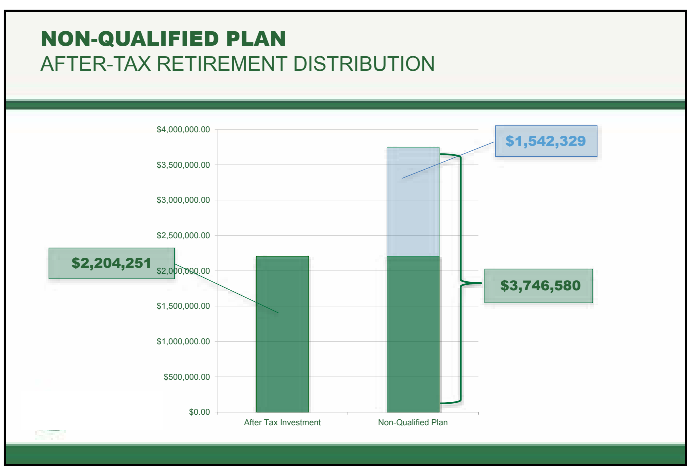
NON-QUALIFIED PLAN AS OPTION

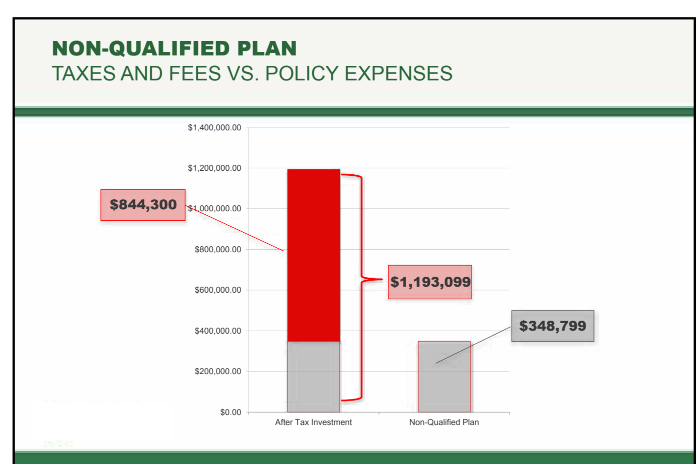
- No limitations on contributions – reasonable compensation
- In addition to 401k, profit-sharing, pension
- Owners can vary how much/if they participate
- Employee participation not required
- No tax deduction, tax-free growth and on withdrawal
- **Ideal hedge against future income/cg tax increases**

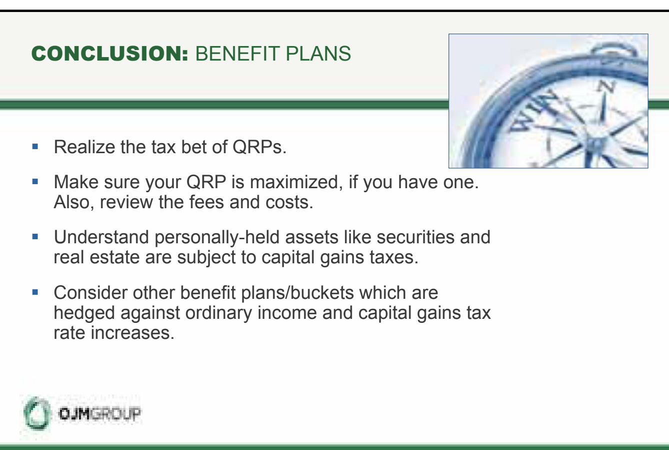
ASSUMPTIONS FOR CASE STUDY

Example taken from Actual OJM Group Client:

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







FIGURING OUT THE BASICS

- What are the qualified plan options offered through your employer?
- When do you become eligible to participate?
- Does your employer offer any matching arrangement? (Safe Harbor, Discretionary Match, Profit Sharing)
  - What is the vesting schedule for those employer contributions?
- Do contributions lower your taxable income – and is there a Roth option?

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MANAGING YOUR PLAN

- What are the investment fund options offered in your plan?
- Will the plan allow individuals to select his/her own investments ("self-direct")?
  - Are there fees to self-direct?
- Are statements, tools and planning resources available online?
- What are the conditions for borrowing from the account, if it's allowed?
- Can you make emergency withdrawals during a financial hardship?
- At what age can distributions start?

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RETIREMENT IS #1 GOAL FOR PHYSICIANS

- Providing a comfortable retirement for themselves and spouse/partner is the #1 financial goal – having enough to retire is their #1 personal financial concern.
- Same for the past 5 years of the AMA surveys

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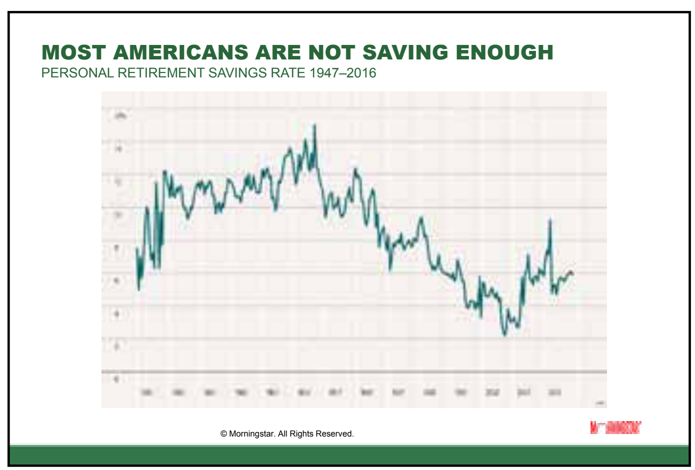

EFFICIENCY FOR RETIREMENT MEANS...

- To efficiently get to retirement, your assets must work for you, while you work as well.
- Knowing that your assets are working for you reduces stress. Your "partner" in retirement planning.
- Goal-based planning is crucial!
  - Investing only as valuable as it get you to YOUR goals

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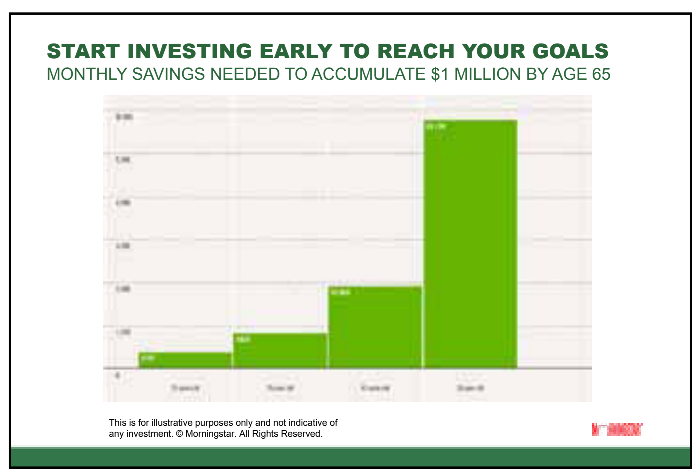
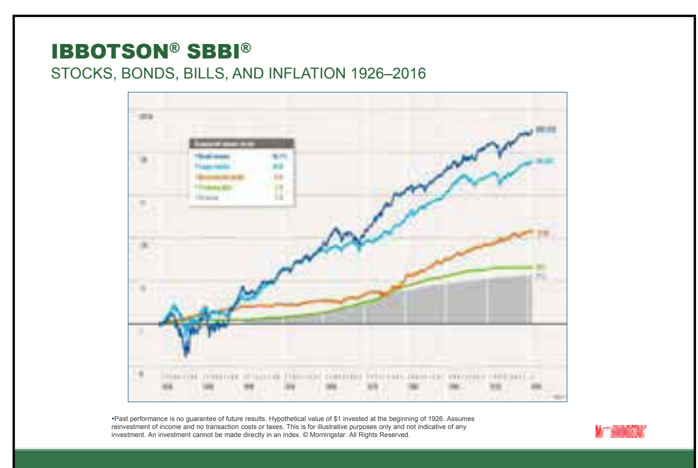
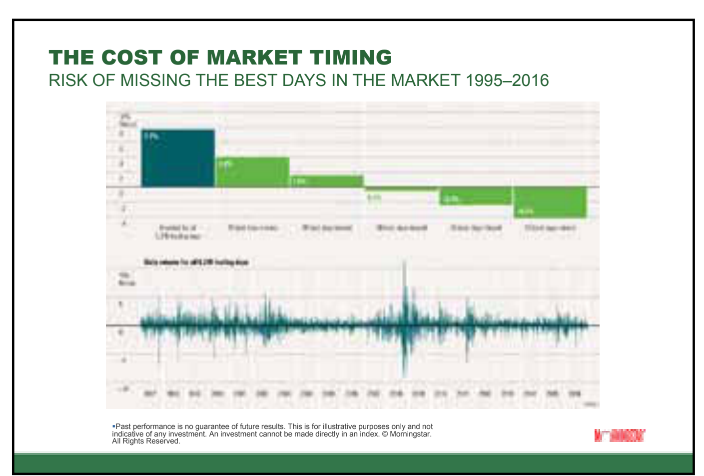


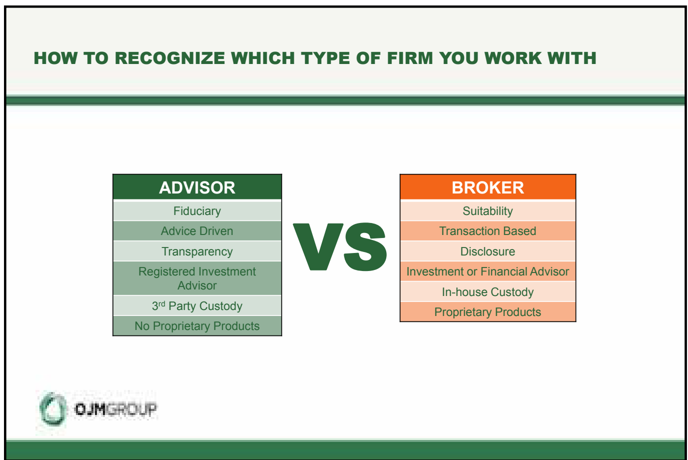




GETTING THE RIGHT GUIDANCE

- A fiduciary advisor has a ***fiduciary*** duty to his or her clients, which means that he or she has a fundamental obligation to provide suitable investment advice and ***always act in the clients' best interests***.
- A broker ***does not need to act in the best interests of the underlying customer.*** Instead, their actions must only must be ***suitable*** for the client.
- A key distinction in terms of loyalty is also important, in that ***a broker's duty is to the broker-dealer he or she works for***, not necessarily the client served.

HOW TO RECOGNIZE WHICH TYPE OF FIRM YOU WORK WITH



5 QUESTIONS TO ASK YOUR ADVISOR/PROSPECTIVE ADVISOR

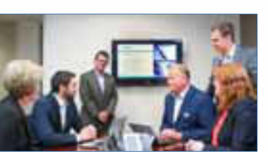
1. Does your advisor owe you a fiduciary duty as a client, or are they held only to a “suitability” standard?
2. Can your advisor provide a detailed explanation of all the ways they are compensated?
3. Does your advisor’s firm make money in other ways on your individual investments?
4. Does your advisor utilize proprietary securities?
5. Does the advisor’s firm engage in investment banking activities?

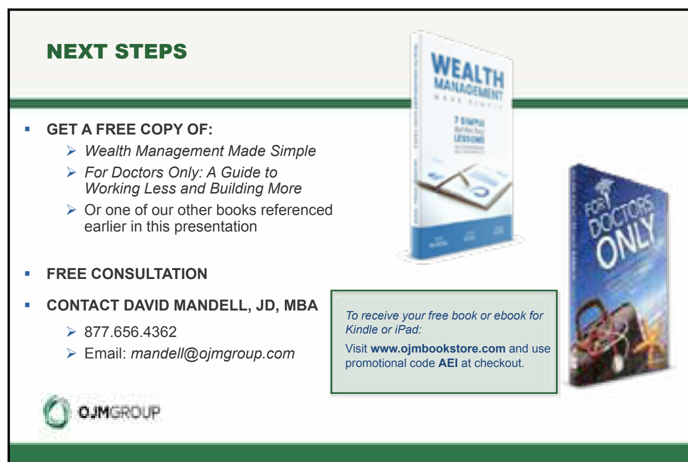
INVESTING WITHIN HOLISTIC WEALTH MANAGEMENT FOR RETIREMENT

- Investing is one discipline within a client’s comprehensive wealth management.
- Wealth management also incorporates:
  - Asset Protection Planning
  - Tax Planning
  - Insurance Planning
  - Education Planning
  - Savings Planning
  - Financial Modeling/Retirement Projections
  - Estate Planning
  - Flexibility
- Such holistic planning can reduce stress and improve a physician’s well-being.

ABOUT OJM GROUP

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





SELF EVALUATION

Reducing Professional Financial Stress Through More Effective Benefit 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. 10%
- b. 25%
- c. 39%
- 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. The new tax law impacted federal capital gains taxes as follows:

- a. Reduced
- b. Increased
- c. Did not change

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

7. In managing their qualified plan, employed physicians should ask all of the following questions EXCEPT:

- a. What are the conditions for borrowing from the account, if it's allowed?
- b. Can I make emergency withdrawals during a financial hardship?
- c. What will tax rates be when I retire?
- d. At what age can distributions start?

8. T/F - A financial advisor subject to the "suitability standard" does not need to act in the best interests of the underlying customer. Instead, their actions must only must be suitable for the client.

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

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C. Wayne Weart, PharmD, of Charleston, South Carolina, is professor of the Department of Clinical Pharmacy and Outcome Sciences in the South Carolina College of Pharmacy, Medical University of South Carolina (MUSC), as well as professor of Family Medicine in the College of Medicine, MUSC. Prior to MUSC he instructed at West Virginia University.

Dr. Weart has authored more than 100 publications and he has presented hundreds of hours of lectures to numerous professional groups and societies, medical and house staffs at both West Virginia University and MUSC, and national pharmacy and medical seminars across the country. He has received numerous awards and honors in his field including: "Outstanding Teacher" awards at both West Virginia University and MUSC, "Hospital Pharmacist of the Year" in both South Carolina and West Virginia; and designation as a Fellow of the American Society of Health Systems Pharmacists. In 1991 Dr. Weart was among the first pharmacists to become a board certified Pharmacotherapy Specialist.

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Medication Adherence: A Major and Curable Medical Problem

Faculty Disclosure

- I do not have a vested interest in or affiliation with any corporate organization offering financial support or grant monies for this continuing education activity, or any affiliation with an organization whose philosophy could potentially bias my presentation.
- I do not speak for or consult with any pharmaceutical manufacturer.

The Cost of Not Taking Your Medicine

- **"There is an out-of-control epidemic in the United States that costs more and affects more people than any disease Americans currently worry about. It's called nonadherence to prescribed medications, and it is — potentially, at least — 100 percent preventable by the very individuals it afflicts."**
  - The Cost of Not Taking Your Medicine by Jane Brody NY Times 4-17-2017

Quote from former Surgeon General C. Everett Koop

- **"Drugs don't work in patients who don't take them."**
  - C. Everett Koop, MD

Adherence vs. Compliance

- **"The word "adherence" is preferred by many health care providers, because "compliance" suggests that the patient is passively following the doctor's orders and that the treatment plan is not based on a therapeutic alliance or contract established between the patient and the physician.** Both terms are imperfect and uninformative descriptions of medication-taking behavior. Unfortunately, applying these terms to patients who do not consume every pill at the desired time can stigmatize these patients in their future relationships with health care providers."
  - N Engl J Med 2005;353:487-97.

Medication Adherence and Persistence

- Medication adherence usually refers to whether patients take their medications as prescribed (eg, twice daily), as well as whether they continue to take a prescribed medication.
- **Medication adherence behavior has thus been divided into 2 main concepts, namely, adherence and persistence. Although conceptually similar, adherence refers to the intensity of drug use during the duration of therapy, whereas persistence refers to the overall duration of drug therapy.**
  - Circulation. 2009;119:3028-3035

"White - Coat Adherence"

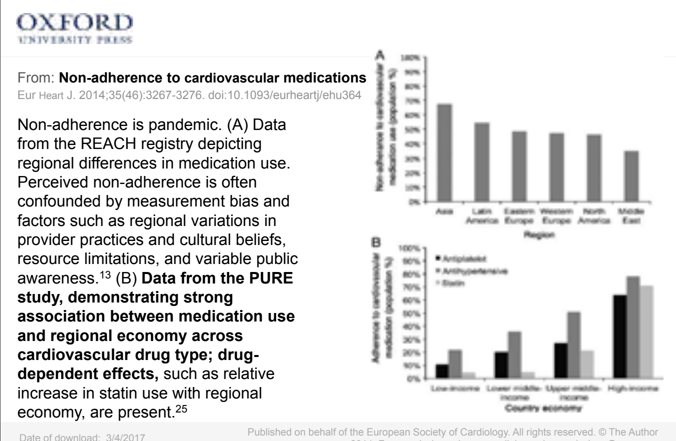
- **Patients commonly improve their medication-taking behavior in the 5 days before and after an appointment with the health care provider, as compared with 30 days after, in a phenomenon known as "white-coat adherence."**
  - Arch Intern Med 1990;150:1377-8.
  - Arch Intern Med 1990;150:1509-10.

Prevalence of Medication Nonadherence

- After acute myocardial infarction hospitalization, Jackevicius et al (Circulation 2008;117:1028 –1036) found that almost one fourth of patients **(~24%) did not even fill their cardiac medications by day 7 of discharge.**
- **Among patients discharged with prescriptions for aspirin, statin, and beta-blockers after acute myocardial infarction, 1 study found that ~34% of patients stopped at least 1 medication and 12% stopped all 3 medications within 1 month of hospital discharge.** (Arch Intern Med. 2006;166:1842–1847).

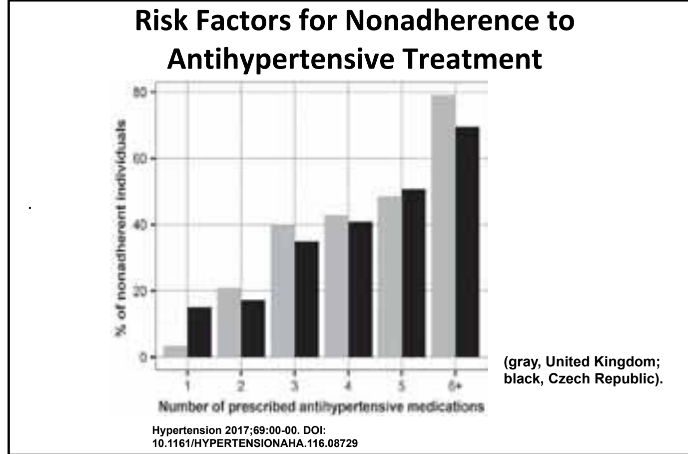
Prevalence of Medication Nonadherence

- Newby et al (Circulation. 2006;113:203–212) found that **patient self-report of consistent use of cardiac medications over 6 to 12 months was low, with approximately three fourths of patients reporting persistent aspirin use (71%), whereas less than half reported persistent use of beta-blockers (46%), lipid-lowering agents (44%), and all 3 medications (21%) after diagnosis of coronary artery disease by coronary angiography.**



Risk Factors for Nonadherence to Antihypertensive Treatment

- Using HPLC-tandem mass spectrometry of urine and serum to detect nonadherence **in 1348 patients with hypertension from the UK and Czech Republic .**
- **The rates of nonadherence to antihypertensive treatment were 41.6% and 31.5% in the UK and Czech populations, respectively. Nonadherence was inversely related to age and male sex.**
  - **the odds of the overall nonadherence were ≈65% and 55% higher in women than in men in the UK and Czech patients, respectively**
  - **every 10-year increase in age was associated with just >30% reduction in the odds of nonadherence in the UK and the Czech populations**
    - **Hypertension. 2017;69:00-00. DOI: 10.1161/HYPERTENSIONAHA.116.08729**.



Risk Factors for Nonadherence to Antihypertensive Treatment

- **Each increase in the number of antihypertensive medications led to 85% and 77% increase in nonadherence (P<0.001) in the UK and Czech populations, respectively.** The odds of nonadherence to diuretics were the highest among 5 classes of antihypertensive medications (P≤0.005 in both populations).
- After adjustment for age, sex, and the number of prescribed medications, **the odds of nonadherence to diuretics were the highest among 5 classes of antihypertensive medications, ≈1.8- and 1.6-fold higher than the reference category (ACEI/ARB) in the UK and Czech populations, respectively.**
  - **The 5 classes were diuretics, ACEI/ARB, CCB, Beta Blocker and other antihypertensives**
  - **Hypertension 2017;69:00-00. DOI: 10.1161/HYPERTENSIONAHA.116.08729**

Association Between Medication Adherence and Mortality

- **Nonadherence to statins in the year after hospitalization for myocardial infarction was associated with an ~12% to 25% increased relative hazard for mortality.** (JAMA 2007;297:177–186)
- **In patients with chronic coronary artery disease, nonadherence to cardioprotective medications (beta-blockers, statins, and/or angiotensin-converting enzyme inhibitors) was associated with a 10% to 40% relative increase in risk of cardiovascular hospitalizations and a 50% to 80% relative increase in risk of mortality.** (Am Heart J. 2008;155:772–779)

Effects of Poor Medication Adherence

- **At least 125,000 Americans die annually due to poor medication adherence.** (Bus Health. 1998;16:27-33)
- **As adherence declines, emergency room visits increase by 17% and hospital stays rise 10% among patients with diabetes, asthma, or gastric acid disorder**.(JAMA 2004; 5/19)
- **Poor medication adherence results in 33% to 69% of medication-related hospital admissions in the United States, at a cost of roughly $100 billion per year**.(New Engl. J. Med., 2005;353(5):487-497)
- NEHI **estimates that total potential savings from adherence and related disease management could be $290 billion annually — 13% of health spending**. ("Thinking Outside the Pillbox: A System-wide approach to Improving Patient Medication Adherence for Chronic Disease." NEHI, 2009)

Methodology of Assessing Medication Adherence

- Indirect methods of adherence include:
  - Patient questionnaires,
  - **self-reports,**
  - **pill counts,**
  - **rate of prescription refills,**
  - assessment of the patient's clinical response,
  - Electronic medication monitors,
  - measurement of physiological markers, and
  - patient diaries.
    - **The most commonly used indirect methods include patient self-report, pill counts, and pharmacy refills.**
    - N Engl J Med.2005;353:487– 497

Assessing Medication Adherence

- **There is currently no general consensus as to the best measure to use to define adherence or persistence**. The data to date highlight the challenges of measuring medication adherence in routine clinical practice and in research studies given the lack of a "gold standard" criterion.
- On the basis of **pharmacy refill data, patients with medications available 80% of the time have generally been categorized as adherent in the literature**. This dichotomous cutoff is somewhat arbitrary.
  - **human immunodeficiency virus or medications such as oral contraceptives, the 80% cutoff may be too low**.
    - Circulation. 2009;119:3028-3035

TABLE 1

MORISKY ADHERENCE TEST[19]

1. Have you ever forgotten to take your medicine?
2. At times are you not careful about taking your medicine?
3. When you feel better, do you sometimes stop taking your medicine?
4. At times, if you feel worse when you take your medicine, do you stop taking them?

An affirmative answer to any question suggests the presence of an adherence problem.

Basco MR, Smith J. *Primary Psychiatry*. Vol 16, No 8. 2009.

Possible Barriers Questionnaire

- INSTRUCTIONS: Despite our best intentions, almost every person who is prescribed a medication has one or more reasons why they do not take it. **Below are some reasons patients have told us why they don't take medication. We are interested in learning which of these reasons are true for YOU. Think about those times when you didn't take your prescribed medication. For each reason below, indicate what was true for you. There are no right or wrong answers. (Each statement is answered by one of the following 3 responses: A. Not true for me; B. Sometimes true for me; C. Very true for me.**
  - **1. I just forgot to take my medicine.**
  - **2. The medication cost too much**
  - **3. I was concerned about the side effects of the medication**
  - **4. I felt fine and didn't see the need to take the medication**
  - **5. I don't believe in taking medication**

Possible Barriers Questionnaire

- **6. I had trouble swallowing the medication**
- **7. I couldn't understand how or when to take the medication.**
- **8. My regimen was too difficult to follow.**
- **9. I was concerned about becoming too dependent on the medication.**
- **10. I was embarrassed to take that medication.**
- **11. I felt too pressured by other people.**
- **12. Drugs or alcohol got in the way.**
- **13. I had no one to talk to about taking the medication**
- **14. I just felt too sick to take the medication.**
- **15. I ran out of medication because I didn't refill it in time.**

How to Ask about Missed Doses?

- **The simplest and most practical suggestion for physicians is to ask patients non-judgmentally how often they miss doses.** Patients generally want to please their physicians and will often say what they think their doctor wants to hear. It can be reassuring to the patient when the physician tells them,
- **"I know it must be difficult to take all your medications regularly. How often do you miss taking them?" or "In an average week about how many times do you miss a dose?"** This approach makes most patients feel comfortable in telling the truth and facilitates the identification of poor adherence. **A patient who admits to poor adherence is generally being candid.**
  - N Engl J Med 2005;353:487-97.

Motivational Interviewing (MI)?

- **MI is a client centered, semi-directive method of engaging individuals in treatment or behavioral change.**
- **MI aims to promote and increase motivation to change behaviors by exploring and resolving any issues of ambivalence the client may be experiencing.**
- **MI addresses the client at their current state of functioning while addressing the varying levels of readiness for client change.**
- **MI is non-judgmental, non-confrontational and non-adversarial.**

Goals of MI

- **Establish rapport/listen and connect with the patient**
- **Elicit and begin change talk/sense making/get patient to want to change**
  - **Five stages of change:**
    1. **precontemplation**
    2. **contemplation**
    3. **preparation**
    4. **action**
    5. **maintenance**
- **Establish commitment to change language from the patient**
- **Be motivational! (Coach and Cheerleader)**

4 Principles of MI

1) **Express empathy by sharing an understanding with the client of their current situation and/or perspective. (AVOID saying "I understand" but reflect patients responses IE I hear you saying … or It sounds like …")**
2) **Help clients to explore and identify the discrepancies between what they wants in their lives compared to their life current situation. (On a scale of 0 to 10 where 0 means I am not willing to consider stopping smoking and a 10 I am ready today where are you at this time? What might move you from where you are up to an 8 or 9?)**
3) **Understand that resistance and reluctance are a *natural* and not *pathological* response to change for the client.**
4) **Support self efficacy:**
   - **Embrace client autonomy. (If you are not ready to stop smoking that is your decision, but please know that we are here to assist you if and when you want to talk about it and we can offer you assistance anytime you want)**
   - **Help clients transition towards successful change with confidence.**

Motivational Interviewing Clinical Interview: Putting Responsibility for Change on the Patient

- Simple Reflection
- Shifting Focus **"I'm Concerned"**
- Reframing
- Rolling with Resistance
- **Sense Making**
- **Ask Permission" Can I share what some of my patients have found helpful?"**
- Siding with the Negative
- Self-Efficacy
- Avoiding Arguments
- **Open-ended Questions**
- **Listen Reflectively "Sounds like"**
- Expressing Empathy
- Develop Discrepancy
- **Affirm "Will you agree to try …. Between now and our next visit?"**

Potential Reasons for Non-Adherence

- **The World Health Organization has categorized potential reasons for medication nonadherence into 5 broad groupings** that include:
- **Patient,**
- **Condition,**
- **Therapy,**
- **Socioeconomic, and**
- **Health system–related factors.**
  - http://www.who.int/chp/knowledge/publications/adherence_introduction.pdf .

World Health Organization's 5 dimensions of adherence

- **Patient-related — Physical, cognitive, or mental impairment, inadequate knowledge and skills in managing the condition, lack of awareness about the cost and benefits of treatment and forgetfullness**. These barriers can be overcome through behavioral and motivational interventions, good patient–provider relationships, self-management, and memory aids and reminders.
  - World Health Organization. Adherence to long-term therapies: evidence for action; 2003. http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf.

World Health Organization's 5 dimensions of adherence

- **Condition-related — Asymptomatic chronic disease(s), mental health disorders, a lack of understanding about the health problem(s) and poor perceptions about the disease(s).** These barriers can be **overcome through education** on the use of medications.
  - WHO 2003. http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf.

World Health Organization's 5 dimensions of adherence

- **Therapy-related — Primarily include complex treatment regimens, often for multiple chronic diseases and adverse effects of treatment.** To reduce these barriers, the World Health Organization recommends **simplification of treatment regimens.**
  - WHO 2003. http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf.

World Health Organization's 5 dimensions of adherence

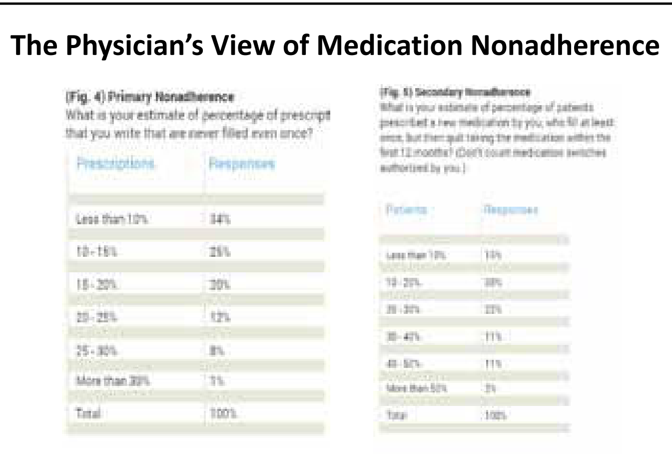
- **Health system–related and health care team–related — Lack of knowledge and training for health care providers on managing chronic diseases, poor patient–provider relationships and communications, and lack of access and/or time by the provider.** Training and education about medicines, **positive patient–provider relationships including continuity of care,** and continuous monitoring of self-management are interventions that reduce the health care barriers.
  - WHO 2003. http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf.

World Health Organization's 5 dimensions of adherence

- **Social and economic — Low literacy/numeracy, unemployment, lack of access to care, high cost of medicines, overall poor socioeconomic status**. Interventions to address these barriers and improve adherence include family's ability to help, patient health insurance, an uninterrupted supply of medicines, and sustainable financing for treatment.
  - WHO 2003. http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf.

The Physician's View of Medication Nonadherence

- A **survey of 100 primary care physicians regarding patient adherence to medications for hypertension, diabetes, and high cholesterol** by Survey Health Care and commissioned by **HealthPrize Technologies**.
  - Seventy-eight percent were male. Half of the respondents have been in practice between 21 to 30 years following training, with the remainder in practice up to 20 years, but not less than 2 years.
  - The Physician's View of Medication Nonadherence – White Paper by HealthPrize Technology



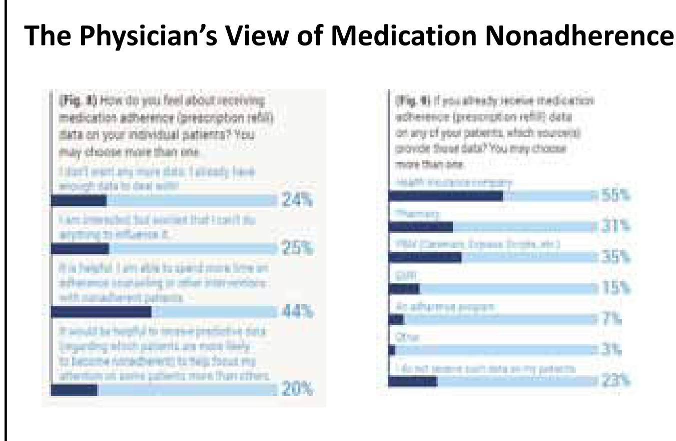
The Physician's View of Medication Nonadherence

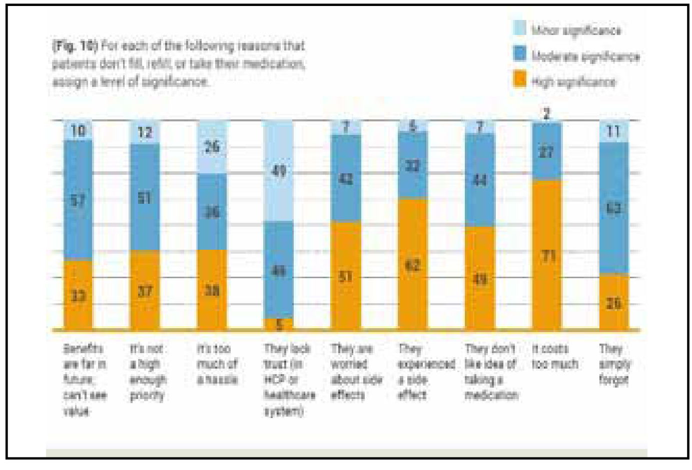
(Fig. 4) Primary Nonadherence
What is your estimate of percentage of prescript[ions] that you write that are never filled even once?

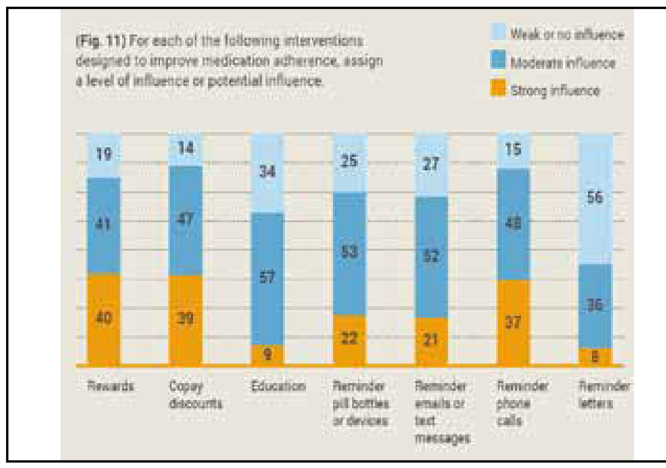
Prescriptions	Responses
Less than 10%	34%
10 - 15%	25%
15 - 20%	20%
20 - 25%	12%
25 - 30%	8%
More than 30%	1%
Total	100%

(Fig. 5) Secondary Nonadherence
What is your estimate of percentage of patients prescribed a new medication by you, who fill at least once, but then quit taking the medication within the first 12 months? (Don't count medication switches authorized by you.)

Patients	Responses
Less than 10%	15%
10 - 20%	38%
20 - 30%	22%
30 - 40%	11%
40 - 50%	11%
More than 50%	3%
Total	100%







What should we do to improve medication adherence?

- **Practitioners should always look for poor adherence and can enhance adherence by emphasizing the value of a patient's regimen, making the regimen simple, and customizing the regimen to the patient's lifestyle.**
- **Asking patients nonjudgmentally about medication-taking behavior is a practical strategy or identifying poor adherence.**
- **A collaborative approach to care augments adherence**.
- Patients who have difficulty maintaining adequate adherence need more intensive strategies than do patients who have less difficulty with adherence, a more forgiving medication regimen, or both. Innovative methods of managing chronic diseases have had some success in improving adherence when a regimen has been difficult to follow.
- New technologies such as reminders through **cell phones** and **personal digital assistants and pillboxes** with paging systems may be needed to help patients who have the most difficulty meeting the goals of a regimen.
  - N Engl J Med 2005;353:487-97.

Forgetfulness

Tips for remembering:

- **Take your medications when you do something that's part of your daily routine, like brushing your teeth**.
- **Use a pillbox**. They're inexpensive.(Note you might even want to use more than one, one in the morning and another one in the evening).
- **Set your watch, phone, or clock to ring as a reminder**.
- **Sign up for auto-refills at your pharmacy** to make sure you don't run out or request your pharmacy to call you to remind your before your refills are due and you can **also request that your pharmacy move your medications to all need to be refilled at the same time each month (known as synchronization) or every 3 months**
- **Ask for a 90-day supply** - you'll need fewer refills.

Pillboxes and Reminder Apps

367 unique apps were evaluated for design, functionality and health literacy (HL). The median initial score based on descriptions was 15 (max of 68; range: 3 to 47). Only 77 apps of the top 100 highest-scoring apps completed user-testing and HL evaluations. The median overall user-testing score was 30 (max of 73; range: 16 to 55).

CONCLUSION:

App design, functionality, and level of HL varies widely among adherence apps. While no app is perfect, several apps scored highly across all domains. **The website www.medappfinder.com is a searchable tool that helps HCP and patients identify quality apps in a crowded marketplace. The 2 highest rated free apps are shown on the next 2 slides. Journal of the American Pharmacists Association 56 (2016) 293e302**

CVS Health Medication Timer Caps

- Introducing the **Timercaps**! No alarms to program or set make it the easiest medication reminder on the market! Timer Caps helps answer the simple question **Did I take my meds today?** Without any complicated timer to set, or spreadsheet to keep track of. Simply put the cap on your CVS prescription and the smart cap will do it for you. **Like a stopwatch, it resets every time you close the container and begins to displays time passed since last closed.**
- Lets you keep your medication organized in the original bottles.
- Simple for easy identification of medication and last dosage in case of emergency.
- What Youll Receive: **3 Timer Caps With Built-in LCD Timers - 2 Small (13/16 Dram) And 1 Large (30/40/60 Dram) For CVS Prescription Bottles. Cost: $9.99/3 caps**

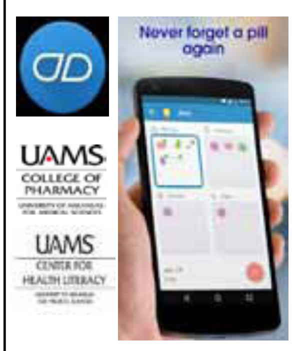
CVS Health Medication Timer Caps

Rx Timer Caps

Cost: $19.95 for two vials with caps on Amazon

NOTE: does not fit on traditional prescription vials and would require a new label

Medisafe Meds & Pill Reminder

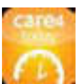


FREE Medisafe Features:

• Intuitive visual interface with easy-to-use medication reminder
• Sync family members' devices and medications in real time
• Track other measurements - such as blood pressure, weight - to make sure you're in great health
• Choose your medication reminder sound
• View your medication reminder list to see "what's due today?"
• Rx refill reminders so you can restock your meds
• List PRN medication
• Medication progress reports that you can send to a doctor or nurse
• Registration (not required) features automatic backup and restore on the Medisafe HIPAA-compliant servers

- / http://medappfinder.com

Care4Today® Mobile Health Manager and Medication Reminder (Janssen)



- Care4Today® Mobile Health Manager and Medication Reminder
  - **a self-directed pill reminder**
  - **Care4Family®—Support your family members and loved ones by monitoring their medications and encouraging them to stay on schedule.**
  - **Adherence Reports—Share graphs on how you're staying on your medication schedule with loved ones and your healthcare pr**
- / http://medappfinder.com

UAMS COLLEGE OF PHARMACY UAMS CENTER FOR HEALTH LITERACY

Medication Reminder App Search

Check the features you would like on your medication reminder app from the list below. Results will be shown on the right.

Features

- **Free App**
- **Has Non-English Option**
- **Tracks Missed/Taken Doses**
- **Can "Snooze" Reminders**
- **Has Refill Alerts**
- **Identifies Potential Adverse Interactions**
- **Orders Refills**
- **Provides Reminders without Cellular Service (or wi-fi)**
- **Easy to Read (common words)**

- / http://medappfinder.com

Cost and Medication Adherence

- A number of studies have evaluated the impact of changing costs of medications on individual patient adherence.
  - **Among Medicare + Choice beneficiaries, patients who had drug benefit caps were more likely to be non-adherent to medications for hypertension, hyperlipidemia, and diabetes**. (N Engl J Med. 2006;354:2349 –2359)
  - In addition, **patients with caps on drug benefits had worse intermediate outcomes (eg, LDL levels and blood pressure) and higher rates of emergency department visits and non-elective hospitalizations**. In separate studies, **changes to out-of-pocket spending doubled the risk of stopping statin therapy, and higher copayments were associated with lower adherence to statins.** (Circulation. 2007;115:2128 –2135, Am J Manag Care.2006;12:509 –517)
  - Taira et al (Am J Manag Care. 2006;12:678–683) demonstrated a **graded relationship between the level of copayment and medication adherence, with patients more likely to refill medications for antihypertensive medications that had a lower copays.**

How to make medications more affordable

- **Ask for generics whenever possible.**
- **Ask your doctor for medications with low co-pays** or medications that have lower cash prices
- Ask a pharmacist or social worker about special discounts from drug companies.
- Ask for a 90-day supply instead of a 30-day supply - pay 1 co-pay instead of 3. (May not save $ as some insurance plans will charge you for three co-pays for a 90 day supply, check with you pharmacist to see if this will save you $?)
- **Pay out of pocket for generics when the cost is less than your co-pay.** (Some generics of commonly used medications may be on a list of medications that is available for a lower co-pay like the $4.00 list at some pharmacies or even with a zero co-pay for some medications at selected pharmacies **– check with your pharmacist or GoodRx.com).**
- Ask your pharmacist for discounts when paying out of pocket.
- Use sites like goodrx.com, lowestmed.com, or others to shop around for the lowest cash price.
- When you pay out of pocket, use discount cards from AARP, AAA, or others. Even the NRA can get you discounts.
- **Tell your doctor or pharmacist if the cost of medication is likely to be a problem** for you or your family they may be able to assist you and even help you obtain an expensive medication by **working with a patient assistance program with the medications manufacturer**

Formulary Exclusions for 2017

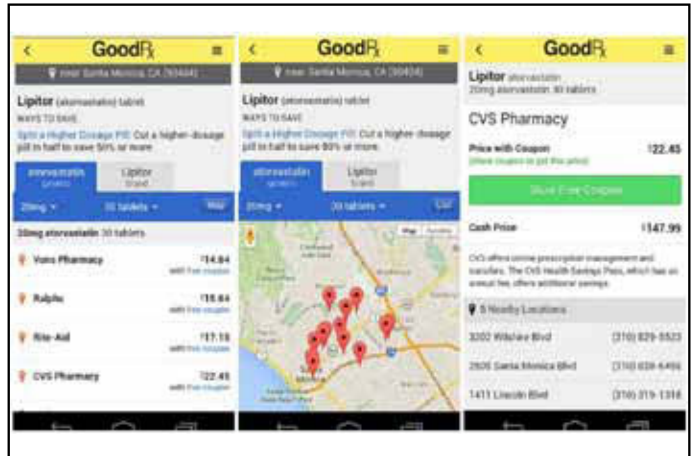
- **CVS/Caremark 154 medications**
  - Including the following diabetes meds: Byetta, Bydureon, Glumetza, Humalog, Humalin 70/30, Humalin N and R, Lantus, Invokana and Toujeo
  - Also includes: Abilify, Crestor, Lipito, Livalo, Macrodantin, Beconase AQ, Veramyst, Proventil HFA, Ventolin HFA, Xopenex HFA, Incruz Ellipta, Symbicort, Nexium, Zegerid
- **Express Scripts 85 medications**
  - Including the following diabetes meds: Victoza, Tanzeum, Novalog, Apidra, and Glumetza
  - Also includes: Beconase AQ, Veramyst, doxycycline 40 mg caps, levalbuterol HFA, Xopenex HFA, Proventil HFA
- **Optum Rx (United Healthcare) 89 medications**
  - Including the following diabetes meds: Tanzeum, Novolin, Novolog, Apidra, Levemir, Tresiba, Farxiga, Xigduo XR, Alogliptin, alogliptin with metformin, alogliptin with pioglitazone, Kazano, Nesina, Oseni, Kombiglyze XR, Onglyza
  - Also includes: Duexis, Dulara, Vimovo, Xopenex HFS and Proventil HFS

(Patients will be required to pay 100% out of pocket)

What does this mean to you and your patients?

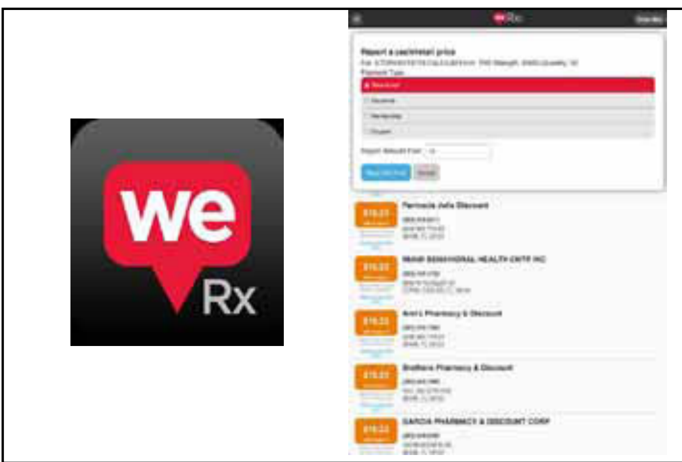
Can a phone app help you find cheaper drugs?

- **According to Consumer Reports who tested 4 apps states "GoodRx and WeRx worked well",** GoodRx and WeRx are both free for iPhone, iPod touch, and iPad, and GoodRx is also Android-compatible.
- **Why we liked them: Both apps are easy-to-use, offer money-saving tips, information about $4 generic and pharmacy rewards programs, search by condition, and the option to search for pharmacies by ZIP code or detect your location using GPS.** But GoodRx was best at finding the lowest prices in stores and online.
- **One inconvenience: Neither app found prices for the over-the-counter drugs Advil and ibuprofen.** We searched for several other OTCs, and also came up empty. GoodRx instead provided a link to Advil prices on Amazon.com
  - Consumer Reports August 2013



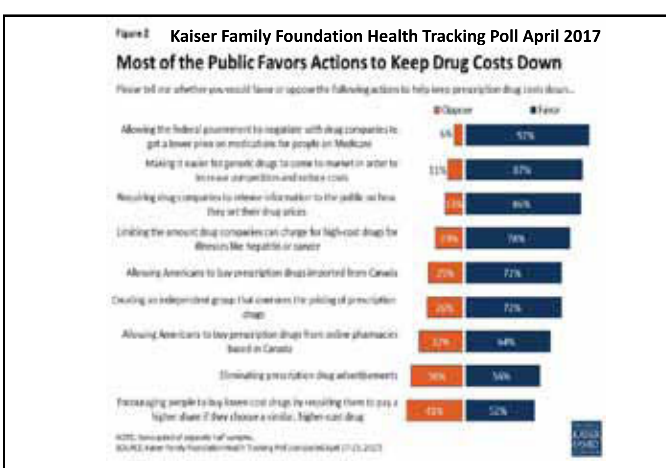
GoodRx Discounts?

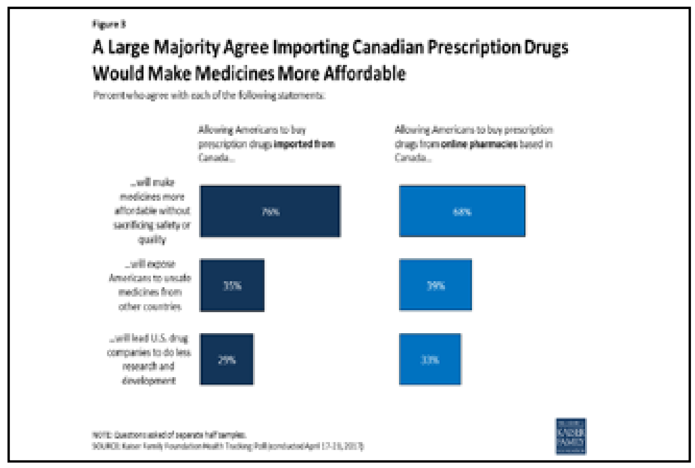
- **May 8, 2017 GoodRx** "Today, we're proud to announce a **partnership with Inside Rx, a new subsidiary of Express Scripts, that reduces the cost of more than 40 popular brand-name drugs by an average of 34% off the retail price.** Included on the list are Proair, Lantus, Humalog and many other popular prescriptions that treat diabetes, asthma, COPD and other conditions. On average, these discounts will provide savings of about $1,600 per year."
  - **Example Lantus Solostar (5 pens) ~$427.00**
  - **Inside Rx $266.79 (an ~ 37% discount but does not apply to co-pays or Government plans including Medicare, Medicaid, DOD, VA, TriCare, etc.).**
    - **Takes into account the rebate/discount Express Scripts has with Sanofi. Available at Walmart, CVS, Walgreens, Bi-Lo, Target**



Still Can't Afford Your Meds?

- **Consumer Reports suggests you start with the website RXassist.org.** This website has a couple of great features. One - it'll tell you if the manufacturer of your drug has any assistance programs. And they have a prescription drug card that should get your generic prescription for less than $10.





Counterfeit Meds and Internet Pharmacies

- **Many Internet pharmacies give the impression that they are located in Canada and are selling legitimate brand-name drugs that have been manufactured in Canada**, but many of these legitimacy claims are blatantly false. In these cases, the drugs are not approved by the FDA and they are not safe or effective. They are often not even approved by the Canadian government.
- Medicines that are not used in Canada are not subject to the scrutiny of Canada's safety laws. Therefore, **drugs from Canadian Internet pharmacies can come from anywhere in the world. The fact is that many so-called Canadian Internet pharmacies are not Canadian at all, but are actually based in places such as Belize, Russia, and Vietnam, to name a few.**
- **A 2005 study found that only 214 of 11,000 online pharmacies claiming to be Canadian were actually registered in Canada. This has made "Canadian" Internet pharmacies the primary supplier of counterfeit drugs to the United States.**
  - Am Health Drug Benefits 2014;7(4):216-224

Reynolds Drug Store, Andrews, SC

Some illicit internet pharmacies have hijacked web-sites previously operated by legitimate pharmacies, such as Reynolds Drug.

Years ago EVApharmacy hijacked the pharmacies domain name: while reynoldsdrug.com retains the pharmacies address and branding, orders placed on the web-site are filled by EVApharmacy with drugs being shipped from Pakistan and China. When you click on buy now it takes you to a site called Canadian Online Pharmacy

The site advertises Viagra 25mg - $1.85; 50 mg - $2.17; 75 mg - $1.89; 100 mg - $2.55; 120 mg - $4.88; 130 mg - $4.89; 150 mg - $5.45; 200 mg - $7.50
Brand Viagra only comes as 25, 50 and 100 mg tabs and costs $50.00 per tablet

The Internet Pharmacy Market in 2016: Prepared by LegitScript.com for The Center for Safe Internet Pharmacies

CAUTION Buyer Be Ware!

The Counterfeiting Superhighway landmark research by the European Alliance for Access to Safe Medicines in 2008 found that:

- **96% of online pharmacies researched were operating illegally**
- **94% of websites did not have a named, verifiable pharmacist**
- **over 90% of websites did not require a prescription to sell prescription only medications**
- **More than eight in 10 internet pharmacies do not 'physically exist' –** in order to comply with the law all online pharmacies must be traceable to a verifiable bricks and mortar address.
- Fewer than five in 100 internet pharmacies are licensed by a board of pharmacy or appropriate pharmacy listing.
- 86% of internet pharmacies link to a bogus 'approval' web page 'stamp of approval' from a recognized society or association

FDA Campaign: BeSafeRx – Know Your Online Pharmacy

- **Patients should only buy prescription medicine through online pharmacies that:**
  - **require a valid prescription from a doctor or other health care professional;**
  - **are located in the United States and provides a physical address and telephone number**
  - **have a licensed pharmacist available for consultation; and**
  - **are licensed by the patient's state board of pharmacy.**
  - **are VIPPS verified by the National Assoc of Boards of Pharmacy (NABP)**
    - **http://www.nabp.net/programs/accreditation/vipps/find-a-vipps-online-pharmacy/**
    - http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm321470.htm 9-28-2012

Canada adopts VIPPS for on-line pharmacies

- **Canadian pharmacy officials have adopted the Verified Internet Pharmacy Practice Sites program developed by the National Association of Boards of Pharmacy, but on-line pharmacies that ship drugs into the United States will not be eligible for Canada's seal of approval.**
- Just like its American counterpart—NABP—the National Association of Pharmacy Regulatory Authorities (NAPRA) will thoroughly investigate the practices of on-line pharmacy applicants and issue a seal of approval—VIPPS Canada—to those that pass muster
- **"None of the sites shipping into the United States can have VIPPS certification because they are violating U.S. law," said executive director Carmen Catizone of NABP.**

Collaborative Practice

- **Creating Community-Clinical Linkages Between Community Pharmacists and Physicians. Atlanta, GA: Centers for Disease Control and Prevention**, U.S. Department of Health and Human Services; 2017.
  - https://www.cdc.gov/dhdsp/pubs/docs/ccl-pharmacy-guide.pdf
  - **describes a framework for creating linkages between community pharmacists and physicians that benefit community collaborators and the patients they serve.**

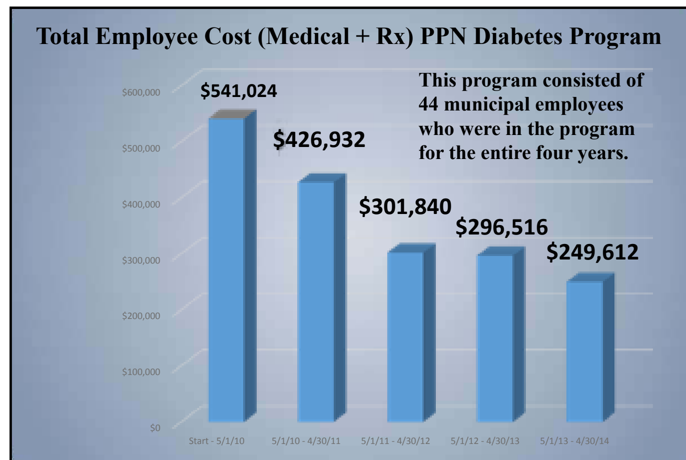
Collaborative Drug Therapy Management (CDTM)

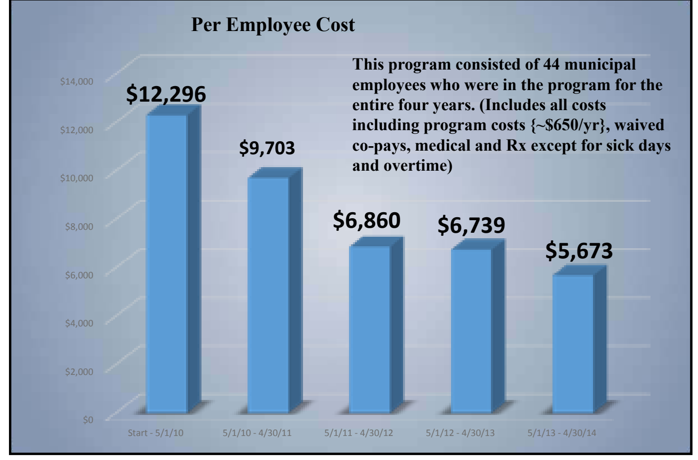
- **"CDTM is a formal collaborative practice model between physicians and pharmacists where pharmacists—per a collaborative practice agreement—assume the responsibility for monitoring and managing drug therapy to optimize patient outcomes and safety."**
- **"Seek to understand the scope of services pharmacists can provide for your patients** (e.g., medication therapy management, **medication adherence counseling**, lifestyle modification counseling, chronic disease management, identification of drug-related problems, smoking cessation guidance, and patient self-management education for hypertension, diabetes, and other chronic conditions)"
- **The CDC provides examples including the Diabetes Ten City Challenge**
  - https://www.cdc.gov/dhdsp/pubs/docs/ccl-pharmacy-guide.pdf

DIABETES TEN CITY CHALLENGE

- **Objective:** Assess the clinical, humanistic, and economic outcomes of a community-based health program for patients with diabetes.
- **Setting:** 21+ employers in 10 different geographic locations **(4 from Charleston, SC, met the inclusion criteria)**
- **Design:** Quasiexperimental observational
- **Sample:** 573 patients with DM
- **Intervention:** Community-based pharmacist provided patient care services
- **Outcomes:**
  - Decreased HgA1c, LDL, BP, BMI.
  - Increased patient satisfaction, vaccinations, foot & eye exams, nutrition/exercise/weight goals met
  - **$1079 reduction in average total health care costs per patient per year**

Fera T, et al. JAPhA. 2009 May;49(3):383-391.





Data from Charleston and Mt Pleasant Palmetto Pharmacists Network

- These health care **costs INCLUDE the cost of all prescription drug and supplies, co-pay waivers, pharmacist/coach compensation** but DO NOT include municipal savings from 'paid sick days' and 'overtime' paid for essential municipal employees such as fire and police.
- **Medications are covered with a zero co-pay for participants and includes all medications for DM, BP and Lipids.**

5 things you can do to stay safe by talking with your doctor and pharmacist

1. Confirm that you understand the basics of your medication: The name (generic and Brand if appropriate) indication (what the medication is supposed to do) and dose of the medication; How much should you take, when (what time(s)), and how (with or without food, milk, with a full glass of water, etc.). Also be sure you know what to do if you miss a dose, how to store our medication and anything you need to know and do to get the dose ready to take or administer (shaking the bottle, rolling NPH insulin, etc.). Take time at the pharmacy counter to talk with the pharmacist. Even if he or she seems busy, don't feel reluctant to ask.

2. Ask about food, supplements, and vitamins that should be avoided. And what about alcohol?

3. Ask about the expected effects including the possible side effects, both common and rare, as well as which are the most serious.

4. Read the patient information sheets that come either stuffed into or stapled to the prescription bottle bag.

5. Determine when you can stop taking the medication. Some drugs, like antibiotics, should be taken until they're finished. You might be able to discontinue other medication as you feel better.

SELF EVALUATION

Medication Adherence: A Major and Curable Medical Problem

True/False:

1. "There is an out-of-control epidemic in the United States that costs more and affects more people than any disease Americans currently worry about. It's called nonadherence to prescribed medications."

2. Patients commonly improve their medication-taking behavior in the 5 days before and after an appointment with the health care provider, as compared with 30 days after, in a phenomenon known as "white-coat adherence."

3. According to data from the NEJM in 2005 Poor medication adherence results in 33% to 69% of medication-related hospital admissions in the United States, at a cost of roughly $100 billion per year.

4. On the basis of pharmacy refill data, patients with medications available 80% of the time have generally been categorized as adherent in the literature.

5. Motivational Interviewing or MI is non-judgmental, non-confrontational, patient centered and aims to promote and increase motivation to change behaviors by exploring and resolving any issues of ambivalence the patient may be experiencing.

6. One of the phases that is suggested to improve patient acceptance when using MI is the phase "I understand".

7. The Health Prize Survey of 100 primary care physicians found that the most important reason their patients did not fill, refill or take a medication(s) was related to forgetfulness.

8. According to a Kaiser Family Foundation Poll in April 2017 most Americans are in favor of making it legal to buy prescription drugs from Canada but a major concern is that most (about 98%) internet pharmacies that say that they are in Canada are NOT registered or located in Canada and you are at great risk of getting counterfeit medications which may not contain the medication you need.

9. Patients should only buy prescription medicine through online pharmacies that are VIPPS (Verified Internet Pharmacy Practice Sites) which is a program developed by the US Food and Drug Administration (FDA).

10. In 2017 the Center for Disease Control and Prevention (CDC) issued a resource that encourages "Collaborative Drug Therapy Monitoring, a formal collaborative practice model between physicians and pharmacists where pharmacists—per a collaborative practice agreement—assume the responsibility for monitoring and managing drug therapy to optimize patient outcomes and safety."

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

Richard A. Honaker, MD, FAAFP

Richard A. Honaker, MD, FAAFP, of Charlottesville, Virginia, is a board-certified, family practice physician who received his medical degree from University of Virginia School of Medicine. Dr. Honaker has been listed in "Best Doctors", *D Magazine's* "Best Doctors in Dallas", *Texas Monthly's* "Texas Super Doctors", and Consumers' Research Council of America's "Guide to America's Top Family Doctors". He is a diplomate of the American Board of Family Medicine, has been in practice for over 30 years, and was the senior physician and president of a 10-provider group in a suburb of Dallas, Texas. Dr. Honaker was also co-founder of the Jefferson Physician Group, a prominent primary care IPA in Dallas, and has been a contributing medical columnist and commentator for numerous publications and television programs.

You may contact Dr. Honaker with any questions or comments at (214) 532-1420 or by email at honaker@aol.com.

RICHARD A. HONAKER M.D., F.A.A.F.P.

Diplomate, American Board of Family Medicine

Healthcare Practice Risk: A Survey

Concepts

Generalist vs Specialist
Fee for service vs fee for value (population health)
Volume vs not Volume
EMR vs Paper
Small vs Medium vs Large practice
Outpatient vs Inpatient

Medical Malpractice

Standard of Care

Gestalt
Evidence based
Literature
Guidelines

Practice Guidelines

National Library of Medicine - www.nlm.nih.gov/
National Guideline Clearinghouse - guideline.gov
Others
Guidelines-good and bad

Know when you are over your head

Keep up

Journal Watch
Prescriber's Letter
Medical Letter
Audio CME
Journals
Speed reading course

Top Ten Lists for malpractice-for example, delayed diagnosis and missed diagnosis

Urgent Care Centers

Mid-Level Providers

Lab. Imaging, and tests: not received, not reviewed, not acted upon

Initial ALL labs, imaging reports, new records, letters - foolproof method that nothing in charted or scanned without review- 100%

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Recall System
- Double check system
- Tickler file-so important
- Follow-up system
- Encounter form section to commit to follow-up
- Set up next appointment at all visits

Doctor Detective
- Goal is 100%
- Every Single Chart – 4 sites to review: last progress note, last phone call, last refill, data Base list of meds and diseases
- Assume something is missing
- Health Recommendation charts

In office consults

Call sick patients in the evening

Cancel and No Show review/action

Samples

ROS on scattered patients

Imaging log

What to tell the patient regarding how they will hear about test results

Complete Physicals-The Key to fine care
- Make it happen
- Specialty specific physicals

Volume
- For patients seen in the past 3 years, but not seen in the past 1 year
- 30 day refills
- 90 day rule
- Letter received and chart reviewed and it is time for….

Mole/Skin lesion tickler file

Website email dangers

Documentation
- Primary defense
- Legibility
- Abbreviations
- EMR back up

Alterations

Informed consent

Mid-Levels – P.A.'s and N.P.'s
- Formal agreement
- Review – percentages and intervals
- Teaching
- Sign offs
- Consult on important diagnoses and medications

RTC if worsening, not better, not well- give day intervals.

Discharge Summary dangers

Computer interface for procedures

EMR documentation

Medication errors
- Allergies
- Interactions
- Lists
- OTC

Ask: "Any questions? Did we cover everything?"

<u>Patient Safety</u>

Vasovagal syncope

Infections control and prevention

O2, epinephrine, EMT, ambu bag, defibrillator issues

Blue dot, yellow dot, red dot

<u>Insurance Companies</u>

Skin coding

Compliance program

Consultant

Do the right thing and always look for right things to do

Government

MACRA

MIPS

Get a consultant

Record storage

Record destruction

General

“Schedule” and “Recall” boxes

See work-ins

Phone medicine

Win-win questions

Complete Physicals

Ransomware

HIPAA

Embezzlement

Patient Satisfaction Surveys

Termination of patients

Avoid questions with a “No” answer.

Commit staff and patient to action and follow-up.

SELF EVALUATION

Healthcare Practice Risk: A Survey

True/False

1. It is not important to have a formal practice agreement when hiring a mid-level provider.

2. It is a good idea to depend upon your patients to call back if they do not hear from you about their tests results.

3. A termination notice to a patient should be sent by registered mail only.

4. The standard of care is a formal, written document.

5. To comply with infection control protocols, you must culture the nose of all clinical personnel for Staph.

6. When a patient calls for a refill, the physician should have a system in place that evaluates the overdue medical needs the patient may have.

7. There are always dependable warning signs before vasovagal syncope occurs.

ANSWER KEY: 1. F, 2. F, 3. F, 4. F, 5. F, 6. T, 7. F

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Aspirin as an Agent of Primary Prevention

Disclosures

No relationships with Industry to disclose

Off-label discussion:
Aspirin for Primary Prevention

What you *MAY* Have Been Thinking As You Entered This Presentation

- Most everybody over 50 should probably take aspirin
- Diabetics probably benefit the most from aspiring, since DM has been identified as a 'CVD risk equivalent'
- I Knew I Should Have Looked at the Meeting Schedule Ahead of Time! Aspirin? I Could Have Slept in Another Hour….

What I'm Going to Try to Convince You

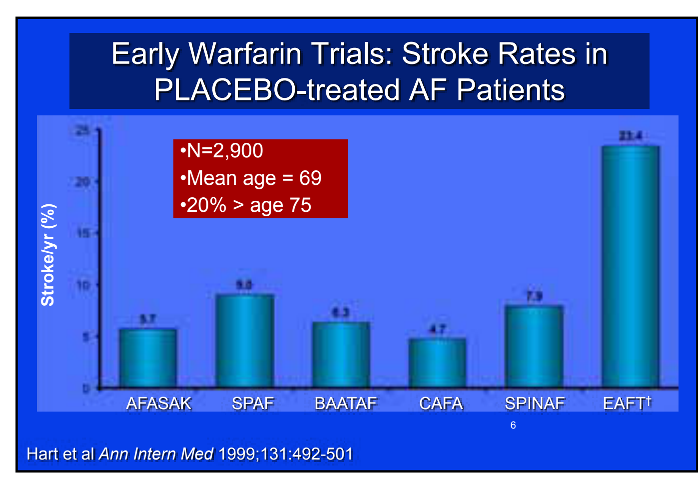
- ASA is VERY GOOD for 2^0 prevention of CV events
- ASA MAY be good for some SOME high risk patients for 1^0 prevention of CV events
- For diabetics, ASA is of dubious, if any, value
- …but you should probably still give it!
- ASA reduces Colon CA Risk, but the risk is small, and may take 10-20 years to occur

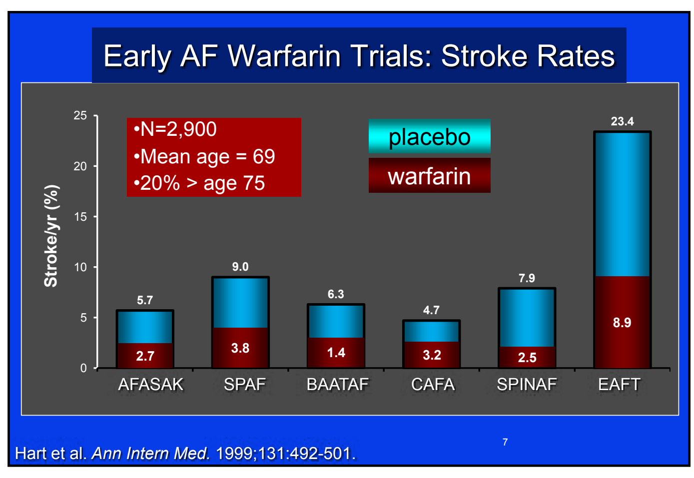
Prevention Strategies: Primary Prevention

- Intervention intended to prevent a specific adverse health event prior to it occurring for the first time
  - In persons *without* prior CVA, BP control to reduce incidence of CVA
  - In persons *without* prior MI, statins to reduce incidence of MI
  - Immunizations (*Most*)

Prevention Strategies: Secondary Prevention

- Intervention intended to prevent a specific adverse health event AFTER a person has experienced one or more prior such events
  - Anticoagulants for AF patients who have already had a stroke
  - Post-MI beta blocker prophylaxis
  - Clopidogrel post-stroke





A Hypothetical Study
AOM: Zithromax vs Placebo

A Nobel-prize winning St. Mary's Hospital pediatrician has done a randomized controlled trial to compare azithromycin (Zithromax) with placebo for otitis in Pennsylvania elementary school children. His hypothesis: azithromycin will shorten the duration of acute otitis media compared to placebo.

Study Endpoint: Relative likelihood of being febrile 48 hours after treatment initiation

Trial Results: PA Elementary Schools
AOM: Azithromycin vs Placebo

0.65 (0.35, 0.75)

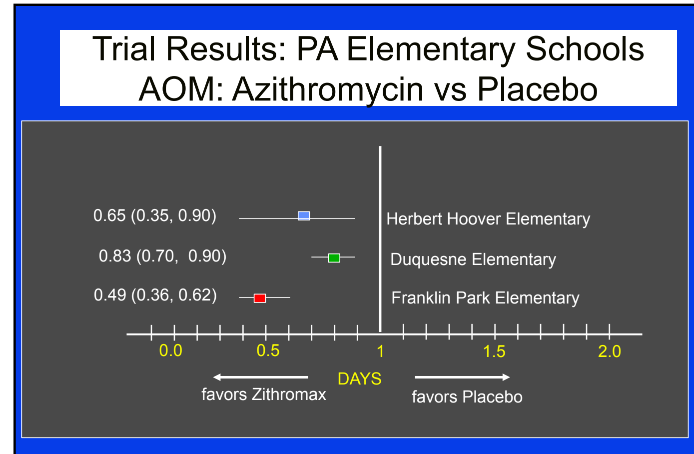
Herbert Hoover Elementary

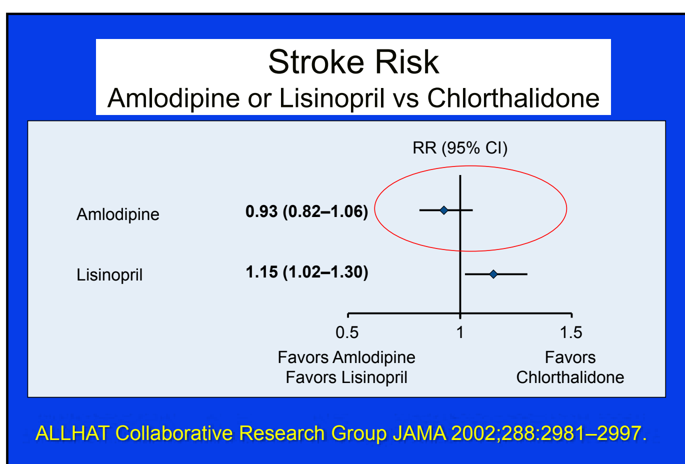
0.0 0.5 1 1.5 2.0

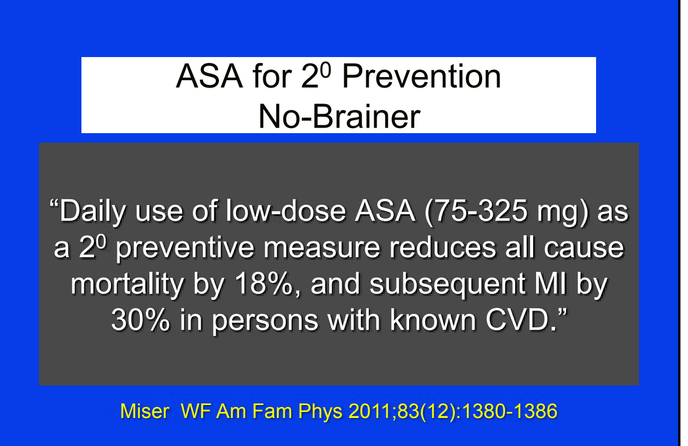
DAYS

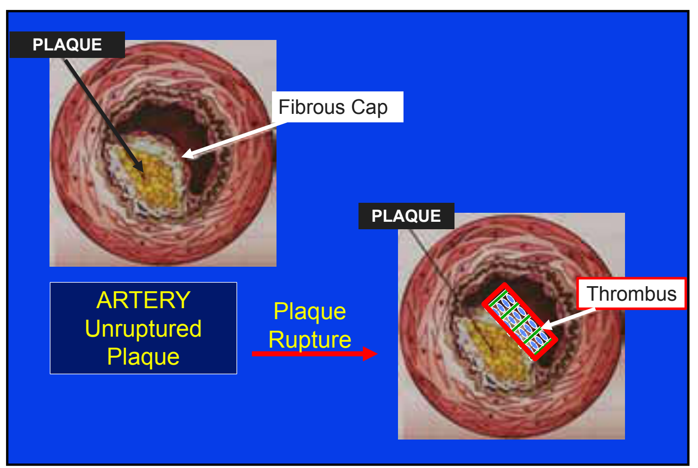
favors Zithromax

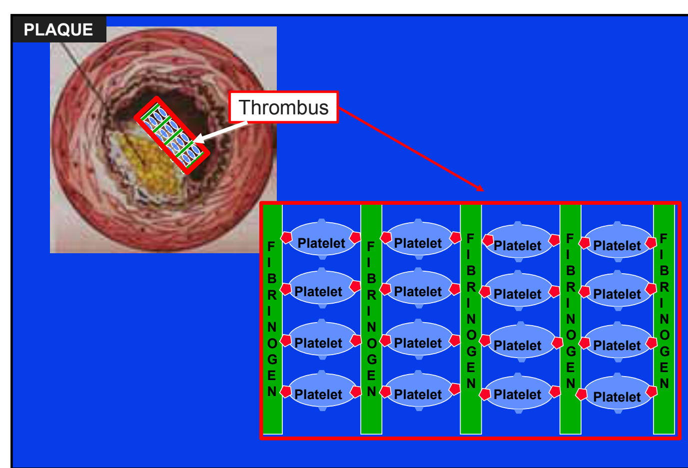
favors Placebo

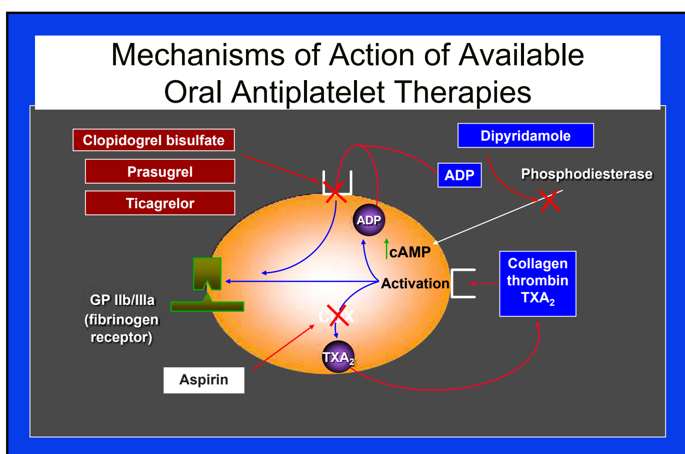


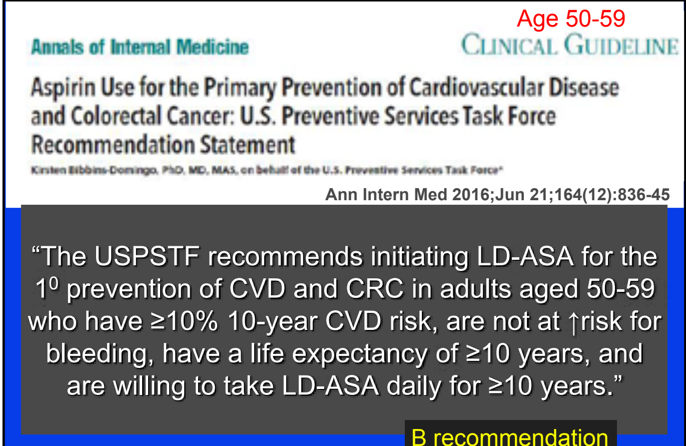












USPSTF Recommendation Grading 2016

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 at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits	Discourage the use of this service
I	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

www.uspreventiveservicestaskforce.org

USPSTF Recommendation Grading 2016

Grade	Definition	Suggestions
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial	Offer or provide this service
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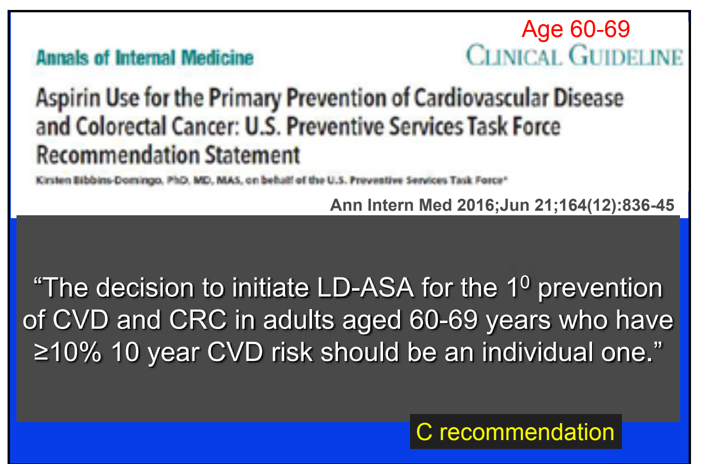
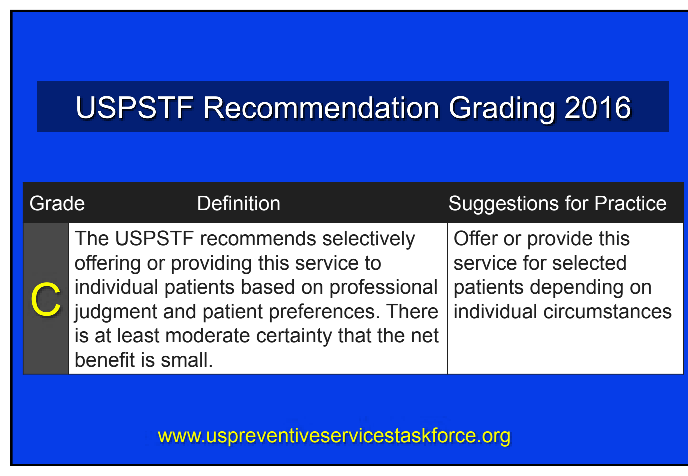
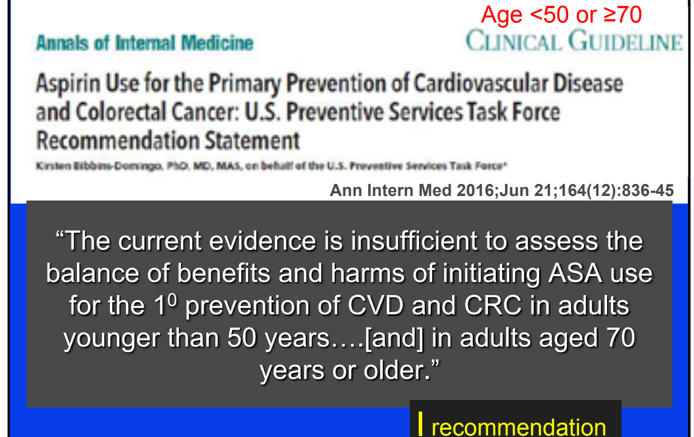
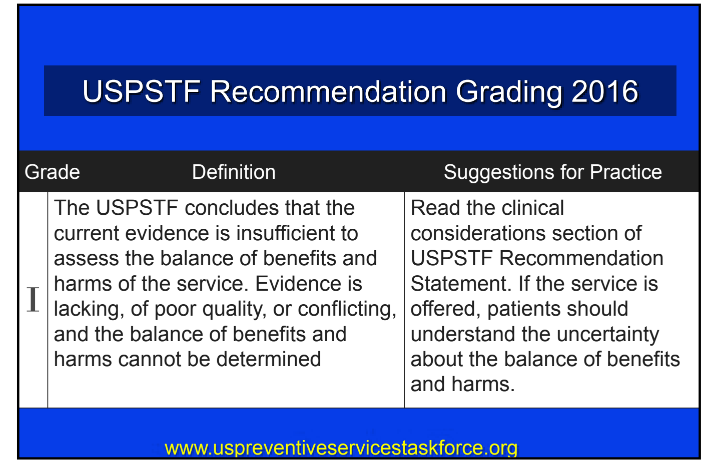






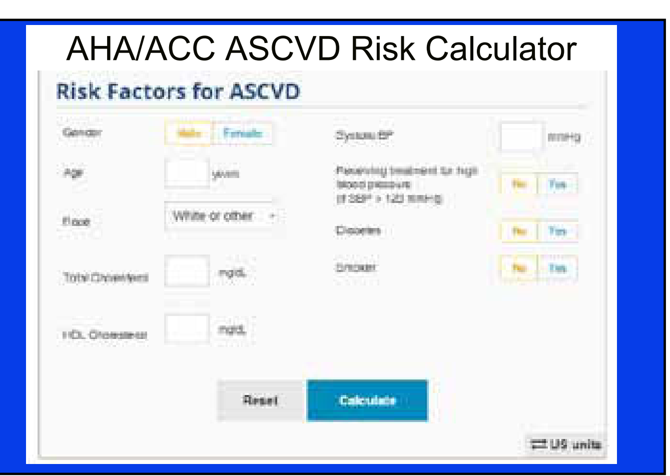


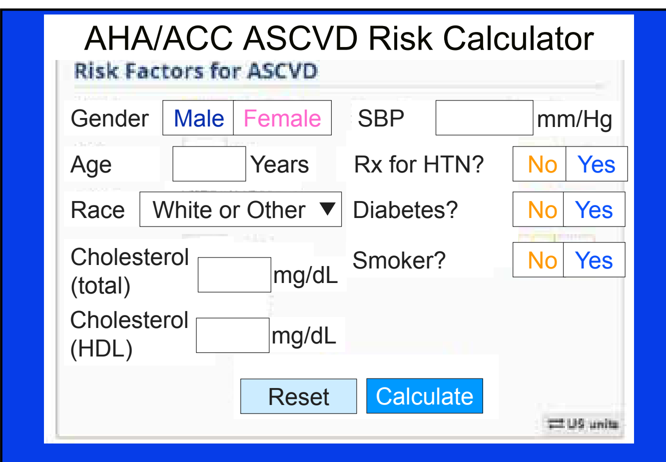
LD-ASA for 1⁰ Prevention of CVD/CRC
USPSTF: Adults Age 50-59

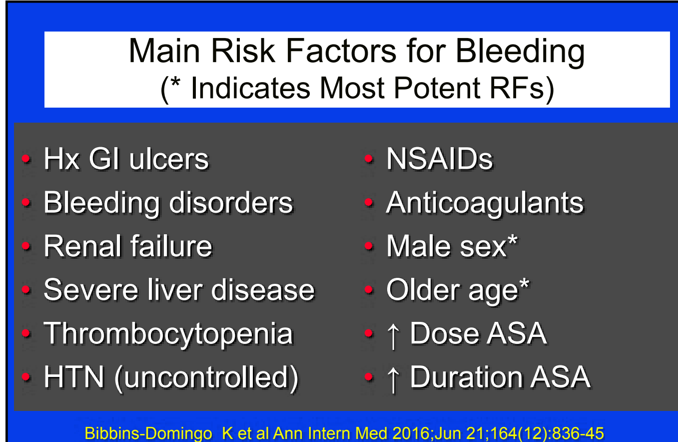
- ≥10% 10-yr CVD risk
- No ↑ bleeding risk
- ≥ 10 yr life expectancy
- Willing to take LD-ASA for at least 10 yrs

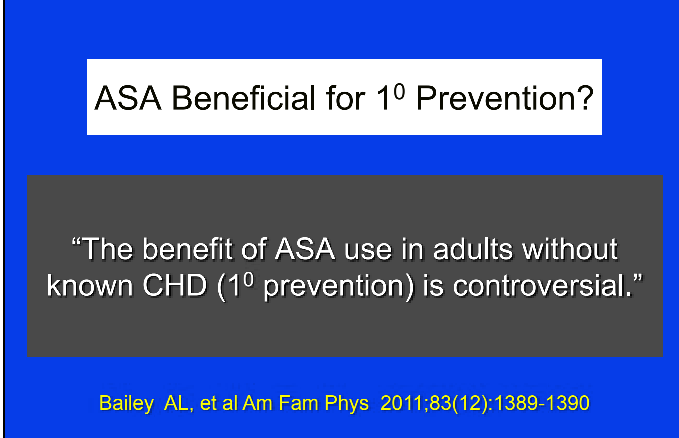
Grade B Recommendation

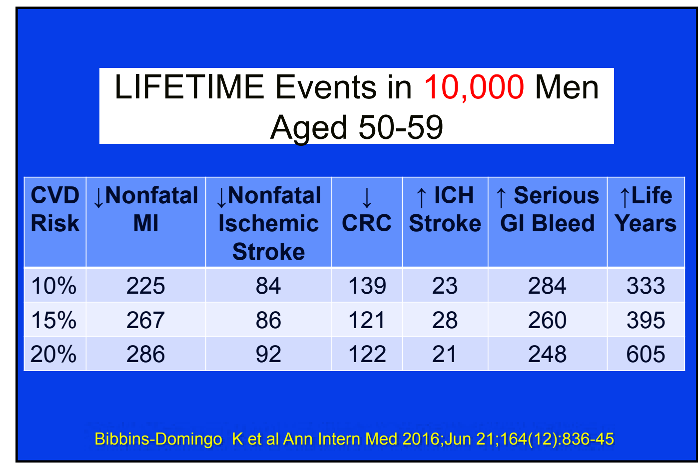
Bibbins-Domingo K et al Ann Intern Med 2016;Jun 21;164(12):836-45





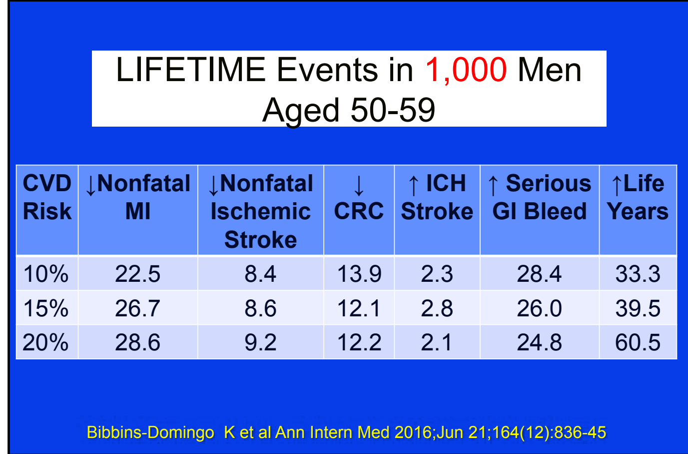





LIFETIME Events in 10,000 Men Aged 50-59

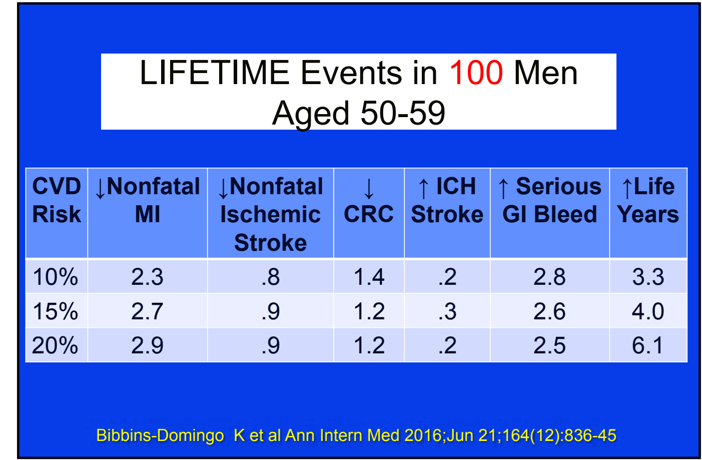
CVD Risk	↓Nonfatal MI	↓Nonfatal Ischemic Stroke	↓ CRC	↑ ICH Stroke	↑ Serious GI Bleed	↑Life Years
10%	225	84	139	23	284	333
15%	267	86	121	28	260	395
20%	286	92	122	21	248	605

Bibbins-Domingo K et al Ann Intern Med 2016;Jun 21;164(12):836-45


LIFETIME Events in 1,000 Men Aged 50-59

CVD Risk	↓Nonfatal MI	↓Nonfatal Ischemic Stroke	↓ CRC	↑ ICH Stroke	↑ Serious GI Bleed	↑Life Years
10%	22.5	8.4	13.9	2.3	28.4	33.3
15%	26.7	8.6	12.1	2.8	26.0	39.5
20%	28.6	9.2	12.2	2.1	24.8	60.5

Bibbins-Domingo K et al Ann Intern Med 2016;Jun 21;164(12):836-45


LIFETIME Events in 100 Men Aged 50-59

CVD Risk	↓Nonfatal MI	↓Nonfatal Ischemic Stroke	↓ CRC	↑ ICH Stroke	↑ Serious GI Bleed	↑Life Years
10%	2.3	.8	1.4	.2	2.8	3.3
15%	2.7	.9	1.2	.3	2.6	4.0
20%	2.9	.9	1.2	.2	2.5	6.1

Bibbins-Domingo K et al Ann Intern Med 2016;Jun 21;164(12):836-45

ASA for 1^0 Prevention Not So Easy

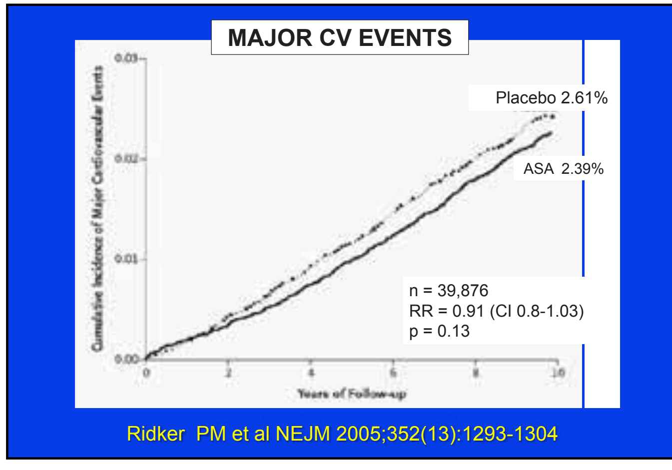
"….recent studies have questioned whether the benefits of daily ASA for 1^0 cardioprevention outweigh the risks of GI and IC hemorrhage."

Miser WF Am Fam Phys 2011;83(12):1380-1386

Low-Dose ASA for 1^0 CVD Prevention in Women

- Study: RDBPCT women ≥45 (n=39,876)
- Rx: ASA 100 mg qod vs placebo
- 1^0 Outcome: major CV Events
- Results: Failed 1^0 Endpoint

Ridker PM et al NEJM 2005;352(13):1293-1304



Ridker PM et al NEJM 2005;352(13):1293-1304

ASA for 1^0 Prevention Just What Component of CVD Did You Mean?

"…. A recent RCT (n = 39,876) relatively healthy women ≥45 years suggested that daily ASA Rx may not decrease the risk of acute MI in women, although there was a 18% decreased risk of stroke." *

*Stroke was a 2^0 endpoint; 1^0 failed

Miser WF Am Fam Phys 2011;83(12):1380-1386

Low-Dose ASA & CA The Women's Health Study

CONTEXT

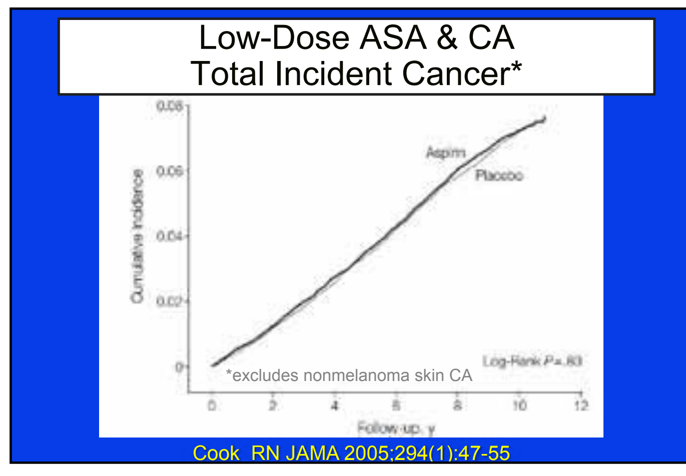
"Basic research and observational evidence as well as results from trials of colon polyp recurrence suggest a role for ASA in the chemoprevention of cancer."

Cook RN JAMA 2005;294 (1):47-55

Low-Dose ASA & CA The Women's Health Study

- Study: RPCT (n=38,876) ♀
  - age ≥45
  - no Hx CA
- Rx: ASA 100 mg qod vs placebo
- Outcome: Incident CA over 10 years (avg)

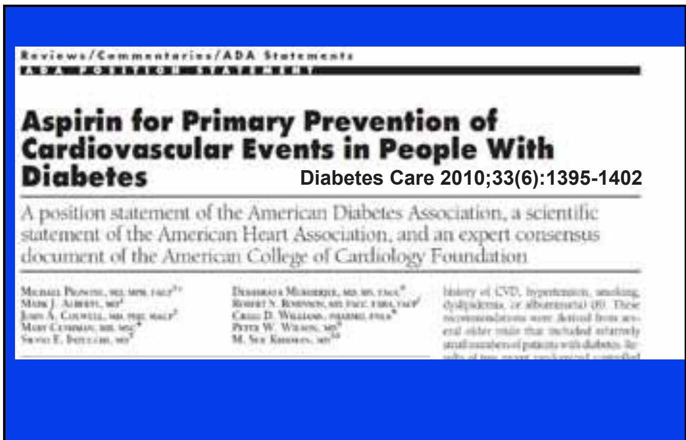
Cook RN JAMA 2005;294(1):47-55



Low-Dose ASA & CA
The Women's Health Study

"No effect of ASA was observed on total cancer, breast cancer, colorectal cancer, or cancer of any other site…."

Cook RN JAMA 2005;294(1):47-55



Reviews/Commentaries/ADA Statements

ADA POSITION STATEMENT

Aspirin for Primary Prevention of Cardiovascular Events in People With Diabetes

Diabetes Care 2010;33(6):1395-1402

A position statement of the American Diabetes Association, a scientific statement of the American Heart Association, and an expert consensus document of the American College of Cardiology Foundation

So, What Says the ADA? (2017)

"ASA has been shown to be effective in reducing CV morbidity and mortality in….secondary prevention*."

*emphasis added

ADA "CVD and Risk Management" Diabetes Care 2017;40(Suppl1):S75-S87

So, What Says the ADA? (2017)

"Its net benefit in primary prevention* among patients with no previous CV events is more controversial both for patients with DM and for patients without DM."

*emphasis added

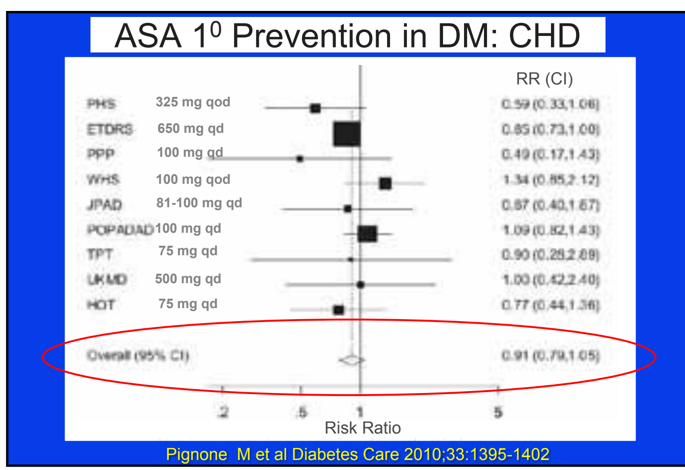
ADA "CVD and Risk Management" Diabetes Care 2017;40(Suppl1):S75-S87

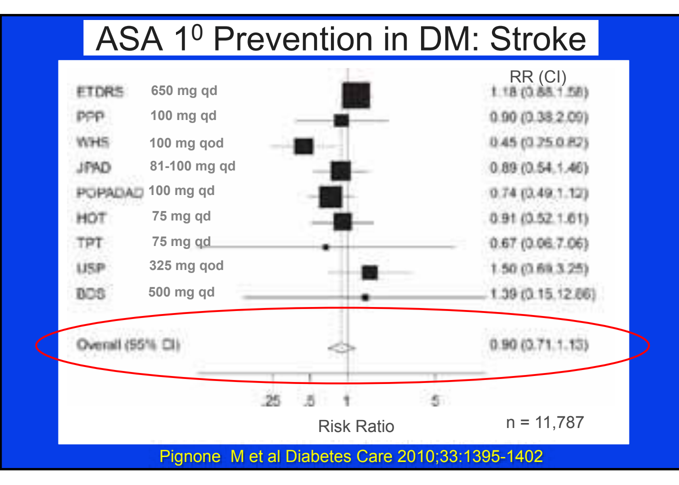
So, What Says the ADA? (2017)

"Previous RCTs of ASA specifically in patients with DM failed* to consistently show a significant reduction in overall ASCVD end points, raising questions about the efficacy of ASA for 1^0 prevention in people with DM…"

*emphasis added

ADA "CVD and Risk Management" Diabetes Care 2017;40(Suppl1):S75-S87

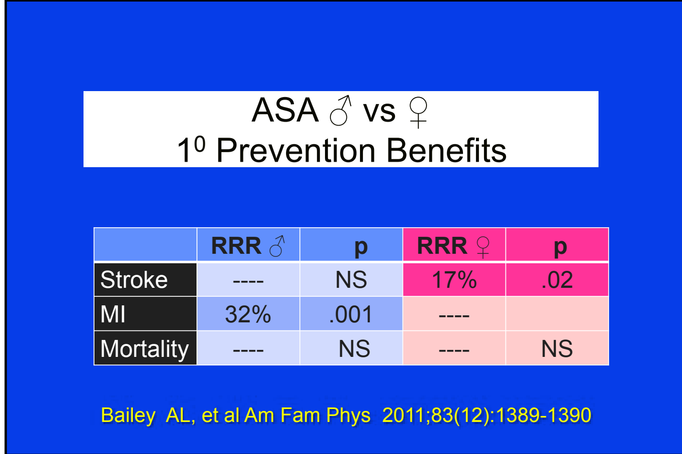




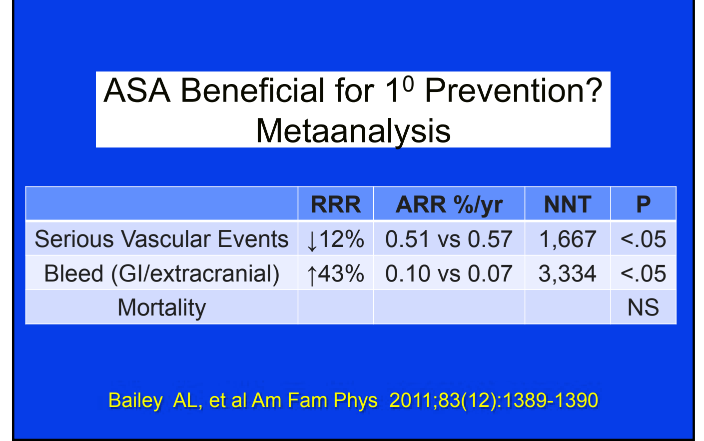
ASA 1⁰ Prevention
ADA Standards of Care 2017

- Consider ASA 75-162 mg/d if CV Risk↑
  - Age ≥50
  - FHx premature ASCVD
  - HTN
  - Dyslipidemia
  - Smoking
  - Albuminuria
  - No ↑ bleeding risk

Diabetes Care 2017;40(Suppl 1):S75-S87



	RRR ♂	p	RRR ♀	p
Stroke	----	NS	17%	.02
MI	32%	.001	----	
Mortality	----	NS	----	NS



	RRR	ARR %/yr	NNT	P
Serious Vascular Events	↓12%	0.51 vs 0.57	1,667	<.05
Bleed (GI/extracranial)	↑43%	0.10 vs 0.07	3,334	<.05
Mortality				NS

ASA Beneficial for 1⁰ Prevention?

"…ASA use does not affect total mortality in either sex, perhaps because of an increase in bleeding events that occur at roughly similar rates in women and men."

Bailey AL, et al Am Fam Phys 2011;83(12):1389-1390

ASA Beneficial 1⁰ Prevention Summary Comments

"In summary, a policy of generalized ASA use in adults for the 1⁰ prevention of CVD is probably not warranted. "

Bailey AL, et al Am Fam Phys 2011;83(12):1389-1390

ASA Beneficial for 1⁰ Prevention?

"Even among patient populations traditionally thought to be at high risk of CV events, such as … DM or PVD, ASA use does not clearly provide benefit in the 1⁰ prevention setting."

Bailey AL, et al Am Fam Phys 2011;83(12):1389-1390

ASA Science 1988-2005 The First 6 Major RCTs (1⁰ Prevention)

	n	Sex	1⁰ Endpoint	HR*
BDT	5,139	♂	Major CVD	0.98 (0;.81-1.19)
PHS	22,071	♂	All MI	0.56 (0.45-0.70
HOTT	18,790	♂/♀	Major CVD	0.85 (0.73-0.99)*
TPT	5,085	♂	All MI, CHD death	0.80 (0.64-0.99)*
PPP	4,495	♂/♀	CV Death, nonfatal MI, CVA	0.71 (0.48-1.04)
WHS	39,876	♀	Major CV events	0.91 (0.80-1.03)

* p <0.05

Miedema MD, et al Am Coll Cardiol "Latest in Cardiology" Articles 2016

ASA Science 2008-2014 The Next 4 Major RCTs (1⁰ Prevention)

	n	Sex	1⁰ Endpoint	HR*
POPA DAD	1,276	♂/♀	Fatal/non-fatal MI/CVA	0.98 (0.76-1.26)
JPAD	2,539	♂/♀	All CV Events	0.80 (0.58-1.10)
AAA	3,350	72%♀	Fatal/nonfatal MI or Stroke, revascularization	1.03 (0.84-1.27)
JPPP	14,464	♂/♀	CV Death, nonfatal MI, CVA	0.94 (0.77-1.15)

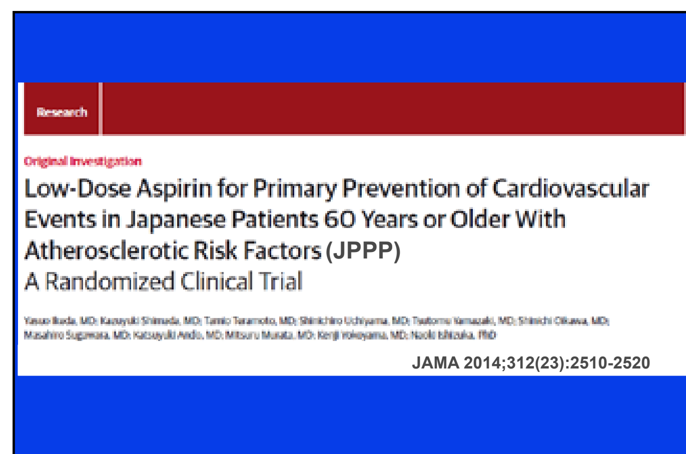
* p <0.05

Miedema MD, et al Am Coll Cardiol "Latest in Cardiology" Articles 2016

WHY Did ASA Efficacy Lag?

- Better BP control
- Better Lipid control
- Less Smoking
- Well-controlled CHD risk factors removes 'low-hanging fruit' success

Miedema MD, et al Am Coll Cardiol "Latest in Cardiology" Articles 2016



Research

Original Investigation

Low-Dose Aspirin for Primary Prevention of Cardiovascular Events in Japanese Patients 60 Years or Older With Atherosclerotic Risk Factors (JPPP)

A Randomized Clinical Trial

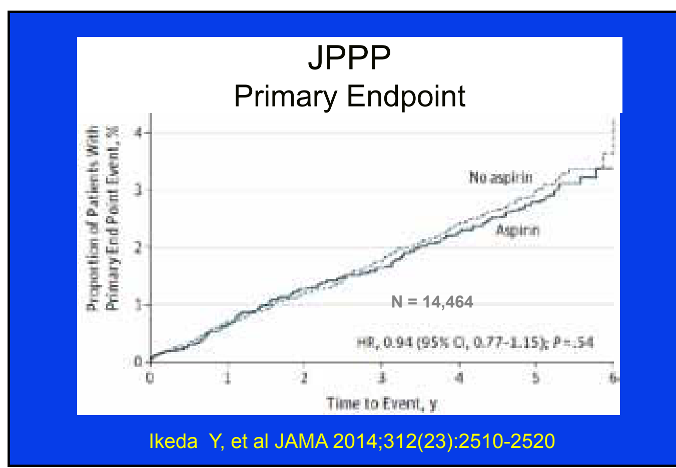
Yasuo Ikeda, MD; Kazuyuki Shimada, MD; Tamio Teramoto, MD; Shinichiro Uchiyama, MD; Tsutomu Yamazaki, MD; Shinichi Oikawa, MD; Masahiro Sugawara, MD; Katsuyuki Ando, MD; Mitsuru Murata, MD; Kenji Yokoyama, MD; Naoki Ishizuka, PhD

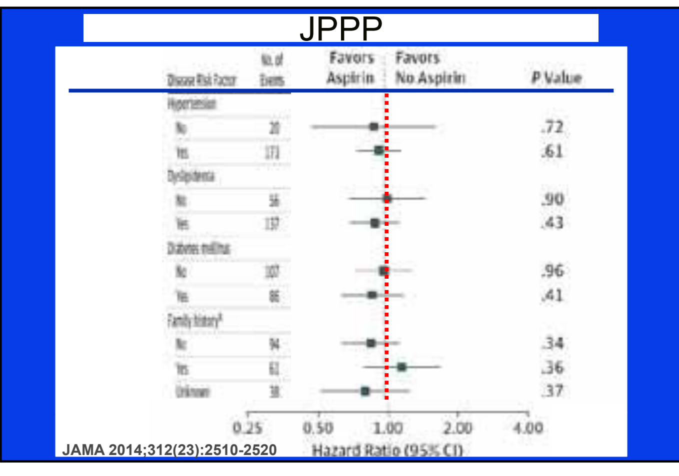
JAMA 2014;312(23):2510-2520

Japanese Primary Prevention Project (JPPP)

- PRCT persons with CV RF (n= 14,464)
- Inclusion:
  - Age 60-85
  - HTN, dyslipidemia, or DM
- Primary Exclusion: Known CVD
- Rx: EC-ASA 100 mg/d vs no Rx X 6.5 years
- Outcome: CV death, fatal/non fatal MI/CVA

Ikeda Y, et al JAMA 2014;312(23):2510-2520



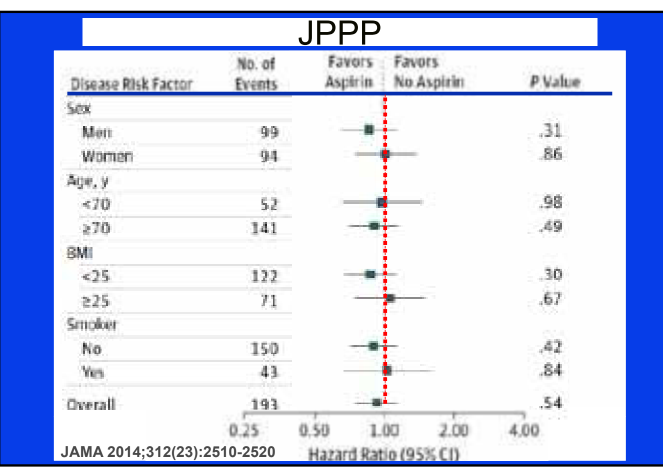


JPPP

Disease Risk Factor	No. of Events	Favors Aspirin / Favors No Aspirin	P Value
Hypertension			
No	20		.72
Yes	171		.61
Dyslipidemia			
No	56		.90
Yes	137		.43
Diabetes mellitus			
No	107		.96
Yes	86		.41
Family history			
No	94		.34
Yes	61		.36
Unknown	38		.37

Hazard Ratio (95% CI): 0.25, 0.50, 1.00, 2.00, 4.00

JAMA 2014;312(23):2510-2520



JPPP

Disease Risk Factor	No. of Events	Favors Aspirin / Favors No Aspirin	P Value
Sex			
Men	99		.31
Women	94		.86
Age, y			
<70	52		.98
≥70	141		.49
BMI			
<25	122		.30
≥25	71		.67
Smoker			
No	150		.42
Yes	43		.84
Overall	193		.54

Hazard Ratio (95% CI): 0.25, 0.50, 1.00, 2.00, 4.00

JAMA 2014;312(23):2510-2520

Japanese Primary Prevention Project (JPPP) Conclusions

"Once-daily, low-dose ASA did not significantly reduce the risk of the composite outcome of CV death, nonfatal stroke, and nonfatal MI among Japanese patients 60 years of older with atherosclerotic risk factors."

Ikeda Y, et al JAMA 2014;312(23):2510-2520

ASA Seeks FDA Labeling for 1^0 Prevention of CVD

DENIED: 5/2/2014

ASA 1^0 Prevention: FDA Weighs In

"The FDA has reviewed the available data and *does not* believe the evidence supports the general use of ASA for 1^0 prevention of a heart attack or stroke."

www.fda.gov/Drugs/ResourcesForYou/Consumers
Accessed Dec 24. 2016

ASA 1^0 Prevention: FDA Weighs In

" In fact, there are serious risks associated with the use of ASA, including increased risk of bleeding in the stomach and brain, in situations where the benefit of aspirin for 1^0 prevention has not been established."

www.fda.gov/Drugs/ResourcesForYou/Consumers
Accessed Dec 24. 2016

USPSTF Recommendations Limitations Colon Cancer

"Colorectal caner prevention plays an important role in the overall health benefit of aspirin,

but this benefit is not apparent until 10 years after aspirin therapy is started."

Bibbins-Domingo K et al Ann Intern Med 2016;Jun 21;164(12):836-45

ASA for 1^0 Prevention Conclusions:Cancer

"Estimates of cancer benefit rely on selective retrospective re-analysis of RCTs and more information is needed."

Sutcliffe P et al PLOS One 2013;8(12):1-11

How Long Until ASA Benefit is Seen? CVD vs CRC

"It takes at least 5-10 years…to obtain a **CRC** benefit; however, due to a longer latent period the benefit may take 10-20 years to appear."

Bibbins-Domingo K et al Ann Intern Med 2016;Jun 21;164(12):836-45

Overall, Will ASA Save Lives?

"Reduction in all-cause mortality was **not significant** in any of the trials reporting it. However, when trial results were pooled, all cause mortality risk was reduced by 5% in participants takir low-dose aspirin." (RR 0.95, CI 0.89-1.01)

Bibbins-Domingo K et al Ann Intern Med 2016;Jun 21;164(12):836-45

Do Other Vested-Interest Agencies Support ASA for CRC Risk?

"No organizations recommend ASA use for the primary prevention of CRC in average risk adults….the AGA and the NCCN limit their recommendations to patients who are at increased risk for CRC."

Bibbins-Domingo K et al Ann Intern Med 2016;Jun 21;164(12):836-45

Commercial Interests: FDA Labelling

"The US FDA recently DENIED a manufacturer's request to add primary prevention of MI as an indication for ASA use in any risk group."

Bibbins-Domingo K et al Ann Intern Med 2016;Jun 21;164(12):836-45

ASA for 1^0 Prevention

Hoping That You Have Not Perchance Fallen Into the

Abyss of Aspirin Despair

Is there SOMETHING We Could Use to Enhance ASA Risk:Benefit Ratio

Original Article

Use of Coronary Artery Calcium Testing to Guide Aspirin Utilization for Primary Prevention: Estimates From the Multi-Ethnic Study of Atherosclerosis (MESA)

Michael D. Miedema, MD, MPH; Daniel A. Duprez, MD, PhD; Jeffrey R. Misialek, MPH; Michael J. Blaha, MD, MPH; Khurram Nasir, MD, MPH; Michael G. Silverman, MD; Ron Blankstein, MD; Matthew J. Budoff, MD; Philip Greenland, MD; Aaron R. Folsom, MD, MPH

Circ Cardiovasc Qual Outcomes 2014;7:453-4

MESA
Multi-Ethnic Study of Atherosclerosis

- Longitudinal epidemiologic study X 7.6 yrs (median)
- Multi-ethnic adults age 45-84 (n = 6,814)
  - NY
  - Chicago
  - LA
  - Baltimore
  - Forsyth Co, NC
  - St. Paul

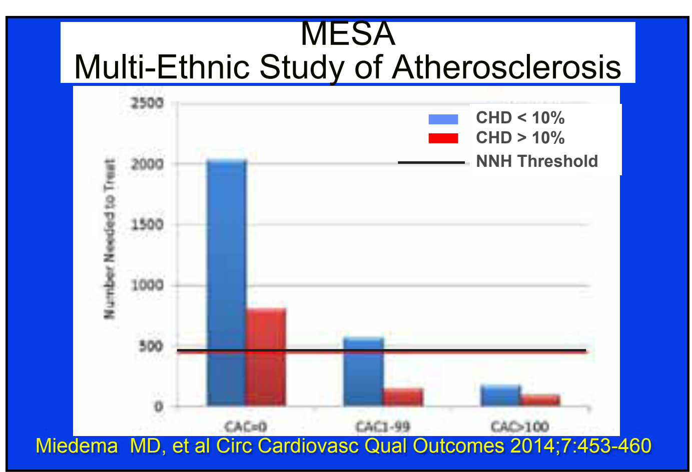
Miedema MD, et al Circ Cardiovasc Qual Outcomes 2014;7:453-460

MESA
Multi-Ethnic Study of Atherosclerosis

- Inclusion: white, black, Hispanic, or Chinese adults
- Exclusions:
  - Known vascular disease
  - DM
- Outcome: MACE (fatal/nonfatal MI, CHD death, fatal/nonfatal stroke, resuscitation)

Miedema MD, et al Circ Cardiovasc Qual Outcomes 2014;7:453-460

MESA
Multi-Ethnic Study of Atherosclerosis



Miedema MD, et al Circ Cardiovasc Qual Outcomes 2014;7:453-460

MESA:
CAC vs AHA Risk Stratification?

- >10% AHA *sub*threshold men & women had CAC >100
- >30% AHA *supra*threshold men and women have CAC = 0

Miedema MD, et al Circ Cardiovasc Qual Outcomes 2014;7:453-460

MESA
Multi-Ethnic Study of Atherosclerosis

CONCLUSIONS

"For the 1^0 prevention of CHD, MESA participants with CAC ≥100 had favorable risk-benefit estimations for ASA use while participants with zero CAC were estimated to receive net harm from aspirin."

Miedema MD, et al Circ Cardiovasc Qual Outcomes 2014;7:453-460

What I Tried to Impart

- ASA: YES for for 2^0 prevention of CV events
- ASA MAY be good for some SOME high risk patients for 1^0 prevention of CV events
- For diabetics, ASA is of dubious, if any, value…but for now, you should probably still offer it
- ASA reduces Colon CA Risk, but the risk ↓ is small, and may take 10-20 years to occur
- CAC scores can tip the risk:benefit relationship of ASA into the 'favorable zone"
- It's NEVER quite as simple as it seems on the surface

SELF EVALUATION

Aspirin as an Agent of Primary Prevention

1. What is the effect of low dose ASA (75-325 mg/d), when used for secondary prevention, on all-cause mortality?

a. There is no effect on all-cause mortality
b. All-cause mortality is reduced by approximately 20%
c. All-cause mortality is reduced by about 50%
d. All-cause mortality is slightly increased due to GI bleeding

2. What is the effect of low dose ASA (75-325 mg/d), when used for secondary prevention, on MI?

a. The rate of MI is not altered
b. MI is reduced by about 30%, predominantly due to efficacy in men
c. MI is reduced by about 30%, predominantly due to efficacy in women
d. MI is reduced by about 50% in both genders

3. ASA blocks the ability of platelets to aggregate with fibrinogen by reducing

a. Prostaglandin H
b. Thromboxane A2
c. ADP
d. P2Y-12

4. For adults age 50-59, USPSTF (2016) recommends 1⁰ CV/Colon CA prevention with low dose ASA

a. When 10 yr CVD risk exceeds 10%
b. When life expectancy is at least 10 years
c. When not at increased bleeding risk
d. When willing to take low dose ASA for at least 10 years to achieve benefit
e. All of the above

5. The GRADE of the 2016 USPSTF ASA 1⁰ prevention CV/Colon CA recommendation for #4 above is

a. high certainty of substantial net benefit
b. high certainty of moderate benefit/moderate certainty of ≥moderate benefit
c. ≥moderate certainty that net benefit is small; individualize
d. Don't do it; no benefit or harms outweigh benefits
e. Insufficient evidence to assess balance of benefits and harms

6. For persons age 60-69 years, the 2016 USPSTF ASA 1⁰ prevention CV/Colon CA recommendation grade is

a. high certainty of substantial net benefit
b. high certainty of moderate benefit/moderate certainty of ≥moderate benefit
c. ≥moderate certainty that net benefit is small; individualize
d. Don't do it; no benefit or harms outweigh benefits
e. Insufficient evidence to assess balance of benefits and harms

7. For persons <50 years, the 2016 USPSTF ASA 1⁰ prevention CV/Colon CA recommendation grade is

a. high certainty of substantial net benefit
b. high certainty of moderate benefit/moderate certainty of ≥moderate benefit
c. ≥moderate certainty that net benefit is small; individualize
d. Don't do it; no benefit or harm outweighs benefits
e. Insufficient evidence to assess balance of benefits and harms

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

Rabbi Elimelech Goldberg

Rabbi Elimelech Goldberg, of Southfield, Michigan, is a clinical assistant professor in the Department of Pediatrics of Wayne State University School of Medicine in Detroit, Michigan. His focus on teaching simple pain and stress reduction tools benefitting physician and patient alike is the subject of many medical grand rounds the Rabbi has presented in leading hospitals around the globe. This methodology is an off shoot of his work as the founder and international director of Kids Kicking Cancer, an organization that lowers the pain of over 3,500 children a year in 45 hospitals. Rabbi Goldberg is a First Degree Black Belt in Choi Kwang Do who, after losing his first child to leukemia at the age of two, merged modern integrative medicine with traditional martial arts to addresses the overwhelming needs of children with illness.

You may contact Rabbi Goldberg with your questions and comments at 248-864-8238, or by email at RabG@KidsKickingCancer.org.

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www.kidskickingcancer.org
info@kidskickingcancer.org

Non-pharmacologic Techniques for Managing Chronic Stress
Rabbi Elimelech Goldberg

Goals

1- Introduce you to the children of Kids Kicking Cancer who will both help to teach this seminar and in turn be positively impacted by this presentation.

2- Review some of the pain theories that shape our current therapeutic practices.

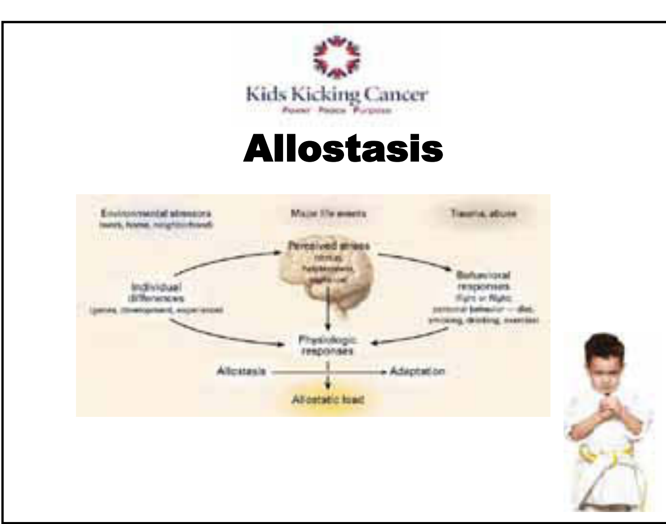
3-Teach you simple pain management techniques that will be simple and time effective in passing on to your patients.

4-Teach you how to create greater patient compliance in their pain management.

5- Demonstrate the therapeutic benefits of integrating an ontological approach with your patients.

The adrenal gland is an essential stress-responsive organ that is part of both the hypothalamic-pituitary-adrenal axis and the sympatho-adrenomedullary system. Chronic stress exposure commonly increases adrenal weight. The onslaught of glucocorticoids can adversely affect myriad aspects of our health.

"Chronic stress induces adrenal hyperplasia and hypertrophy in a subregion-specific manner".
Ulrich-Lai YM[1], Figueiredo HF, Ostrander MM, Choi DC, Engeland WC, Herman JP.
Am J Physiol Endocrinol Metab. 2006 Nov;291(5):E965-73. Epub 2006 Jun 13.



Ongoing secretion of glucocorticoids from the adrenal gland can cause a damaging allostatic load on the body.

Allostasis is the body's response to stress in order to maintain homeostasis.

More emphasize today is being placed in medical education on understanding the allostatic load of the patient beyond the biology of response.

Not to be familiar with the major sources of stress in a patient's life robs a physician of profound diagnostic and interventional tools.

However, beyond the stress implications on morbidity and mortality, stress can significantly influence the perception of pain.

A 2015 study by Prof. Ruth Defrin of the Department of Physical Therapy at TAU's Sackler Faculty of Medicine published in the journal *PAIN* finds that acute psychosocial stress has a dramatically deleterious effect on the body's ability to lower pain perception.

Prof. Defrin, TAU doctoral student Nirit Geva and Prof. Jens Pruessner of McGill University, applied acute stress tests on a large group of healthy young male adults to evaluate the workings of the body's pain modulation mechanisms prior to and after the induction of stress.

The researchers found that there was a significant increase in pain intensification and a decrease in pain inhibition capabilities.

Descartian Model of Pain

Latin for pain is *poena* or punishment.

Assumes all pain is injury with a direct relationship between damage and harm

Leads to overly simplistic and often incorrect treatment

The historic pain model of a "pain center" in the brain, follows Descarte. Although many still follow that model it is not accurate and can lead to ineffective interventions and worse.

Ronald Melzak was one of the pioneers of discovering the sodium voltage channels that articulate the pain message.

Today we have added other pain channels in our efforts of attempting pharmacological interventions.

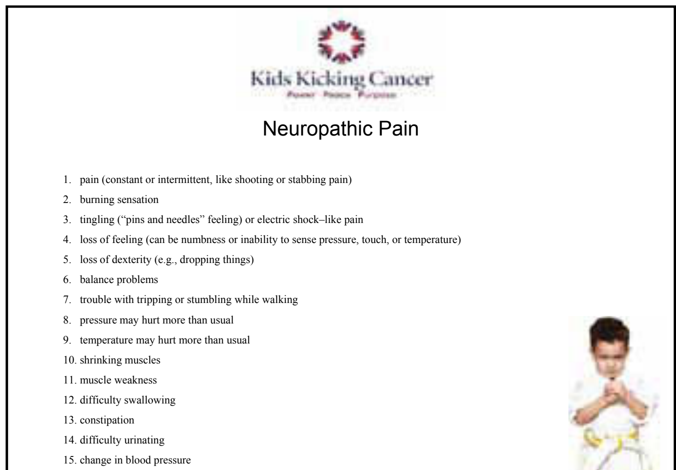
Nociceptive Pain

Somatic Pain

Injury to the skin, muscles, joints, bones, or connective tissue will cause the body to reference somatic pain. If the pain is located deep within the body, it is more likely to be described as dull or aching. If the pain is emanating from the skin layer or just below, it is more likely to be described as sharp, prickly, or burning.

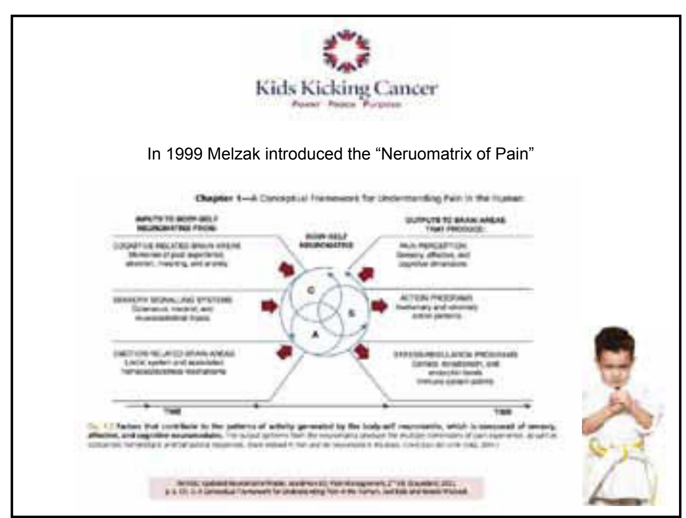
Visceral Pain

When the internal organs and/or their supporting tissues suffer damage, the pain is called visceral. If the injured organ is hollow, like the intestine or gall bladder, the pain is often hard to pin down to a specific location and may feel like cramping. In a non-hollow organ like the liver, the person may experience stabbing pain or deep pressure.



Psychogenic Pain

In the absence of identifiable physical causes that underlie the perception of pain, it is possible to arrive at the conclusion that the pain is generated by psychological causes rather than specific receptors in the nervous system signaling the presence of danger to the body.



An estimated 100 million people suffer from chronic pain mostly as back pain, headaches or arthritis. This affects more people than cancer, diabetes and heart disease combined

Institute of Medicine Report from the Committee on Advancing Pain Research, Care, and Education: *Relieving Pain in America, A Blueprint for Transforming Prevention, Care, Education and Research*. The National Academies Press, 2011.

17.6% of the population experiences some form of moderate to severe chronic pain. That represents 40 million people.

National Health Interview, 2012 National Institute of Health

More than half of respondents (51%) felt they had little or no control over their pain.
Six out of ten patients (60%) said they experience breakthrough pain, one or more times daily, severely impacting their quality of life and overall well-being.

Almost two-thirds (59%) reported an impact on their overall enjoyment of life.
More than three quarters of patients (77%) reported feeling depressed.
70% said they have trouble concentrating.
74% said their energy level is impacted by their pain.
86% reported an inability to sleep well.

2006 Voices of Chronic Pain Survey. (American Pain Foundation)

"Pain is the fifth vital sign"

In 1996 the American Pain Society (APS) described pain as the “Fifth Vital Sign”, an approach accepted by the Department of Veteran Affairs in 1999. It gained growing approbation.

In 2016, the AMA recommended removing pain as a vital sign.

In this shifting environment, doctors have been sued for not giving opioids. Doctors have been sued for prescribing opioids.

Opioid Epidemic

The majority of deaths (60%) occur in patients when they are given prescriptions based on prescribing guidelines by medical boards

20% of deaths in low dose opioid therapy of 100 mg of morphine equivalent dose or less per day and 40% in those receiving morphine of over 100 mg per day.

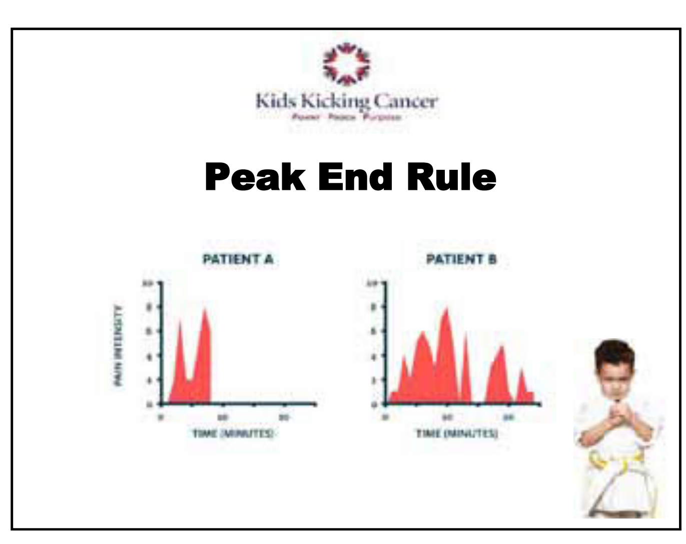
40% of deaths occur in individuals abusing the drugs obtained through multiple prescriptions, doctor shopping, and drug diversion.

Pain Physician. 2012 Jul;15(3 Suppl):ES9-38

Duration Neglect

Barbara L. Fredrickson and Daniel Kahneman1993

Looking at patients’ perception of pain, indicated that the actual stimulation of pain nerves may be mitigated by the patients’ feeling of pain based upon the overall pain experience.



The pain and stress cycle affect ongoing neurological challenges that self-perpetuate and accentuate, loosening the connection to the pre frontal cortex.

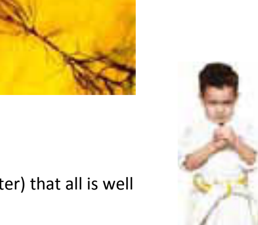
Elevated P.ain S.tress A.nger

1. Change in the neuro-chemical environment
2. Weakening of synaptic connections
3. Stress chemicals release from brain stem
4. Glucocorticoids release from adrenal glands
   A. switches off neurons in the prefrontal cortex
   B. primal areas such as basal ganglia ramp up
      - ➢ habitual emotional responses
      - ➢ cravings …. addictive behaviors

Pyramidal Cells

Neurological Executive Center Reaches into the deep brain structures that control:

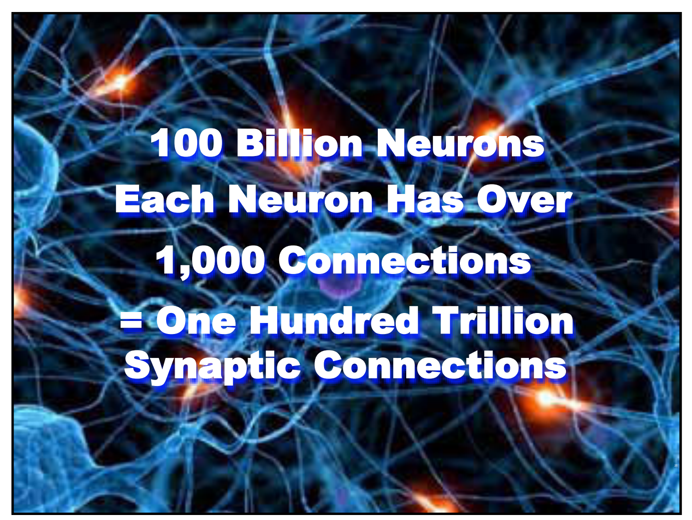
➢Emotions
➢Desires
➢Habits
➢Perception
➢Focus



Assures the amygdala (fear center) that all is well

Researchers found that increased expression of PACAP -- a peptide neurotransmitter the body releases in response to stress -- is also increased in response to neuropathic pain and contributes to these symptoms. Using models for chronic pain and anxiety, as well as models that can trace PACAP neurocircuits, the team members were able to observe where the stress and chronic pain pathways intersected. Chronic pain and anxiety-related disorders frequently go hand-in-hand.

"Parabrachial Pituitary Adenylate Cyclase-Activating Polypeptide Activation of Amygdala Endosomal Extracellular Signal–Regulated Kinase Signaling Regulates the Emotional Component of Pain" Victor May, Ph.D., professor of neurological sciences at the University of Vermont (UVM).



We Become Our Pain

Patients can become defined by their pain.

Pain is often a harbinger of necrosis so it is primed to get a great deal of attention.

However, chronic pain can physically and emotionally cripple a patient.

There is therapeutic value in redefining the ontology of pain into a potentially treatable symptom rather than a definition of "self".

- I have cancer
- I am depressed
- I am angry
- I am short

Tension is a Wall

We have a tendency to build protective walls when confronted with pain, both physical and emotional pain.

American Institute of Stress

To evaluate the relative stress level of individuals, a group of scientists at the University of Oxford have devised a system that associates
hyper-attentiveness with cortisol levels.

Power Breathing

The "Breath Brake®" has been used by Kids Kicking Cancer to help establish a sense of control over pain and stress and thus lower patient discomfort.

We published our pain study in the "Journal of Pediatric Health, Medicine and Therapeutics"; Dove Medical Press 201:67, June, 2016

The study followed 64 participants - 43 males 21 females ages 3 to 19 years old observed during 223 individual sessions. We recorded a decrease in pain intensity in 85.3% of visits with overall pre-score pain reduced by 40%.

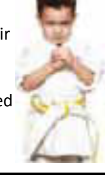
The mantra of Kids Kicking Cancer is "Power Peace Purpose" which the children teach to adult patients in many different settings.

"Power" describes the "energy" that we use in the martial arts as a light that we can visualize and bring into our body.

"Peace" refers to the inner calmness that we feel as we blow out pain, fear and anger.

"Purpose" connects to our ability to teach this to the world around us. During our presentations the children yell out that their purpose is to "teach the world."

This impacts the ontology of pediatric illness significantly as quoted above.

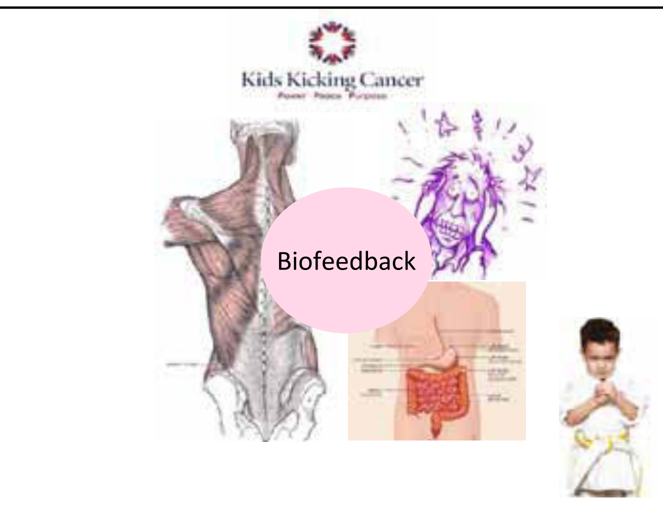


The "Breath Brake®"

The Kids Kicking Cancer "Breath Brake®" is a very simple intervention to use for yourself and then teach to your patients. (The more you integrate this simple breathing technique for your own life, the greater your passion in teaching it to your patients.)

The first step is to observe that you are experiencing stress. Stress chemicals will cause muscles to become tensile. Train yourself to observe that you are "tight". If you are not exercising at that moment, chances are that your body is responding to stress.

Breathing is the only part of your autonomic system that you can so easily control.
Using your breath to relax your muscles signals to your brain that you are not in a sympathetic mode.
You can trigger a parasympathetic response using a "Breath Brake®".
Directions-
This can be done from any position. The key is to use your breath to move your body like a wave.
Keep it simple. The issue for the "Breath Brake®" is not diaphragmatic breathing. However, you are comfortable breathing is fine. With your inhale, slowly breathing through your nose, lift up your body with the breath. Feel your shoulders lift up, your chin rise and your chest expand upwards. At the end of the breath, pull in a little bit more and hold that for three seconds. When exhaling slowly through your mouth, allow your body to fall in the opposite direction. Feel your chin and shoulders fall, your neck, your shoulders and then your chest. At the very end of that exhale, gently blow out a little more and then relax.
Repeating the "Breath Brake®" every time you feel the tightness of stress and then focusing simply on using the breath to relax the muscles has had a significant impact on the people we have trained.



"Significant evidence exists to support the use of guided imagery in the management of cancer -related pain (acute and chronic), as well as cancer treatment-related anxiety, nausea and vomiting, and depression."
"Guided Imagery for Pain Control" Peggy Burhenn, MS, CNS, AOCNS®, Jill Olausson, RN, MSN, CDE, Griselda Villegas, RN, OCN®, and Kathy Kravits, MA, RN, HNB-BC, LPC, NCC, ATR-BC "Clinical Journal of Oncology Nursing" Volume 18, Number 5. October 2014

The martial arts is very focused on imagery. Before karate masters will break a brick or series of boards, they image the target being destroyed. Creating a similar pathway for pain management employs the conceptual framework of the neuro-matrix.

The exercise is best kept very simple. Ask the patient to describe how large the pain is and what color he or she imagines it to be. (We have found that for inflammatory pain, most of our participants answer, "red".) Ask them to imagine that redness as a ball or a fist. (In the martial arts, there is a great deal of focus on our breath coming from different parts of our body.) Request from the patient to imagine the breath coming from right below the pain and as it precedes upward, making small holes in the worst part of the pain. (We have various meditations accessible through my book that create meditations around this theme. – I don't know what you want to do with that but the book is accessible on www.kkcbook.org) Continue that breathing, slowly but rhythmically, only in a manner that the patient is comfortable. At the exhale, the patient is asked to see him or her blowing out the redness as a cloud out of his or her mouth. Allow the patient, if he or she is able to add color to that light to see if it is effective. But also allow the patient to thank the children of Kids Kicking Cancer if this works for them (this creates great incentive to keep trying) On the books website, www.kkcbook.org one can thank the children for these lessons even without purchasing the book or on our kkc contact page www.kidskickingcancer.org

Push Is Weak –
Pull is Powerful

In the martial arts, we learn that is someone is pushing you, you don't get very far by pushing back. Push is weak but pull is powerful. It is natural to try to push out against a pain syndrome. The more we can accept that discomfort and pull it in to ourselves with the breath, the greater our opportunity for "blowing out that pain" in our exhale.

"Optimism does not mean that everything is going to be great. It means that we can respond to everything with greatness!"

A message inspired by Bernard Johnson, age 10

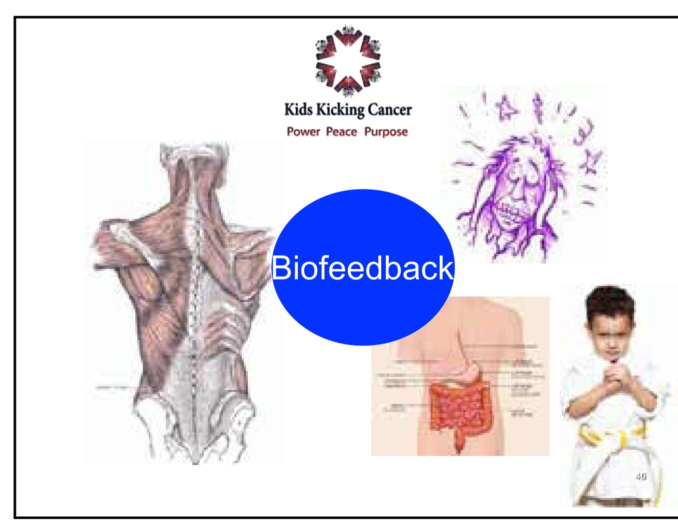
There is a reported 10 year mortality gap in US based upon socio-economic status (SES).

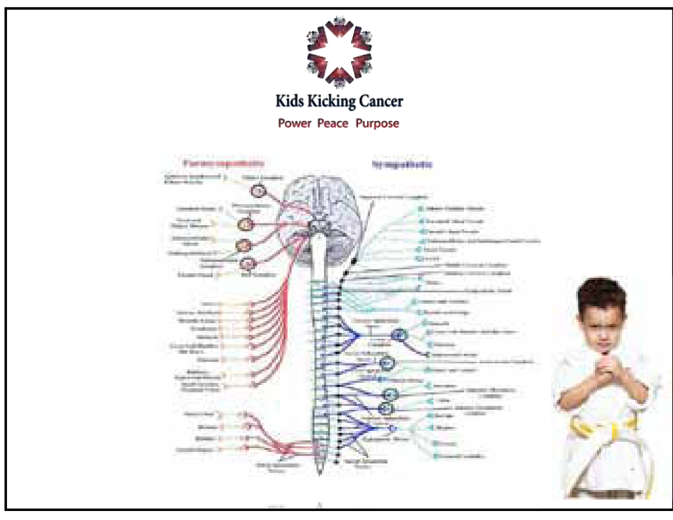
30 year study by Michael G. Marmot of University College, London, indicated that stress may be one of the most important factors. The poorest members of any society will often face the greatest stress.

It is important for patients to not be defined by their disease.

A patient who is depressed, for example, may be harder to treat than a healthy patient who is experiencing depression.

The physician can play a significant role in providing that reframing as part of an overall approach to healing.





The Kids Kicking Cancer "Breath Brake®" is a very simple intervention to use for yourself and then teach to your patients. (The more you integrate this simple breathing technique for your own life, the greater your passion in teaching it to your patients.)

The first step is to observe that you are experiencing stress. Stress chemicals will cause muscles to become tensile. Train yourself to observe that you are "tight". If you are not exercising at that moment, chances are that your body is responding to stress.

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At the end of the breath, pull in a little bit more and hold that for three seconds. When exhaling slowly through your mouth, allow your body to fall in the opposite direction.

Feel your chin and shoulders fall, your neck, your shoulders and then your chest. At the very end of that exhale, gently blow out a little more and then relax.

Repeating the "Breath Brake®" every time you feel the tightness of stress and then focusing simply on using the breath to relax the muscles has had a significant impact on the people we have trained.

In 2010 in the Journal "Psychological Science", Ernest Abel and Michael Kruger of Wayne State University rated the smiles of professional baseball players captured in a 1952 yearbook, then determined each player's age at death (46 players were still alive at the time of the study).

They indicated that smile intensity could explain 35 percent of the variability in survival; in fact, in any given year, players with Duchenne smiles in their yearbook photo were only half as likely to die as those who had not.

SELF EVALUATION

Non-pharmacologic Techniques for Managing Chronic Stress

1. The discovery of helicobacter pylori in the gut proved
- a. There is no correlation between stress and ulcers
- b. That intestinal fortitude is good for business
- c. That bacteria can fly
- d. That the majority of people with that bacteria will develop ulcers
- e. None of the above

2. Stress is linked to
- a. Heart Disease
- b. Cancer
- c. Diabetes
- d. Accidents
- e. All of the above
- f. Some of the above

3. Eustress indicates that
- a. We can all experience stress
- b. Stress will be found in all organisms
- c. Life does not have to be a "stress rehearsal"
- d. There are times that stress can be a positive biological response

4. These messengers are affected by stress
- a. Prolactin
- b. Neurotransmitters
- c. Cytokines
- d. Glucagon
- e. All of the above
- f. Some of the above

5. Stress can create epigenetic changes
- a. In Methylation
- b. In Acetylation
- c. That can last three generations
- d. By changing the envelopment of the histone molecule
- e. All of the above
- f. Some of the above

6. Acute stress is more likely to be provide health benefits than chronic stress
- a. Always true
- b. Never true
- c. Depends
- d. Too stressed to answer another question

7. The "Breath Brake®" focuses on
- a. Diaphragmatic breathing
- b. Simple breathing technique that moves the body with the breath
- c. Breathing in through the mouth and out through the nose
- d. All of the above

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

Cullen Ruff, MD
Associate Professor of Radiology
Virginia Commonwealth University School of Medicine
Fairfax, VA

Chest X-Ray Review

CXR Views:

- PA
- AP (portable, supine, upright)
- Lateral
- Decubitus
- Apical lordotic
- Oblique
- Nipple markers

Leading malpractice claims in radiology include:

Missed lung cancers
Missed breast cancers
Missed fractures
Communication/reporting/documentation issues

"Hidden" areas on CXR:

- Retrocardiac
- Apices
- Costophrenic sulci (lateral on PA/AP, and posterior on lateral views)
- Hilum and mediastinum

Newer developments in chest radiography:

Digital technique and storage
Digital bone suppression software
Lung nodule computer assisted detection (CAD) software programs
Vessel suppression on chest CT

SELF EVALUATION

Chest X-Ray Review

1. Familiarity with chest x-ray findings is clinically important in part because:

a. Chest x-ray studies remain very commonly used
b. Clinically significant findings can often be subtle
c. Findings may vary substantially depending not only on pathology, but also on patients' ages, body habitus, and other co-existing medical conditions
d. All of the above

2. Regions on chest images where abnormalities may be more obscured and harder to detect include:

a. Apices
b. Hilum and mediastinum
c. Retrocardiac
d. Costophrenic sulci
e. All of the above

3. T/F - Missed lung cancers on chest radiographs are a leading cause of litigation in medical imaging

4. The following general approaches to chest radiography typically improve the accuracy in interpreting chest radiographs:

a. Obtaining both frontal and lateral views whenever possible
b. Old film comparison
c. Added special views when warranted, including apical lordotic, decubitus, oblique, or repeat frontal view with nipple markers
d. All of the above

5. T/F - In addition to digital imaging replacing older film technique, newer available developments in chest radiography include software programs that digitally suppress rib markings, and computer-assisted detection software that increases the sensitivity of lung nodule detection

6. Depending on the scanner and technique, a chest CT scan may often administer the radiation dose equivalent of how many single chest x-ray images?

a. 5-20
b. 20-50
c. 50-150
d. 150-400

ANSWER KEY: 1. D, 2. E, 3. T, 4. D, 5. T, 6. C

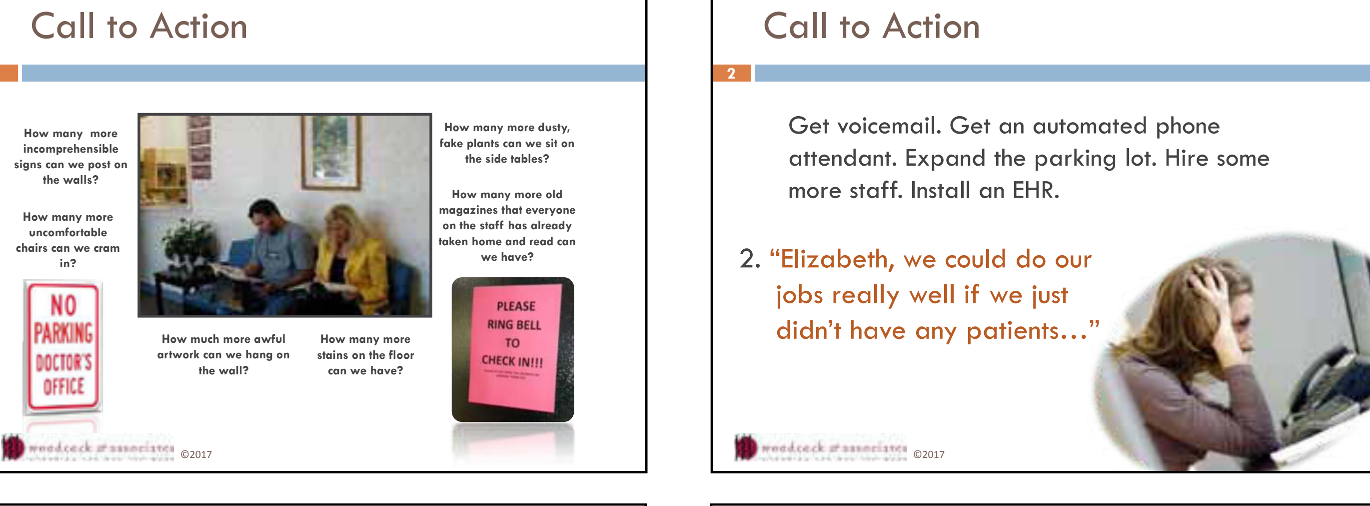
Elizabeth W. Woodcock, MBA, FACMPE, CPC

Elizabeth W. Woodcock, MBA, FACMPE, CPC, of Atlanta, Georgia, received her bachelor's degree, summa cum laude, from Duke University, and earned an MBA from The Wharton School of Business at University of Pennsylvania. She has worked professionally in the healthcare management field for over 25 years and is a nationally renowned speaker, consultant and author. Ms. Woodcock is a principal of Woodcock & Walker Consulting and has written dozens of books, chapters, articles and white papers including *The Physician Billing Process: Avoiding Potholes in the Road to Getting Paid: Third Edition, 2015*, and *Mastering Patient Flow to Increase Efficiency and Earnings: Fourth Edition, 2017*.

You may contact Ms. Woodcock with your questions and comments at 404-373-6195, or by email at Elizabeth@ElizabethWoodcock.com.

Mastering Patient Flow in the Healthcare Practice

Elizabeth W. Woodcock, MBA, FACMPE, CPC



Call to Action

1

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Call to Action

2

Get voicemail. Get an automated phone attendant. Expand the parking lot. Hire some more staff. Install an EHR.

2. "Elizabeth, we could do our jobs really well if we just didn't have any patients…"

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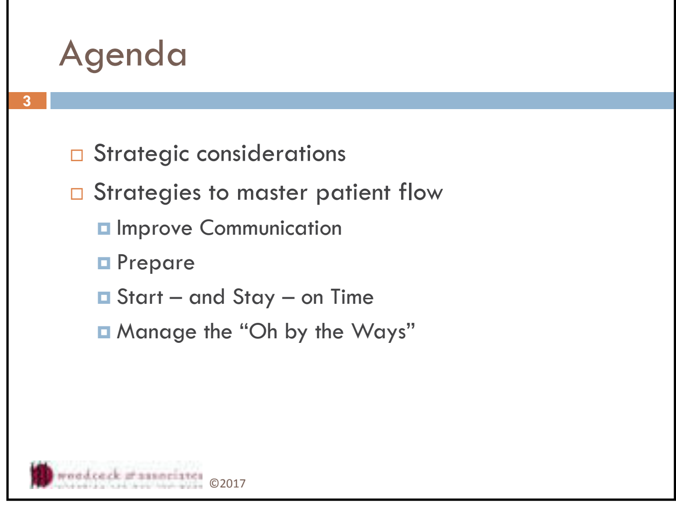

Agenda

3

- Strategic considerations
- Strategies to master patient flow
  - Improve Communication
  - Prepare
  - Start – and Stay – on Time
  - Manage the "Oh by the Ways"

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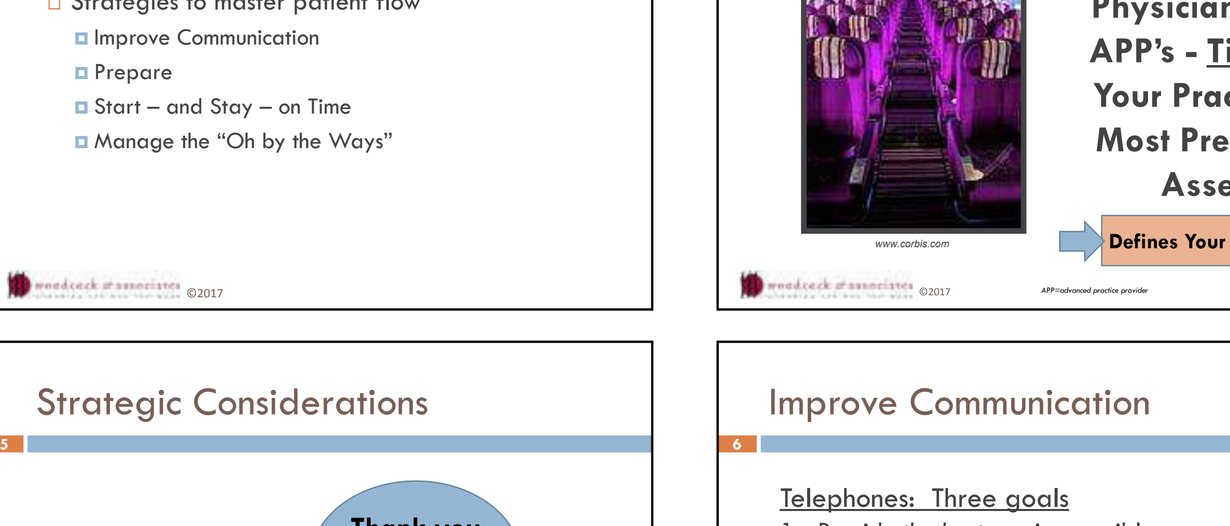

Strategic Considerations

4

www.corbis.com

Your Physician's - & APP's - <u>Time</u> is Your Practice's Most Precious Asset

Defines Your Capacity!

APP=advanced practice provider

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Strategic Considerations

5

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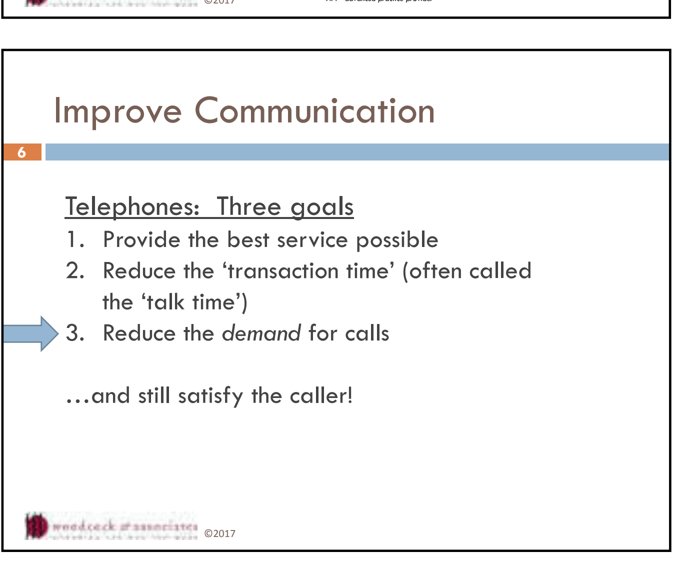

Improve Communication

6

<u>Telephones: Three goals</u>

1. Provide the best service possible
2. Reduce the 'transaction time' (often called the 'talk time')
3. Reduce the *demand* for calls

…and still satisfy the caller!

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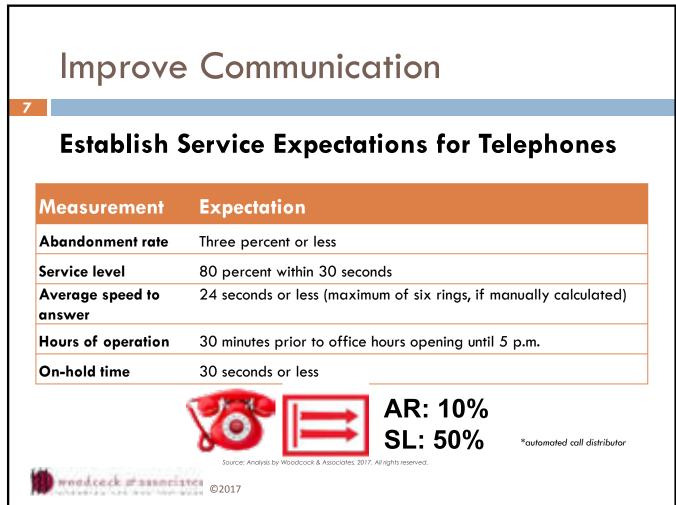
Improve Communication
7
Establish Service Expectations for Telephones
Measurement | Expectation
Abandonment rate | Three percent or less
Service level | 80 percent within 30 seconds
Average speed to answer | 24 seconds or less (maximum of six rings, if manually calculated)
Hours of operation | 30 minutes prior to office hours opening until 5 p.m.
On-hold time | 30 seconds or less
AR: 10%
SL: 50%
*automated call distributor
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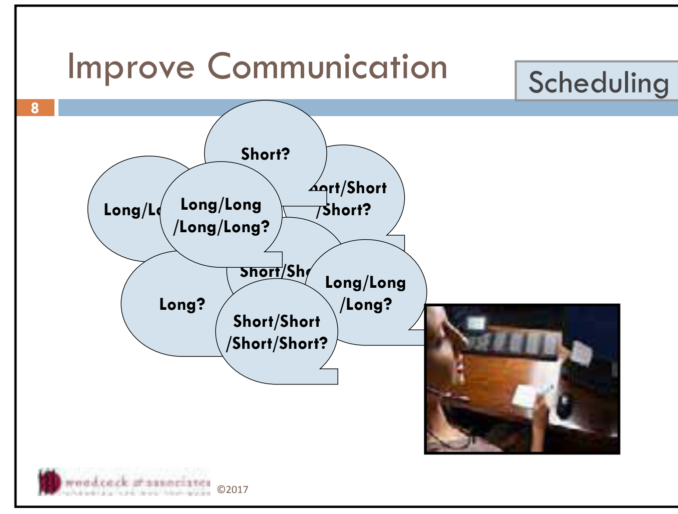
Improve Communication
Scheduling
8
Short?
Long/Long/Long/Long?
Short/Short/Short?
Long?
Long/Long/Long?
Short/Short/Short/Short?
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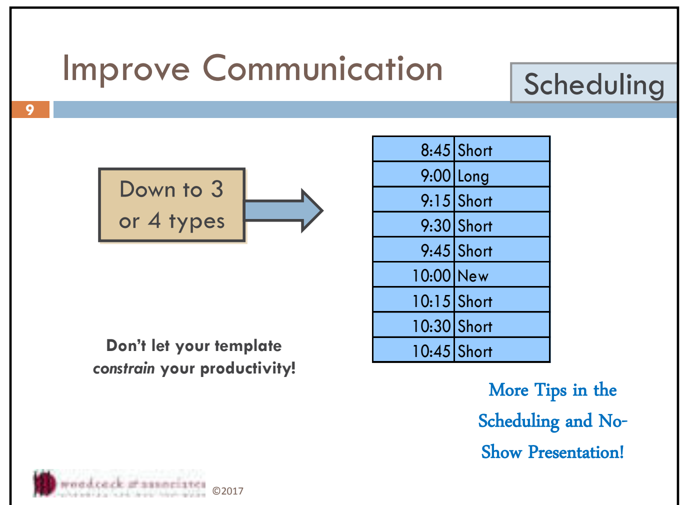
Improve Communication
Scheduling
9
Down to 3 or 4 types
8:45 Short
9:00 Long
9:15 Short
9:30 Short
9:45 Short
10:00 New
10:15 Short
10:30 Short
10:45 Short
Don't let your template constrain your productivity!
More Tips in the Scheduling and No-Show Presentation!
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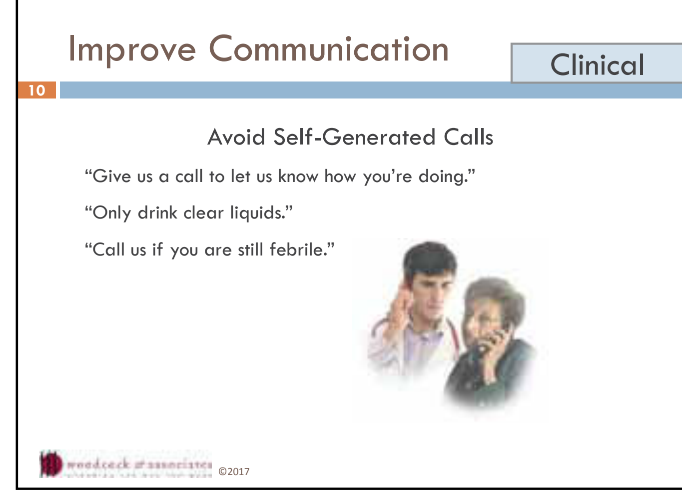
Improve Communication
Clinical
10
Avoid Self-Generated Calls
"Give us a call to let us know how you're doing."
"Only drink clear liquids."
"Call us if you are still febrile."
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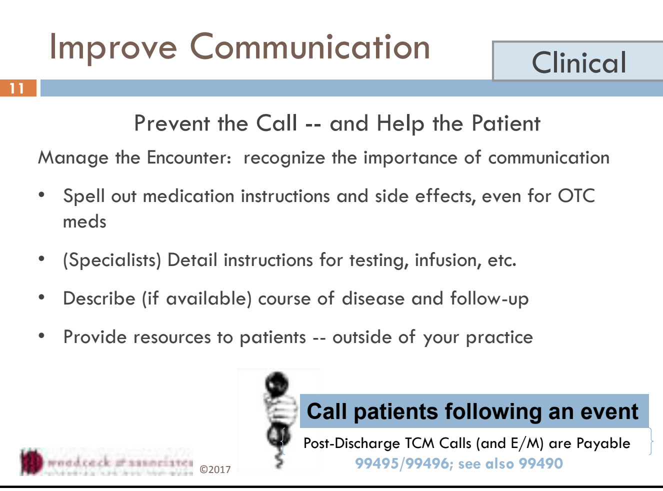
Improve Communication
Clinical
11
Prevent the Call -- and Help the Patient
Manage the Encounter: recognize the importance of communication
Spell out medication instructions and side effects, even for OTC meds
(Specialists) Detail instructions for testing, infusion, etc.
Describe (if available) course of disease and follow-up
Provide resources to patients -- outside of your practice
Call patients following an event
Post-Discharge TCM Calls (and E/M) are Payable
99495/99496; see also 99490
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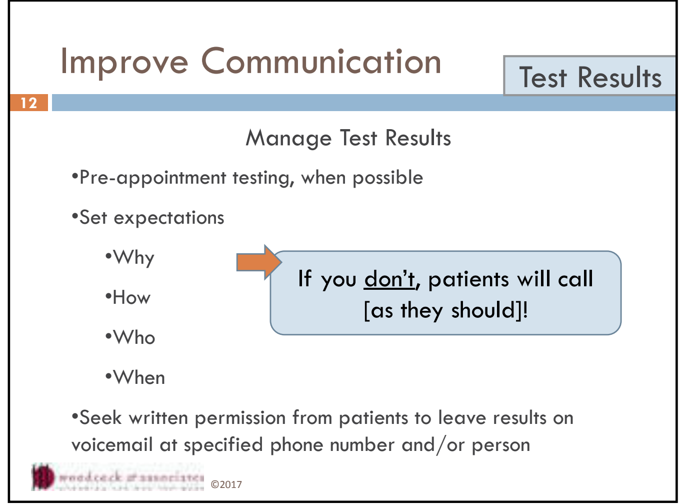
Improve Communication
Test Results
12
Manage Test Results
•Pre-appointment testing, when possible
•Set expectations
•Why
•How
•Who
•When
If you don't, patients will call [as they should]!
•Seek written permission from patients to leave results on voicemail at specified phone number and/or person
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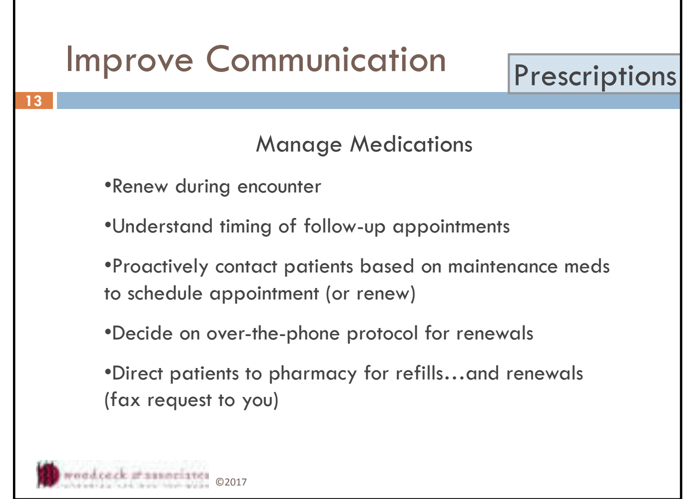

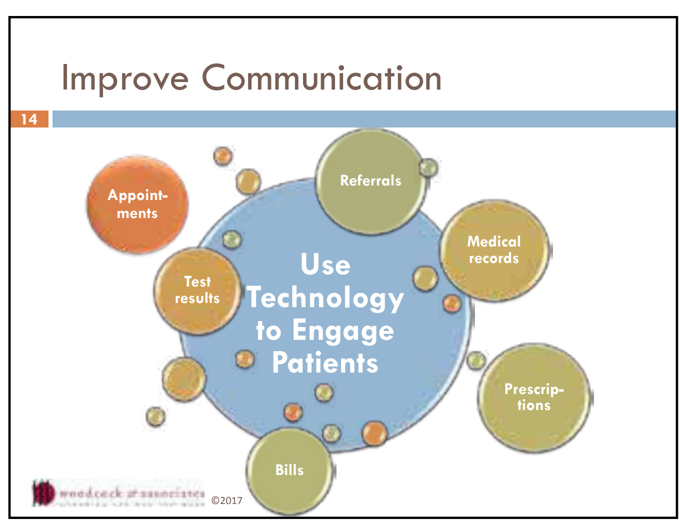

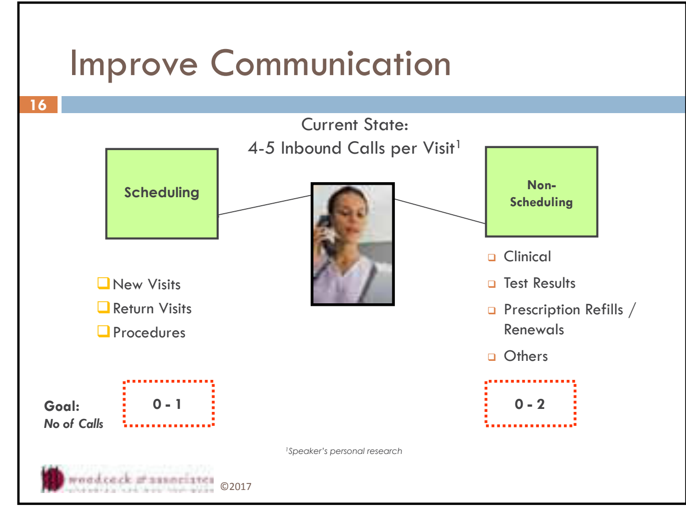

Improve Communication

17

Messages

- Train staff on how to take a comprehensive message
- Get three (3) phone numbers
- Assign responsibility for callback within 3 hours
- Establish distribution protocols, ideally electronically
- Offer secure messaging, which reduces this operational burden

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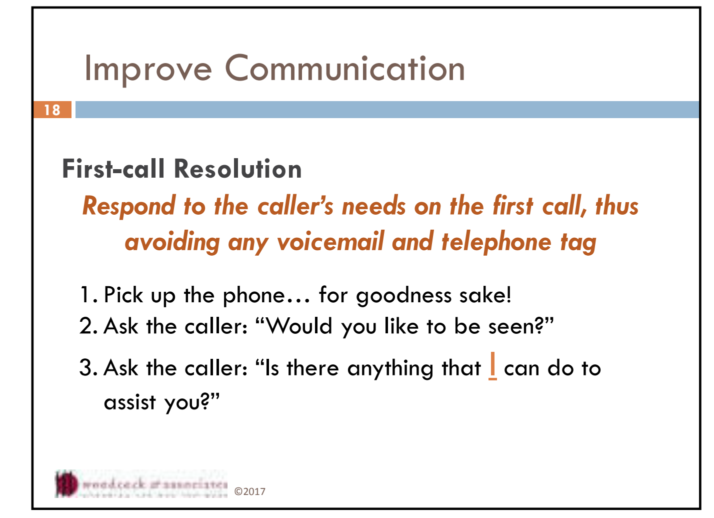

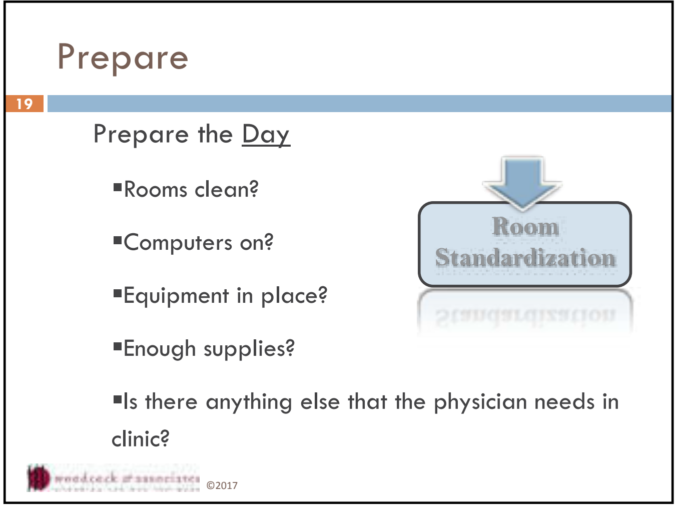
Prepare
19
Prepare the Day
▪Rooms clean?
▪Computers on?
▪Equipment in place?
▪Enough supplies?
▪Is there anything else that the physician needs in clinic?
Room Standardization
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Prepare
20
Source: UCSD
Source: UWisconsin
•Determine product and quantity per exam, procedure, etc., room
•Label bins/containers within drawers
•Create inventory system for each supply with picture, room and place in supply closet
•Develop kits for common procedures
•If applicable (e.g., crash cart), record expiration on a master list
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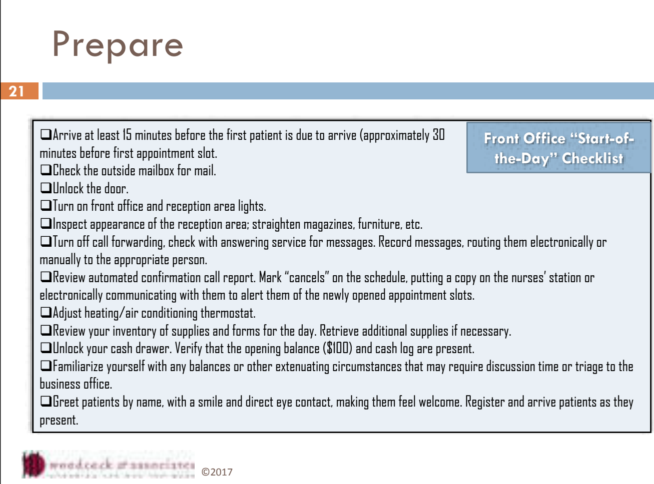
Prepare
21
Front Office "Start-of-the-Day" Checklist
❑Arrive at least 15 minutes before the first patient is due to arrive (approximately 30 minutes before first appointment slot.
❑Check the outside mailbox for mail.
❑Unlock the door.
❑Turn on front office and reception area lights.
❑Inspect appearance of the reception area; straighten magazines, furniture, etc.
❑Turn off call forwarding, check with answering service for messages. Record messages, routing them electronically or manually to the appropriate person.
❑Review automated confirmation call report. Mark "cancels" on the schedule, putting a copy on the nurses' station or electronically communicating with them to alert them of the newly opened appointment slots.
❑Adjust heating/air conditioning thermostat.
❑Review your inventory of supplies and forms for the day. Retrieve additional supplies if necessary.
❑Unlock your cash drawer. Verify that the opening balance ($100) and cash log are present.
❑Familiarize yourself with any balances or other extenuating circumstances that may require discussion time or triage to the business office.
❑Greet patients by name, with a smile and direct eye contact, making them feel welcome. Register and arrive patients as they present.
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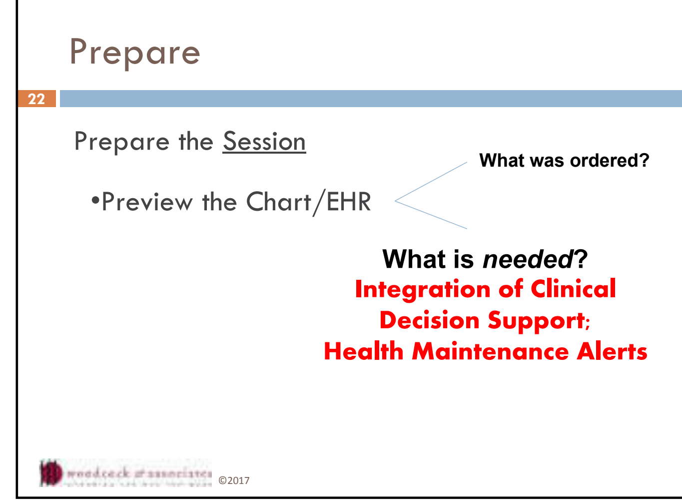
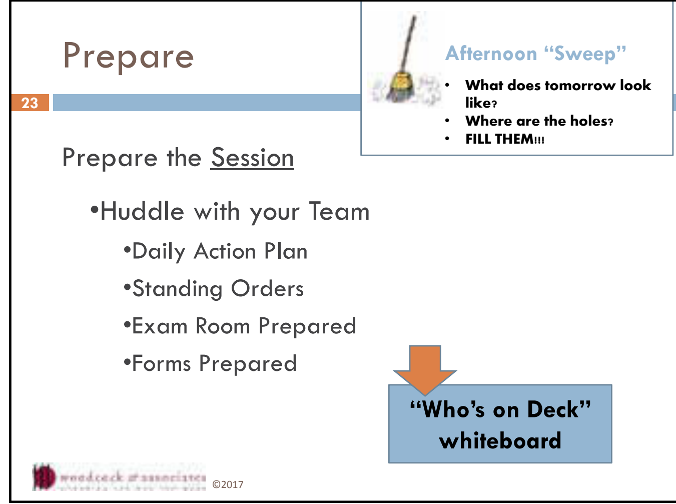
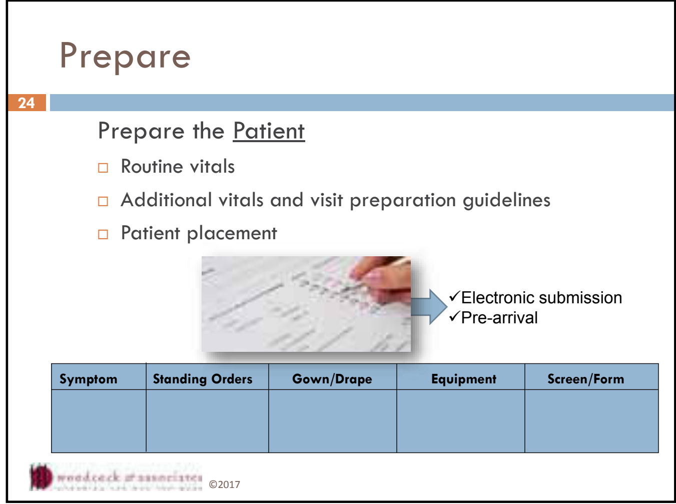
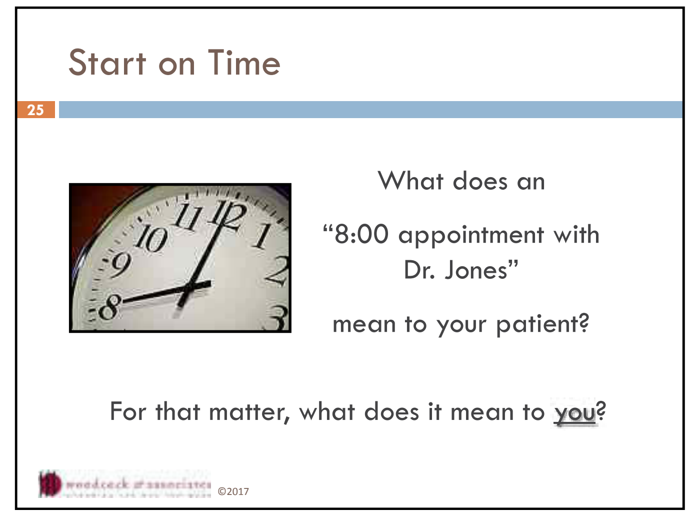

Prepare
22
Prepare the Session
•Preview the Chart/EHR
What was ordered?
What is needed?
Integration of Clinical Decision Support;
Health Maintenance Alerts
©2017


Prepare
23
Afternoon "Sweep"
• What does tomorrow look like?
• Where are the holes?
• FILL THEM!!!
Prepare the Session
•Huddle with your Team
•Daily Action Plan
•Standing Orders
•Exam Room Prepared
•Forms Prepared
"Who's on Deck" whiteboard
©2017


Prepare
24
Prepare the Patient
□ Routine vitals
□ Additional vitals and visit preparation guidelines
□ Patient placement
✓Electronic submission
✓Pre-arrival
Symptom
Standing Orders
Gown/Drape
Equipment
Screen/Form
©2017


Start on Time
25
What does an
"8:00 appointment with
Dr. Jones"
mean to your patient?
For that matter, what does it mean to you?
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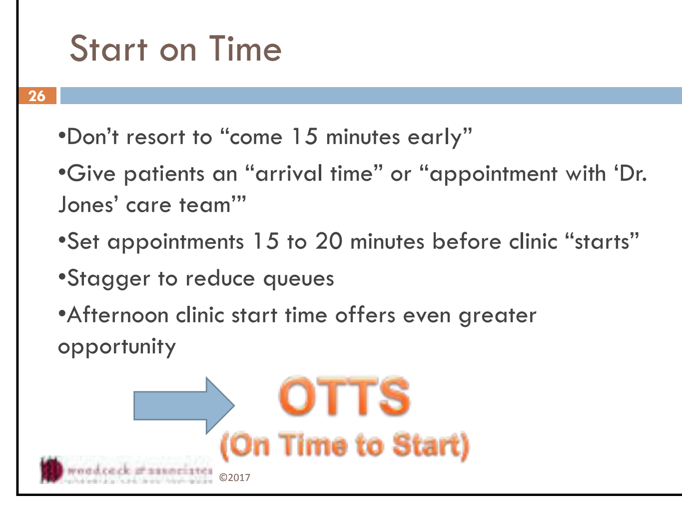
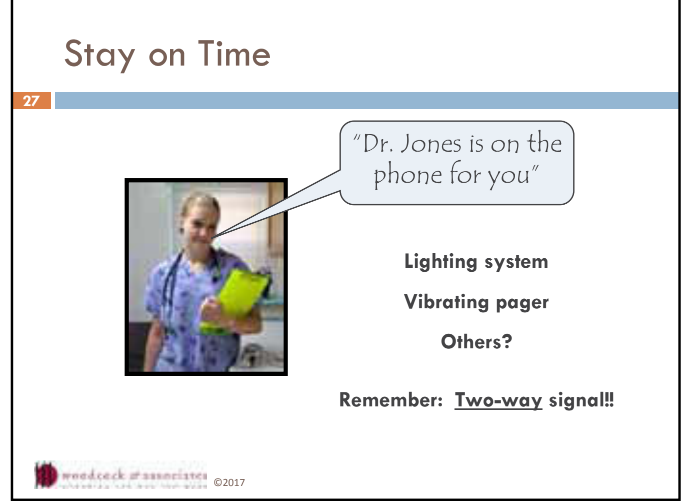
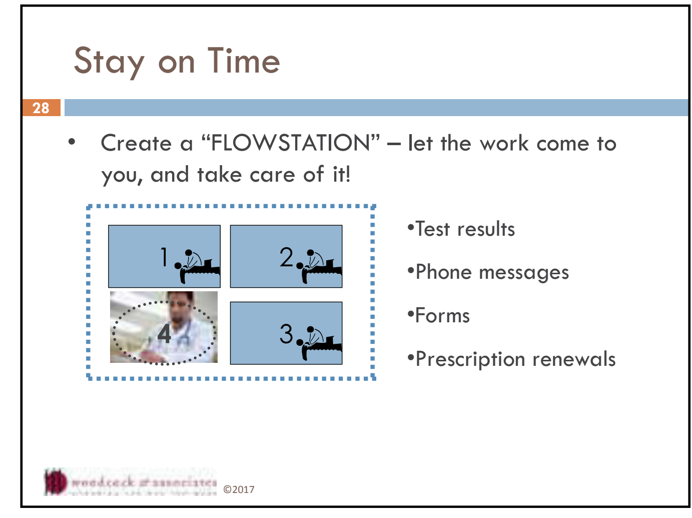
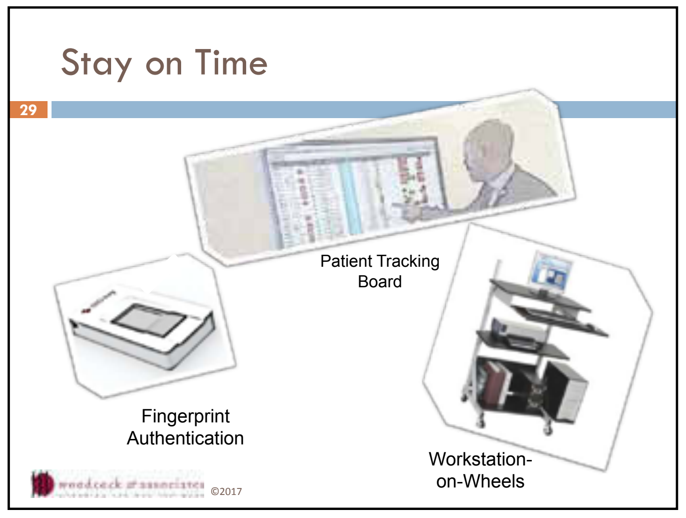
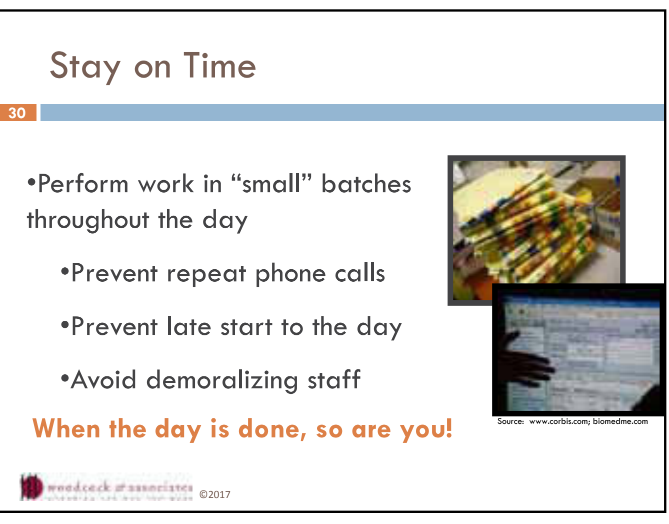

Start on Time
26
•Don't resort to "come 15 minutes early"
•Give patients an "arrival time" or "appointment with 'Dr. Jones' care team'"
•Set appointments 15 to 20 minutes before clinic "starts"
•Stagger to reduce queues
•Afternoon clinic start time offers even greater opportunity
OTTS
(On Time to Start)
©2017


Stay on Time
27
"Dr. Jones is on the phone for you"
Lighting system
Vibrating pager
Others?
Remember: Two-way signal!!
©2017


Stay on Time
28
Create a "FLOWSTATION" – let the work come to you, and take care of it!
1
2
4
3
•Test results
•Phone messages
•Forms
•Prescription renewals
©2017


Stay on Time
29
Patient Tracking Board
Fingerprint Authentication
Workstation-on-Wheels
©2017


Stay on Time
30
•Perform work in "small" batches throughout the day
•Prevent repeat phone calls
•Prevent late start to the day
•Avoid demoralizing staff
When the day is done, so are you!
Source: www.corbis.com; biomedme.com
©2017

Oh By the Ways

31

Prevention? At the beginning of the visit:

"Mr. Jones, I'm going to summarize what you've told me… I'll be addressing those concerns today. Is there anything else you'd like to discuss with me today?"

→ Get control of the "list"

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Oh By the Ways

32

Reschedule?

"Mr. Jones, the issue that you are raising is so important that I'd like to allow enough time to thoroughly discuss it with you…" Give him a follow-up appointment.

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Oh By the Ways

33

- Document, code and bill for it
  - Bill appropriate level of the E/M
    - If counseling or coordination of care… with patient and/or family… dominates the encounter, **bill by time**

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For Further Reading

34

Mastering Patient Flow: 4th Edition by Elizabeth Woodcock, MBA, FACMPE, CPC, Medical Group Management Association, 2016

The Goal by Eliyahu M. Goldratt, North River Press, 1985

Lean Thinking by James Womack and Daniel Jones, Simon and Schuster, 1996

The Perfect Practice by Sherry Delio, Medical Group Management Association, 2005

Reducing Delays and Waiting Times by Tom Dolan, et al., Institute for Healthcare Improvement, 1996

Secrets of the Best-Run Practices by Judy Capko, Greenbranch Publishing, 2010

Service Management by James A. Fitzsimmons and Mona J. Fitzsimmons, Irwin McGraw-Hill, 2003

The Service Profit Chain by James L. Heskett, W. Earl Sasser, Jr. and Leonard A. Schlesinger, The Free Press, 1997

Stop Managing Costs by James P. Mozena, Charles E. Emerick and Steven C. Black, American Society for Quality, 1999

The Successful Physician: A Productivity Handbook for Practitioners by Marshall Zaslove, Aspen Publishers, Inc., April 1998

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SELF EVALUATION

Mastering Patient Flow in the Healthcare Practice

1. The three goals to improving telephone communication are:
   a. Provide best service, reduce transaction time, reduce demand for calls
   b. Get caller's name, schedule follow up appointment, confirm date of appointment
   c. Identify practice's name in format of acronym, transfer as appropriate
   d. Greet the caller quickly, then cancel, schedule and/or reschedule appointment

2. T/F - Using technology can be an effective way to engage patients.

3. T/F - Addressing today's tasks by working in small batches helps prevent a late start to the *next* day.

4. Your time – and that of your colleagues who are billable providers - is your practice's most precious __________:
   a. Coder
   b. Asset
   c. Computer guru
   d. Management expert

5. In addition to improving how you greet callers, using technology wisely and teaching staff to process calls more efficiently, your telephone improvement initiative should include:
   a. Reducing the *demand* for calls
   b. Doubling the volume of calls
   c. Routing calls to an answering service
   d. Finding ways to lay off telephone operators

6. For the "oh, by the way's", you can code based on time when:
   a. You spend more than half of the encounter counseling and/or coordinating care with the patient and/or family members – and document this
   b. There are more than five diagnosis codes that are relevant to the patient's care
   c. You are new
   d. You employ two registered nurses

7. As you are seeing patients during clinic, designate a _______________ as a location for test results, messages, forms, etc., to come to you.
   a. Employee break room
   b. Medication sample closet
   c. Flowstation
   d. Laboratory

8. Provide patients a(n) _______________ time in order to keep you and your practice running on time.
   a. Alarm
   b. Arrival
   c. Meal
   d. Payment

9. Before a message is taken by an employee, require him/her to ask the patient?
   a. "What are you wearing today?"
   b. "How many pills have you taken thus far?"
   c. "Are you sick?"
   d. "Is there anything that I can do to help you?"

10. Using techniques like ______________ and _______________ offers you an ability to "mistake proof" your practice, which is an important mantra of lean.
   a. Pictures; labels
   b. Smiles; laughter
   c. Paper; pens
   d. Nurses; medical assistants

11. T/F - Developing techniques to allow you to be aware of the time contributes to maintaining an efficient practice.

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

Joel Kahn, MD, FAAC

Joel Kahn, MD, FACC, of Detroit, Michigan, is a practicing cardiologist, a clinical professor of medicine at Wayne State University School of Medicine, and an associate professor at Oakland University/Beaumont Hospital medical schools. Known as "America's Holistic Heart Doc", Dr. Kahn is a diplomate of the American Board of Internal Medicine and maintains subspecialty board certification in cardiovascular medicine.

Dr. Kahn has authored scores of publications in his field including articles, book chapters, and monographs. He writes articles for *Huffington Post, MindBodyGreen*, and *Reader's Digest* and has five books in publication including *Your Whole Heart Solution, Dead Execs Don't Get Bonuses*, and *The Plant Based Solution*. He has regular appearances on *Dr. Phil, The Doctors TV Show*, and *Fox 2 News*.

You may contact Dr. Kahn with any questions or comments at www.drjoelkahn.com.

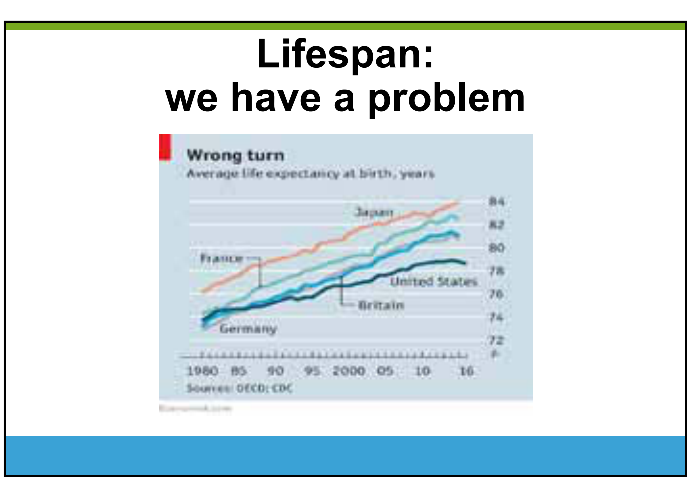
Joel Kahn, MD, FACC

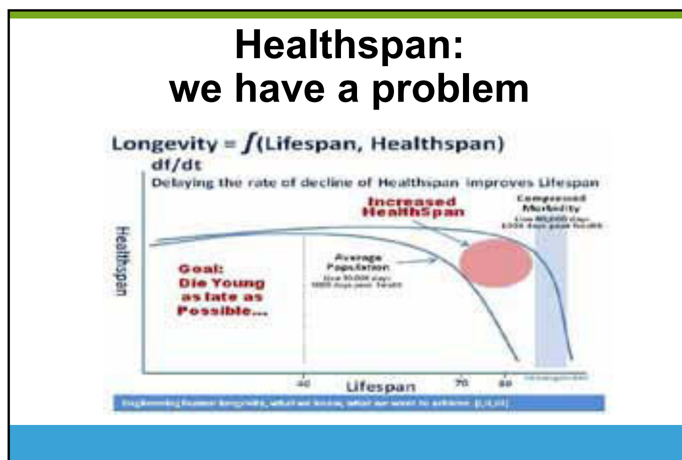
Advanced Preventive Cardiology
Clinical Professor, Wayne State University
www.drjoelkahn.com
248-731-7412

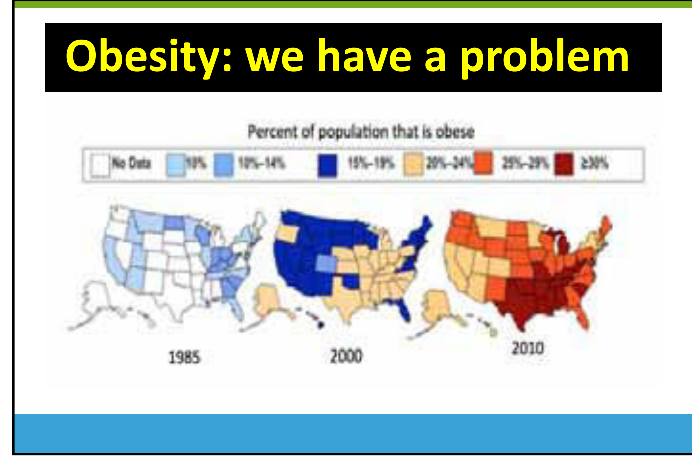
The Longevity Diet

Health: Not dead is not enough

Health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.



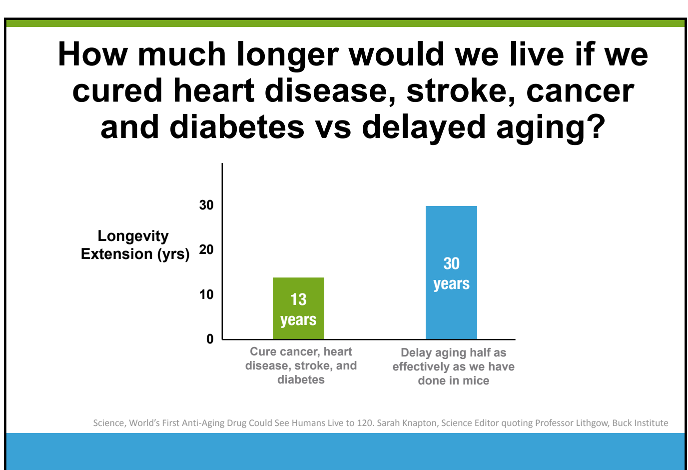




Aging & Heart Disease

- People are living longer lives than ever before and the group >65 will comprise more than 22% of the population by 2030
- Age-associated chronic diseases & conditions are increasing just as fast

(US Census National Population Projections 2012
CDC, National Center for Health Statistics, National Health Interview Survey 2010
CDC, National Center for Chronic Disease Prevention & Health Promotion 2012)

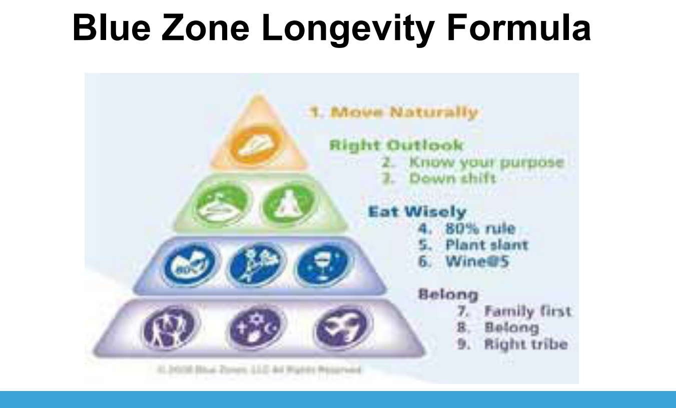


Where Do People Live the Longest?

BLUE ZONES

People live to be 100 at rates 10 times greater than in the U.S. in these Blue Zones

Blue Zone Longevity Formula



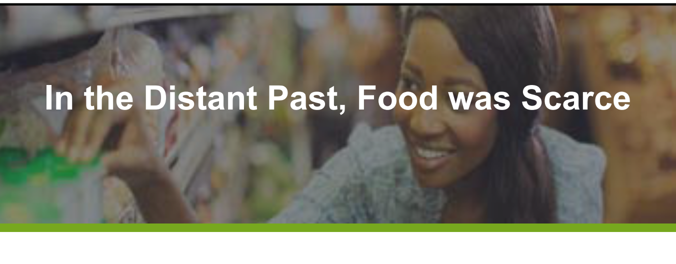
Impact of Healthy Lifestyle Factors on Life Expectancies in the US Population

EXTENDED LIFESPAN 12-14 YEARS

- • Eat a healthy diet (upper 40%)
- • Exercise 30 minutes or more a day
- • Maintain a healthy weight (body mass index between 18.5 and 24.9)
- • Don't drink too much alcohol (No more than one 5 oz. glass of wine per day for women, and two glasses for men)
- • Don't smoke (ever)
- Men and women who followed the healthiest of lifestyles were 82% less likely to die from cardiovascular disease and 65% less likely to die from cancer compared with people who lived unhealthy lifestyles over the course of 30 years.
- The researchers analyzed 34 years of data from more than 78,000 women and 27 years of data from more than 44,000 men. The researchers estimated the women who adopted these five habits would see 14 more years of life, and men would add 12 years.
- Li et al. April 30, 2018 Circulation

How Do Hearts Age (at a cellular level)?

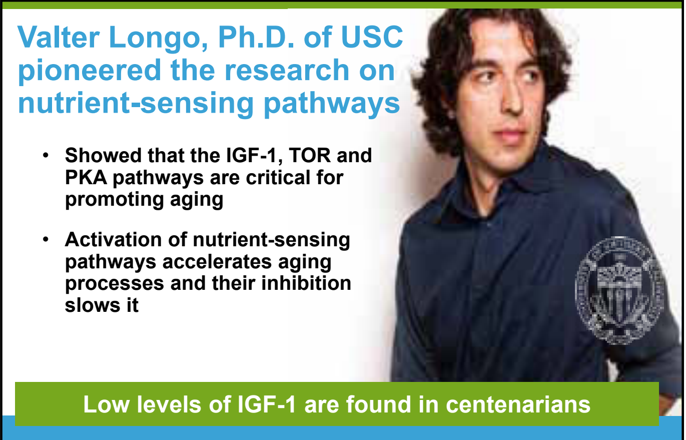
- **Nutrient sensing pathways**: mTOR / AMPK
  Insulin resistance → diabetes and cardiac dysfunction
- **Mitochondrial activity/ROS**
- **DNA damage** response / telomere shortening
- **Autophagy**: Cellular dysfunction and accumulation of toxic protein aggregates

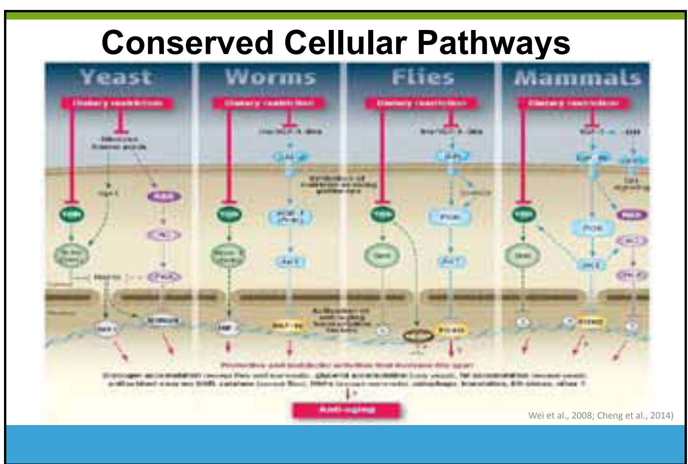


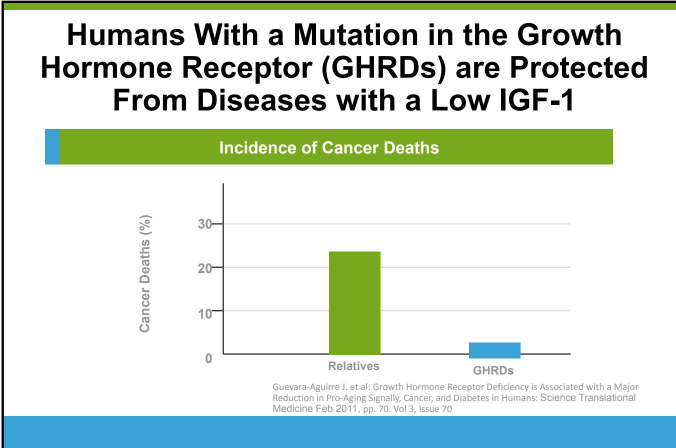
These periods of fasting forced strong evolutionary pressures on the our ability to survive during periods of hunger.

Fasting: conserves cell energy by diminishing cellular growth pathways via key nutrient sensing pathways (IGF-1, mTOR and PKA) resulting in:

- **Increased cellular maintenance and protection**
- **Increased activation of stress resistance pathways**
- **Removal and replacement of damaged cells**
- **Reduction of inflammation**







Growth Hormone Receptor and IGF-1 Deficient (GHRD) (Laron's) Subjects

J. Guevara and The Little Women of Loja Ecuador

Fasting reduces the activity of aging pathways and promotes resilience and protection from aging and disease:

Eat Less, Live More

Prolonged Fasting: 0 Calories for >1 day

- Protects mice against the adverse effects of chemotherapy and ischemia/reperfusion-mediated toxicity and cancer progression
- Promotes stem cell-dependent regeneration and immune system rejuvenation in old animals

Challenges: difficult, concern for dehydration and electrolyte balance

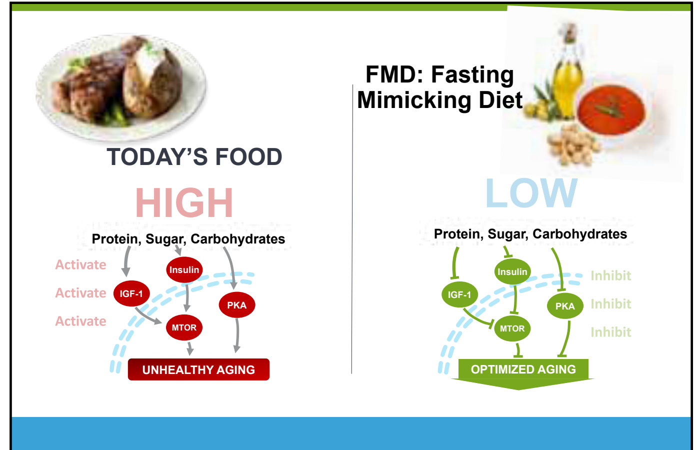
(Mauro et al., 2014, Safdie et al., 2009, Longo & Mattson 2014; Cheng et al., 2014; Levine et al., 2014; Michalsen et al., 2005

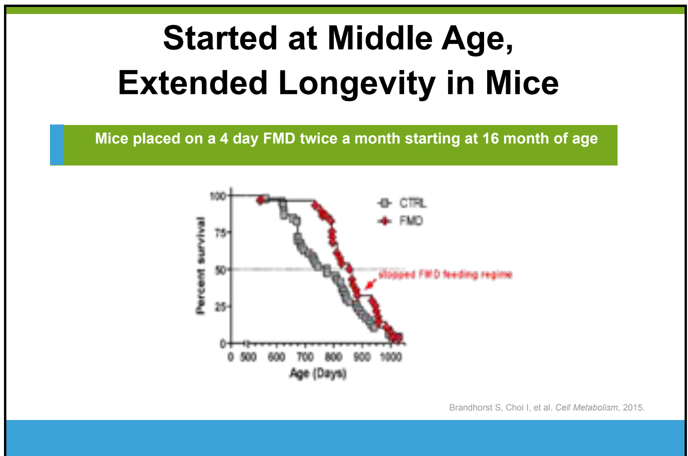
What if There Was a Dietary Intervention That Mimicked Fasting? All the Gain, Less Pain

What if there was a diet that:

"The stomach sees food, the cells see fasting"

- **Combine Protein Restriction, mild Calorie Restriction, and very specific ratios of low-glycemic index food**
- **This combination downregulates the body's key nutrient-sensing pathways, and activate cellular regeneration & rejuvenation**

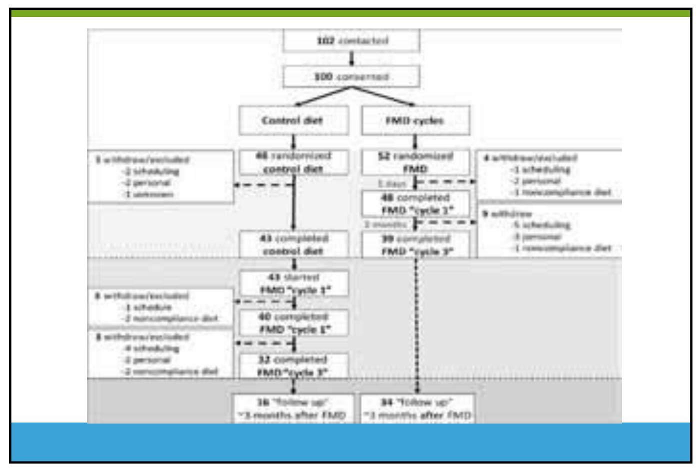


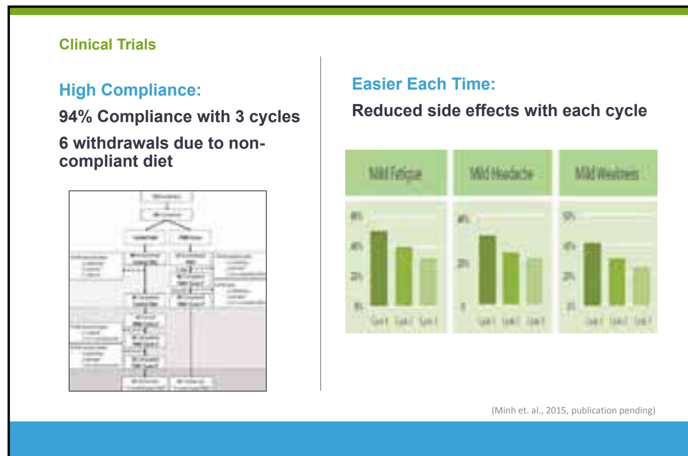


FMD in Humans:

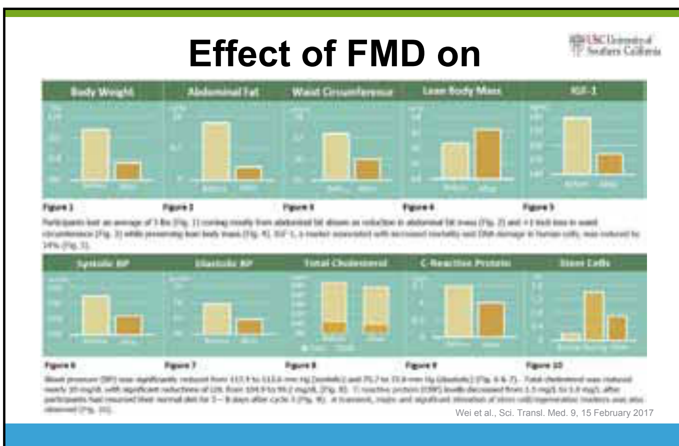
"The stomach receives food, while the metabolism fasts'

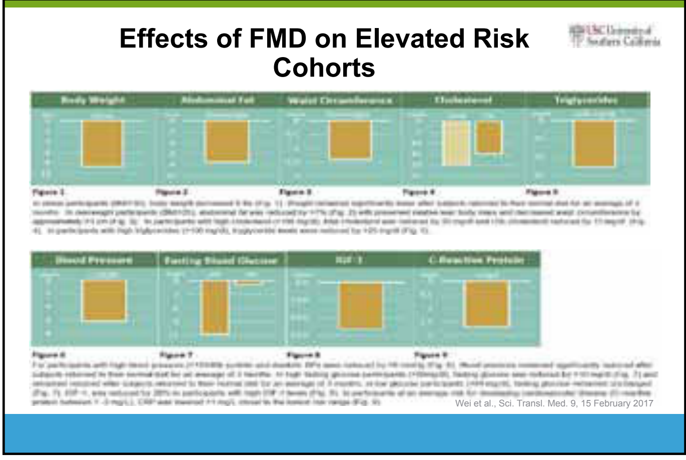
- Consists of soups, bars, teas, drinks, and snacks
- Five consecutive days/month, up to 12 times/year,
- Demonstrated to rejuvenate the body, induce fast fat loss without decreasing muscle or bone mass, and prevent (and potentially reverses) age-related metabolic changes

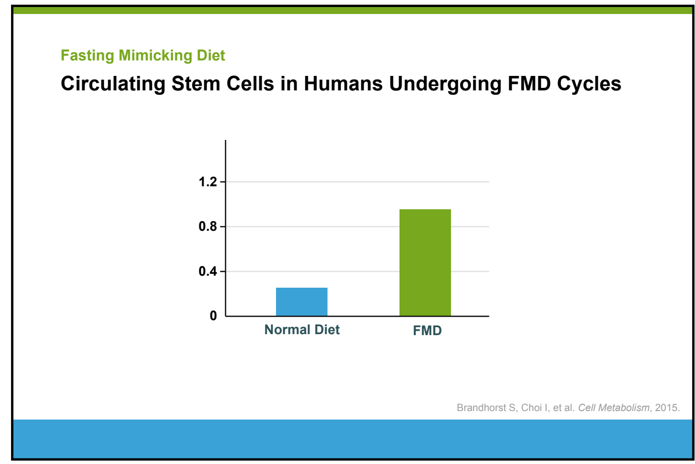


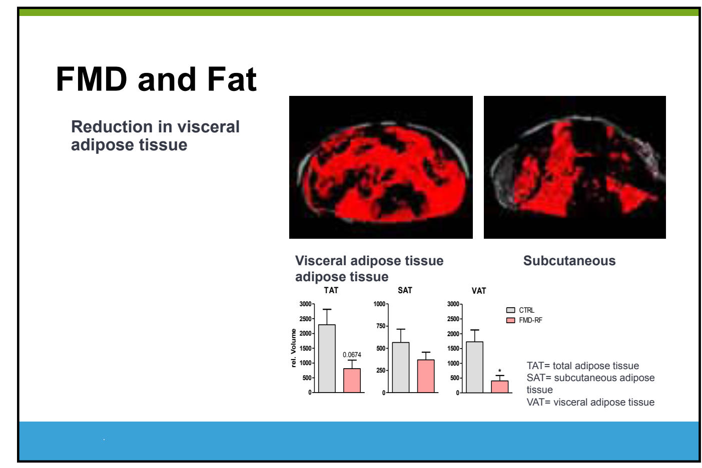

Clinical Trials
High Compliance:
94% Compliance with 3 cycles
6 withdrawals due to non-compliant diet
Easier Each Time:
Reduced side effects with each cycle
Mild Fatigue
Mild Headache
Mild Weakness
(Minh et. al., 2015, publication pending)

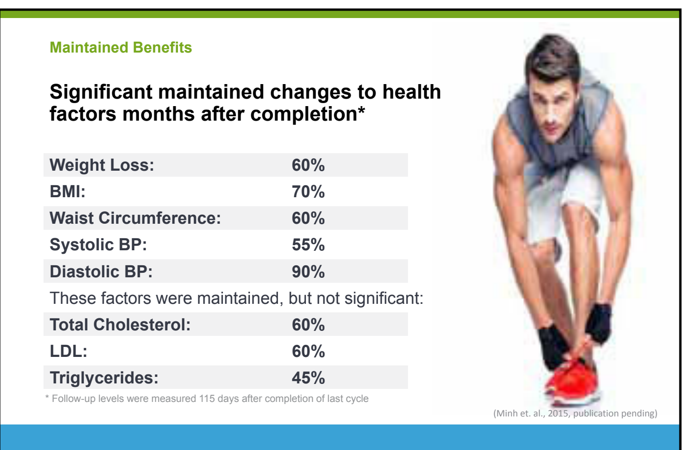
Yeast
Mouse
Human


Effect of FMD on
Body Weight
Abdominal Fat
Waist Circumference
Lean Body Mass
IGF-1
Systolic BP
Diastolic BP
Total Cholesterol
C-Reactive Protein
Stem Cells
Wei et al., Sci. Transl. Med. 9, 15 February 2017

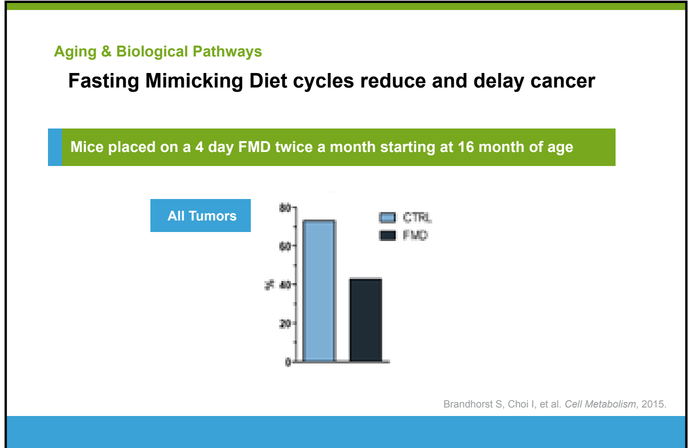

Effects of FMD on Elevated Risk Cohorts
Body Weight
Abdominal Fat
Waist Circumference
Cholesterol
Triglycerides
Blood Pressure
Fasting Blood Glucose
IGF-1
C-Reactive Protein
Wei et al., Sci. Transl. Med. 9, 15 February 2017

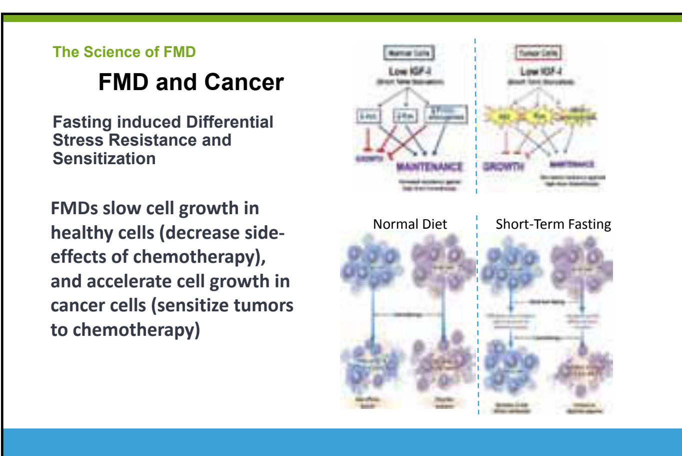

Fasting Mimicking Diet
Circulating Stem Cells in Humans Undergoing FMD Cycles
1.2
0.8
0.4
0
Normal Diet
FMD
Brandhorst S, Choi I, et al. Cell Metabolism, 2015.

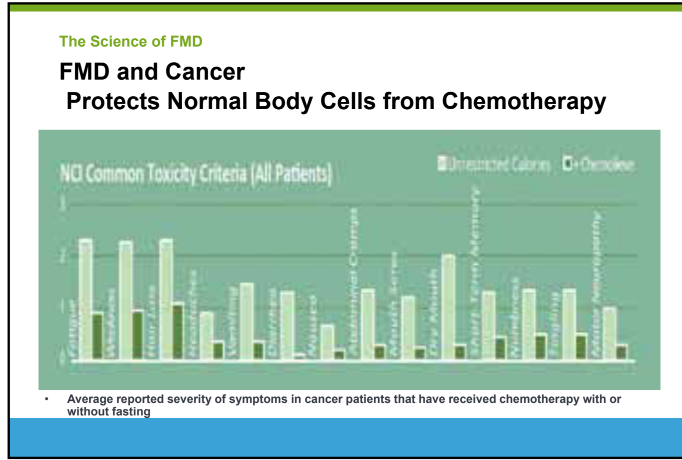

FMD and Fat
Reduction in visceral adipose tissue
Visceral adipose tissue adipose tissue
Subcutaneous
TAT
SAT
VAT
CTRL
FMD-RF
rel. Volume
0.0674
TAT= total adipose tissue
SAT= subcutaneous adipose tissue
VAT= visceral adipose tissue

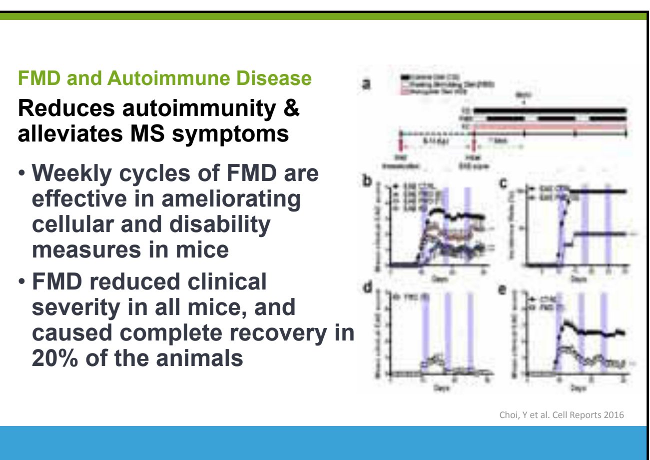

Maintained Benefits
Significant maintained changes to health factors months after completion*
Weight Loss: 60%
BMI: 70%
Waist Circumference: 60%
Systolic BP: 55%
Diastolic BP: 90%
These factors were maintained, but not significant:
Total Cholesterol: 60%
LDL: 60%
Triglycerides: 45%
* Follow-up levels were measured 115 days after completion of last cycle
(Minh et. al., 2015, publication pending)

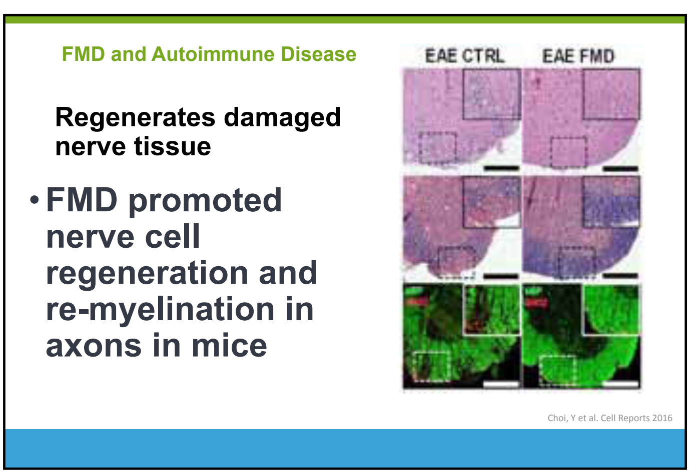
Additional Benefits Of FMD:
Cancer & AutoImmune
Disease

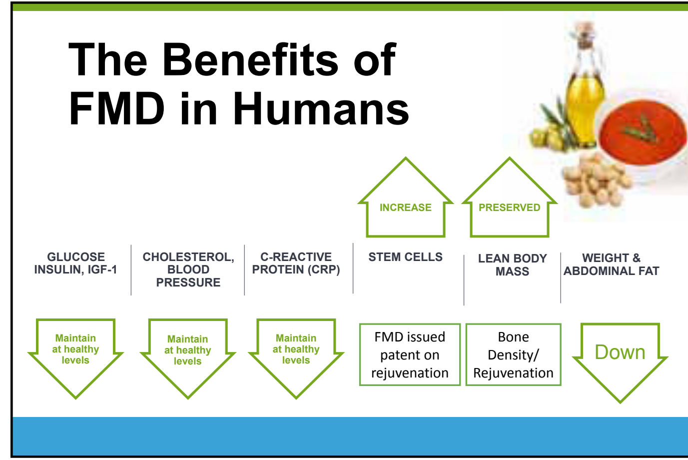

Aging & Biological Pathways
Fasting Mimicking Diet cycles reduce and delay cancer
Mice placed on a 4 day FMD twice a month starting at 16 month of age
All Tumors
CTRL
FMD
Brandhorst S, Choi I, et al. Cell Metabolism, 2015.

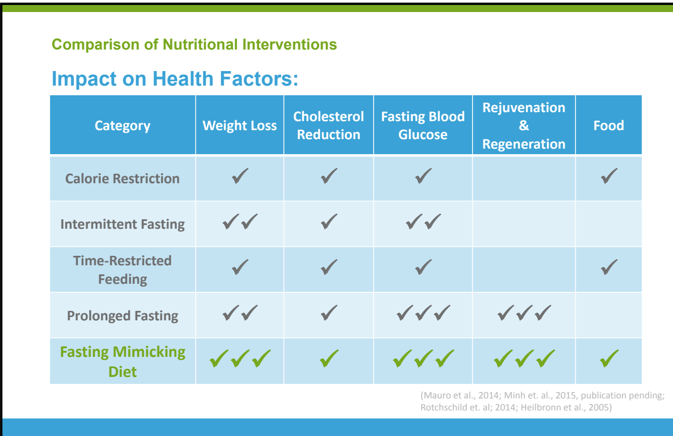

The Science of FMD
FMD and Cancer
Fasting induced Differential Stress Resistance and Sensitization
FMDs slow cell growth in healthy cells (decrease side-effects of chemotherapy), and accelerate cell growth in cancer cells (sensitize tumors to chemotherapy)
Normal Diet
Short-Term Fasting


The Science of FMD
FMD and Cancer
Protects Normal Body Cells from Chemotherapy
NCI Common Toxicity Criteria (All Patients)
Average reported severity of symptoms in cancer patients that have received chemotherapy with or without fasting


FMD and Autoimmune Disease
Reduces autoimmunity & alleviates MS symptoms
• Weekly cycles of FMD are effective in ameliorating cellular and disability measures in mice
• FMD reduced clinical severity in all mice, and caused complete recovery in 20% of the animals
Choi, Y et al. Cell Reports 2016



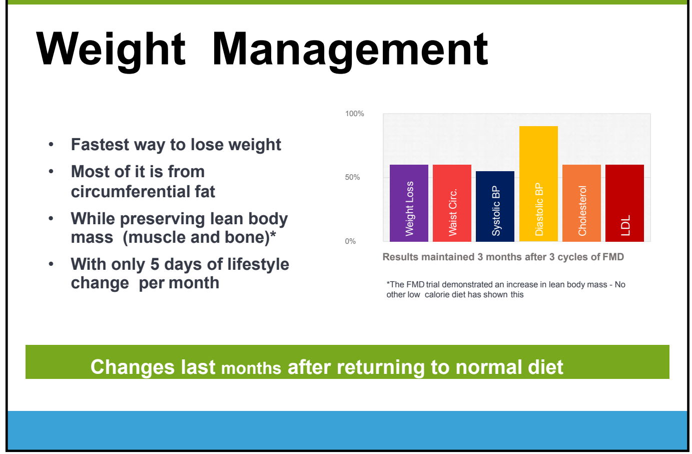


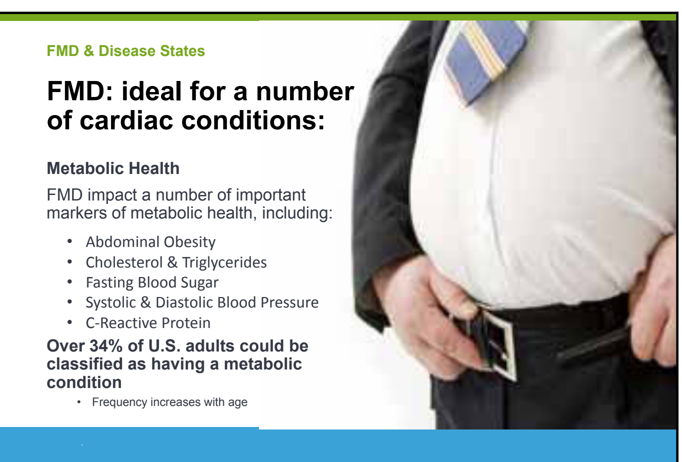

Comparison of Nutritional Interventions

Impact on Health Factors:

Category	Weight Loss	Cholesterol Reduction	Fasting Blood Glucose	Rejuvenation & Regeneration	Food
Calorie Restriction	✓	✓	✓		✓
Intermittent Fasting	✓✓	✓	✓✓		
Time-Restricted Feeding	✓	✓	✓		✓
Prolonged Fasting	✓✓	✓	✓✓✓	✓✓✓	
Fasting Mimicking Diet	✓✓✓	✓	✓✓✓	✓✓✓	✓

(Mauro et al., 2014; Minh et. al., 2015, publication pending; Rotchschild et. al; 2014; Heilbronn et al., 2005)





SELF EVALUATION

The Longevity Diet

True/False

1. Certain amino acids found in animal protein trigger an increase in IGF-1 and aging pathways in adults

2. The Loran Syndrome is characterized by very high IGF-1 levels throughout life and tall body statures with high rates of diabetes.

3. Foods high in added sugar trigger a pathway known as PKU which activates aging mechanism.

4. A fasting mimicking diet provokes responses like a complete fast but permits around 800 calories a day. It is designed to be low in protein and sugar.

5. The fasting mimicking diet is followed one day a week for 5 weeks.

6. The fasting mimicking diet is being studied in universities for its role in diabetes, multiple sclerosis, cancer therapy, dementia, and athletic performance.

7. The Longevity Diet differs from the Western diet by being low in red meat, eggs, dairy and sweets

8. The Longevity Diet is a gluten free diet.

9. The Longevity Diet is an alcohol and oil free diet.

10. The 5 Pillars of Longevity Diet refers an method of analyzing nutrition science to separate fads from proven trends.

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

Malpractice Litigation Stress: Its Nature and Its Management

Dealing with Litigation Stress
Winning Focus, Inc.

The Litigation Process

The civil litigation process is a poor method for determining the clinical competency of a health care provider.

We are a nation of laws, we are a nation that follows the rule of law…unless we don't, because we are not a nation of honor.

Principle of Legitimacy

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The Litigation Process

A huge part of litigation stress is caused by the civil legal system itself because the legal system is about the legal system, not right or wrong, not good or bad…unless and until it gets in front of a jury.

Justice? Judge Judy.

Dealing with Litigation Stress
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The Litigation Process

Four steps to proving negligence, burden of proof is on the plaintiff to prove negligence based on a preponderance of the evidence, not beyond a reasonable doubt (criminal):

1. Professional Relationship
2. Breach of the Standard of Care

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Winning Focus, Inc.

The Litigation Process

2. Standard of Care

What a reasonable person who is comparably trained would or would not do under the same or similar circumstances. You don't have to always be right, you don't have to be heroic, you just must act reasonably, given the circumstances.

Reasonable person or reasonable health care provider?

How will the Standard of Care change:
- Within an ACO?
- With outcome-based medicine?
- With online "best practices?"

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The Litigation Process

3. Harm
- Physical
- Emotional
- Lost wages
- Lost future opportunity

4. Proximate cause

Is there a relationship between what was or was not done and the harm? Can you have an act of negligence and not be found negligent?

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Winning Focus, Inc.

The Litigation Process

Stress is usually based on a lack of control or perceived lack of control. By educating yourself on the litigation process in your jurisdiction you do not gain control over the source of stress, but your understanding will help gain control over the situation as you'll know what to expect, you'll know what will be coming next, you'll know there will be bursts of activity followed by long periods when it appears nothing is going on.

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Dealing with Litigation Stress
Winning Focus, Inc.

The Litigation Process

1. Notice of Claim or Records Request
2. Notice of Suit or Written Demand
3. Discovery
   - Subpoenas
   - Interrogatories
   - Depositions
4. Trial or settlement

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Winning Focus, Inc.

The Litigation Process

Notice of Claim

- Report this to your insurance company or risk manager immediately
- Do NOT contact an attorney
- Do NOT contact the patient
- Do not conduct research
- Do not alter any records
- Await contact from your insurance company or risk manager

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Winning Focus, Inc.

The Litigation Process

Notice of Suit or Written Demand

- Clock is ticking >company>attorney> response
- Educate staff
- Wait for directions from attorney
- Discuss with family
- Help identify potential experts
- Begin physical preparations

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Winning Focus, Inc.

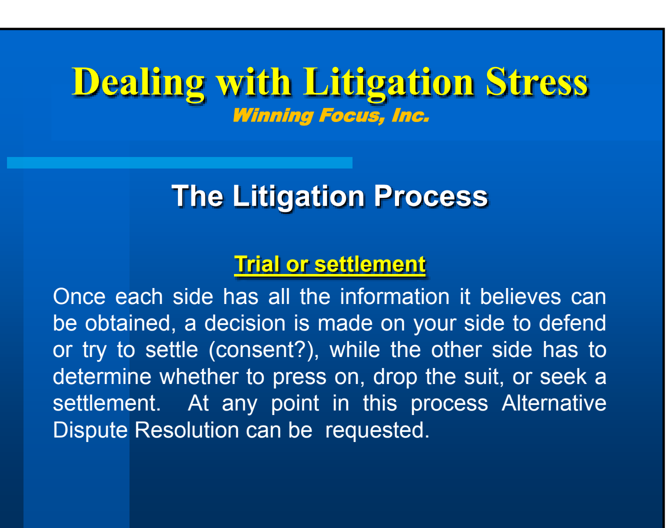
The Litigation Process

Discovery

Subpoenas: Written request for documents, including medical records, emails, texts, phone records, etc.

Interrogatories: Similar to a subpoena, but a written lists of questions to be answered under oath.

Depositions: A chance for each side to question, under oath, you, your staff, any expert witnesses; and, for you to question under oath the patient and his/her experts, family, and anyone else connected to the case.



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The Litigation Process

Alternative Dispute Resolution

- Arbitration
- Binding Arbitration
- Mediation

Each of the above is slightly different in style, but what is consistent with each case is that both parties normally enter into ADR with the expectation of a settlement. A good settlement is said to leave both parties unhappy.

Dealing with Litigation Stress
Winning Focus, Inc.

The Litigation Process

Advantages of Alternative Dispute Resolution

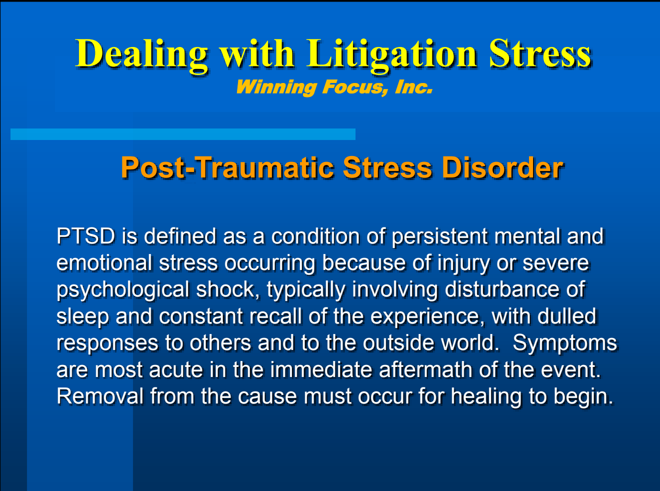
- Less adversarial
- Opportunity for you and patient to hear each other's story, maybe for the first time
- Usually confidential
- Face-to-face can help melt resentment and anger
- Usually much less stressful

Dealing with Litigation Stress
Winning Focus, Inc.

The Litigation Process

Post-litigation

- NPDB
- Board of Medicine
- Credentialing forms
- Malpractice insurance
- Privileges
- Certain aspects are career-long



Dealing with Litigation Stress
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Post-Traumatic Stress Disorder

- "Shell shock" or "combat neurosis"
- 1980, 3rd edition, DSM of Mental Disorders ("DSMIII")
- In the U.S., 3.5% of adults per year, estimated
- PTSD is not just "in your head"

Dealing with Litigation Stress
Winning Focus, Inc.

Post-Traumatic Stress Disorder

PTSD is not just "in your head"

- Prefrontal lobe of brain is adversely affected (language)
- Amygdala pushed into overdrive, can increase in size (emotions)
- "Safe" situations can be perceived as "unsafe" (amygdala) meaning a person is permanently in some level of fight or flight
- Hippocampus can shrink, impacting short-term memory
- Medial prefrontal cortex does not regulate emotions properly

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Post-Traumatic Stress Disorder

Some people may experience short-term symptoms, usually referred to as Acute Stress Disorder. If symptoms last more than a month and there is no other explanation it may well be PTSD. In addition to other effects, PTSD is often accompanied by depression, substance abuse, or anxiety disorders.

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Post-Traumatic Stress Disorder

Key Points

- The more severe the trauma and the longer someone is exposed to it, the more likely they are to develop PTSD.
- Two people experiencing exactly the same event can respond quite differently.
- Persistently having to re-live the event can increase the chances of developing PTSD or can prolong it in a susceptible person.

Dealing with Litigation Stress
Winning Focus, Inc.

Litigation Stress Management

So what do we do? If stress in moderate amounts is OK, how do we handle the distress of a malpractice suit if CONTROL is the key to decreasing or eliminating distress? **Treat the symptoms!** Rule #1 is, you cannot be distressed over something you are not thinking about! Rule #2 is, use the chemicals of stress so they cannot eat you up.

Dealing with Litigation Stress
Winning Focus, Inc.

Litigation Stress Management

Mindfulness

This concept has been around for thousands of years and it is, in one form or another, what we are working towards with each step in our litigation stress program. It has been a part of Buddhism and ancient Greek philosophy, today it might be an app on your smart phone.

What is it?

Dealing with Litigation Stress
Winning Focus, Inc.

Litigation Stress Management

Mindfulness

Mindfulness has been defined as an open, accepting attention to and awareness of internal and external sensations. Sound a little like stress, responding to the world around you? Yes, either normal stress level or eustress. Keep in mind we are trying to reduce distress to manageable levels.

Dealing with Litigation Stress
Winning Focus, Inc.

Litigation Stress Management

Mindfulness

As has been stated frequently, lack of control contributes greatly to litigation stress, which creates distress and soon you find yourself in an endless feedback loop of feeling distressed, knowing why, which then gets you thinking about the litigation, and so on. Your body is there, your mind is somewhere else. STOP! You can choose peace and you can do so now.

Dealing with Litigation Stress

Winning Focus, Inc.

Litigation Stress Management

Mindfulness

The surge in mindfulness is a recognition that our world today has created a low level of "fight or flight" in the lives of most people; from there it is one severe trauma, physical or emotional, to distress levels. The objective of mindfulness is to calm the mind's constant thought processes, most of which involve fear. What are you afraid of? How realistic is it?

Dealing with Litigation Stress

Winning Focus, Inc.

Litigation Stress Management

Mindfulness

There are multiple resources on mindfulness available online, in books and magazines, and even through life and litigation stress coaching. One key concept before starting is that you are making this commitment to you for the good of yourself and those around you. This is not a "should" do; if you make this a "should" you end up "shoulding all over yourself," creating more stress.

Dealing with Litigation Stress

Winning Focus, Inc.

Litigation Stress Management

The Three Cs of Coping

1. Commitment: You consciously and actively involve yourself in your life, which includes conscious efforts to get your stress down to manageable levels. Refuse to be a victim. It may not be easy, but peace is a choice, plus see #2 below for some extra help.

Dealing with Litigation Stress

Winning Focus, Inc.

Litigation Stress Management

The Three Cs of Coping

2. Control: We have discussed control extensively, so you need to behave as if you are in control. Victims of chronic distress often relate to feeling out of control, or as the author Isaac Asimov said, "*Things are in the saddle and riding mankind.*" Smile, even if you don't feel like it, fake it until you can make it. Studies have shown that your brain's happiness circuitry is activated when you smile, regardless of your current mood.

Dealing with Litigation Stress

Winning Focus, Inc.

Litigation Stress Management

The Three Cs of Coping

3. Challenge: Change is normal and unless you opt off the grid completely, it is accelerating. Dealing with litigation is going to change you, period. It changed me. Can you accept the challenge of dealing with this change and using it as a vehicle towards personal growth? Or, in the vernacular of natural law, adapt or die (figuratively).

Dealing with Litigation Stress

Winning Focus, Inc.

Litigation Stress Management

Assessing your fears

Most fear involves the future, which we don't have complete control over, and most fears are unfounded.

- What is causing YOUR stress?
- Why is it affecting YOU?
- HOW is it affecting YOU?
- Why are YOU allowing this to happen?
- What are YOU going to do about it?

Dealing with Litigation Stress
Winning Focus, Inc.

Litigation Stress Management
Lifestyle and Personality

In the first part of this presentation I talked about how your personality has helped drive you to where you are today, good and bad. I talked about loyalty. NOW is the time to start working on a **social network**, especially if you are a male. What you are looking for is something where you are not talking about work. So many studies have shown the importance of a strong social network to happiness and wellness and longevity that I really don't think they need to study it anymore. This includes marriage.

Dealing with Litigation Stress
Winning Focus, Inc.

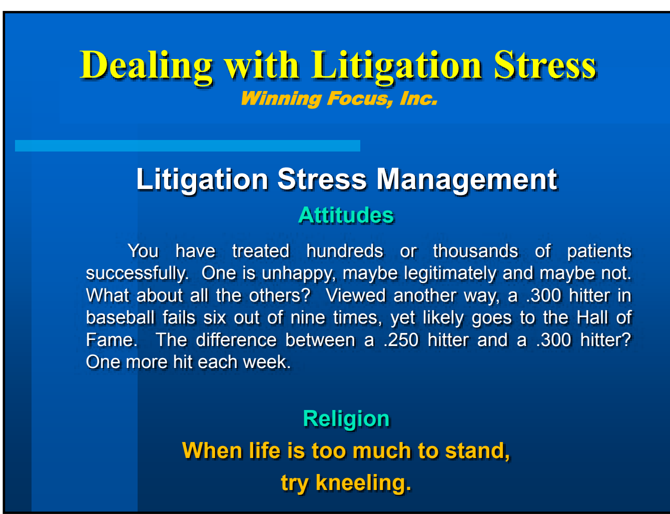
Litigation Stress Management
Ability to use time

Physicians tend towards workaholism. This is less prevalent in dentists who learn early on that the physical demands of their profession do not lend itself to a five-day workweek. Life is a marathon, not a sprint. Litigation is a marathon, not sprint. The more you are able to even your life out between work and everything else the happier you will be, the more in control you'll be of all aspects of your life, and the easier it will be to separate who you are from what you do.

Dealing with Litigation Stress
Winning Focus, Inc.

Litigation Stress Management
Attitudes

In the first presentation I frequently mentioned, directly or indirectly attitude, peace, choices. All professions have the potential to be sued for negligence. The litigation will be stressful. Why don't these other professions tend towards the over-reaction that health care providers have? One reason? Attitude.



Dealing with Litigation Stress
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Litigation Stress Management
Fitness, Activity, Nutrition

- Buffet of ideas
- Fitness: Find a few things you will stick with
- Activity: Develop or grow hobbies and/or involvement with non-healthcare organizations
- Nutrition: A LOT of different ideas being written about, all things in moderation
- PCP: Get a physical exam!

Dealing with Litigation Stress
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Litigation Stress Management
Fitness

- "Live Like You're 50 Until You're 70"
- Strength training
- Cardiovascular work
- Circuit or fartlek training
- Running and walking
- Never the same thing on two consecutive days

Dealing with Litigation Stress
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Litigation Stress Management
Activity

- Mindlessness = mindfulness
- Spending time as a part of something larger than yourself
- Find time to play
- Meaningful vacation (vacation with a goal)
- Disconnect

Dealing with Litigation Stress
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Litigation Stress Management
Nutrition

- Buffet of ideas (no pun intended)
- One approach is to take the results of the physical exam and use that to guide you
- Registered Dietician or Nutritionist
- Basics today: more protein, fewer carbs, decrease or eliminate processed foods, eat it as it grows
- Best diet advice ever?

Dealing with Litigation Stress
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Litigation Stress Management

Neuromuscular Relaxation

- Simple
- The more you practice, the better you get
- Effective
- Any time, any place

1. Take control of your mind
2. Find stress and tension in the body
3. Let it go
4. Can have a long session or several three minute sessions

Dealing with Litigation Stress
Winning Focus, Inc.

Litigation Stress Management
Neuromuscular Relaxation

- Guided "belly breathing" exercise
- Abbreviated tension release exercise
- What have you been thinking about?
- Start NOW! (How you handle stress before a suit…)

Dealing with Litigation Stress
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Litigation Stress Management
Post-Litigation Activities

- "Pity party" is officially over
- Bounce Back: Break the "don't look back" rule
- Learn as much as possible from the experience
- Any fences to mend?
- Anyone to thank?
- Pay it forward
- Kaizan

SELF EVALUATION

Malpractice Litigation Stress: Its Nature and Its Management

1. T/F - There is no relationship between stress management skills prior to being sued for malpractice and how you will handle the stress of litigation.

2. T/F - The civil litigation process is a poor method for determining the competence of a health care provider.

3. Proving a healthcare provider was negligent involves proving:

a. A professional relationship was formed
b. A breach of the standard of care
c. Harm or injury or loss
d. Proximate cause between the action and the harm or injury
e. All of the above

4. T/F - In most states the standard of care is that of a reasonable and prudent provider.

5. T/F - The more knowledgeable you are about the litigation process, the less emotional you are likely to be.

6. Once a claim is settled and done you may still have to deal with it in the form of:

a. The National Practitioner Data Bank (if a payment was made)
b. A Board of Medicine review or complaint
c. Credentialing forms to obtain reimbursement
d. Future malpractice applications
e. Hospital or surgery center privileges
f. All of the above

7. T/F - The two key aspects to managing litigation stress are gaining some semblance of control over the event and treating the symptoms.

8. T/F - In the simplest definition, “mindfulness” means being physically, mentally, and emotionally present.

9. The three ‘Cs’ of coping with stress include all the following EXCEPT:

a. Commitment
b. Cocaine
c. Control
d. Change

10. One way of treating the symptoms of stress is to not think about the source of stress by engaging in:

a. Exercise
b. Neuromuscular or progressive relaxation
c. Engaging in activities that engage the mind, such as gardening or board games
d. Prayer, meditation or yoga
e. Any or all of the above will treat the symptoms by taking your mind off the litigation.

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

Daniel G. Pompa, DDS

Daniel G. Pompa, DDS, of Roslyn Heights, New York is a fellow of both The American Association of Oral and Maxillofacial Surgeons and The International Congress of Oral Implantologists. He has been a guest lecturer at Columbia University College of Dental Medicine and New York University College of Dentistry. Dr. Pompa is a guest lecturer at the University of Florida College of Dentistry, Boston University Henry M. Goldman School of Dental Medicine, University of Maryland School of Dentistry and the University of Pittsburgh School of Dental Medicine. He has lectured extensively both nationally and internationally, and in 2013 became a Seminar Series Speaker/Consultant for the American Dental Association. Dr. Pompa has been published in such journals as *JADA* and *NYSAGD Journal* as well as *Dentistry Today* where he has been listed as a “Leader in Continuing Education.” He is also an inventor, having been issued a U.S. Patent for his innovative work in the field of dental implantology.

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Diabetes and Its Relationship to Oral Health

Diabetes Today…

- DM is the **7th** leading cause of death in the U.S.
- Average loss of **13** years of life
- Leading cause of death with DM is MI and Stroke
- DM is the leading cause of New Blindness
- DM is the leading cause of End Stage Renal Disease
- DM is a leading cause of Disability in the U.S.

Cost of Diabetes in USA

- Over 345 Billion Dollars yearly:
- 75 Billion is Loss of Productivity
- Represents over 35% of all Medicare expenditure

- The increased prevalence of DM is the #1 factor in the increased cost of Medicare
- **86,000,000** people in the US are Pre-Diabetic = increased risk of DM and Cardiovascular Disease. Many will become Diabetics within 10 yrs.

Highest disease correlation with:

BLOOD PRESSURE
DANGER
GET HELP
ELEVATED
NORMAL

- ***Hypertension***

Leading Causes of Death: 2017

1) Heart disease (MI,CA,CHF)
2) Cancer (malignant neoplasms)
3) Chronic Respiratory disease
4) Accidents (unintentional injuries)
5) Stroke (cerebrovascular diseases)
6) Alzheimer's disease
7) Diabetes
8) Influenza and pneumonia
9) Kidney disease
10) Suicide

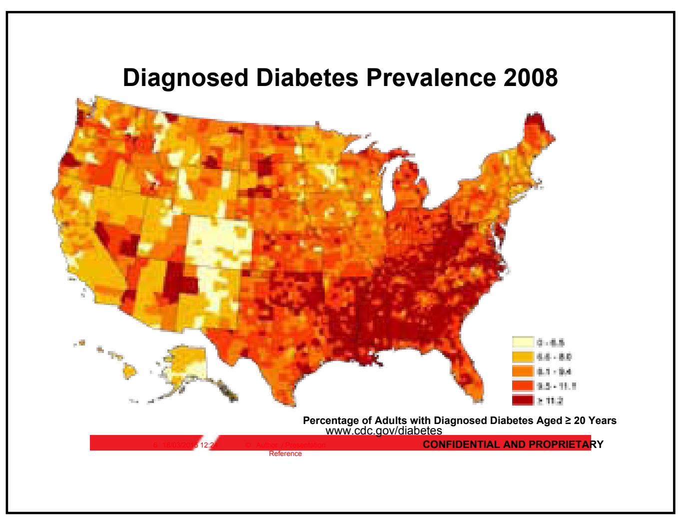
Diagnosed Diabetes Prevalence 2004

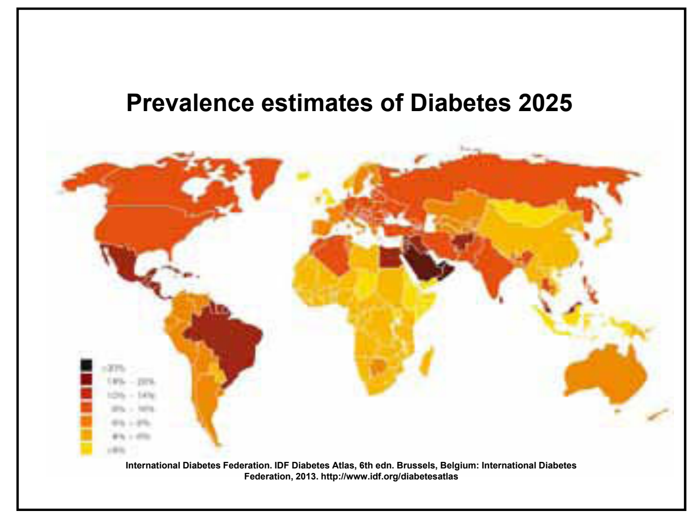
0 - 6.5
6.6 - 8.0
8.1 - 9.4
9.5 - 11.1
≥ 11.2

Percentage of Adults with Diagnosed Diabetes Aged ≥ 20 Years

CONFIDENTIAL AND PROPRIETARY

Diagnosed Diabetes Prevalence 2008



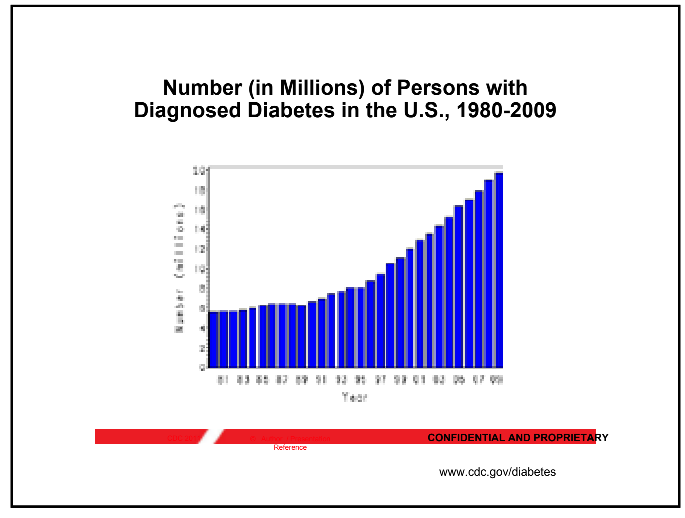


Dr. Kelly West = leading authority on Diabetes Epidemiology — states the **"DM has now killed more people in the 20th Century than all the Wars combined"**

DM is now classified (WHO) as a

- ***PANDEMIC***=A disease that is prevalent over a whole country or the world.

–**WHO projects that diabetes deaths will double between 2005 and 2030**



Type II Diabetes

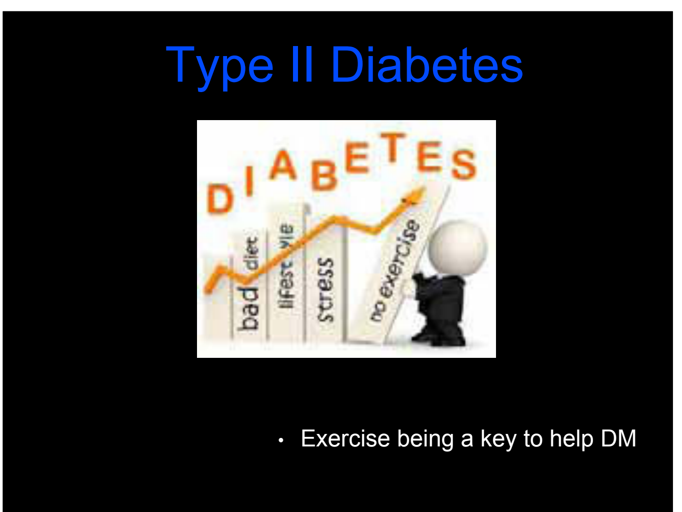
- This has always been associated with overweight and elderly, but now is becoming increasingly prevalent among obese adolescents.

Type II Diabetes

Metabolic Syndrome*

- HTN
- Hyperglycemia = > 100 fasting
- Excess Body Fat = > 40" waist in men and > 35" for women
- High Triglycerides = > 150
- Reduced LDL < 40 men, < 50 women

3 or more



Exercise produces:

- **Temporary Insulin receptors**…that will lower your glucose levels beyond what can be expected by just loosing weight. Also using **muscle will burn glucose more than other tissue** thereby further reducing glucose levels.

Hb A1c

- Hemoglobin A1c, also known as glycated or glycosolated hemoglobin, is a measure of the amount of glucose attached to red blood cells and directly relates to the average blood glucose levels over a period of 3 - 4 months (due to the life span of a RBC ~ 120 days*). **Patient fasting is not required prior to an A1c test. The last 30 days is more significant than 90-120 days ago.**

*Males = 117 days
Females = 106 days

What is A1c

- A 1% change in A1c represents a change of 35 mg/dl in average blood glucose.

A1c Levels…

- If below 7% = well controlled
- If between 7%-8% = moderately controlled
- If over 8% = poorly controlled
- A 1% change in A1c represents a change of 35 mg/dl in average blood glucose.

End Organs for Diabetes are:

- Eyes - Must be below 7 A1c
- Kidney - Must be below 7 A1c
- Cardiovascular - Must be below 6.5 A1c
- **Nerves: Neuropathy Must be below 7 A1c**
- **(PD) Periodontal Disease**

Perio Disease and DM

- The relationship between the two is considered: **"Bi-directional"**
- It is now considered the 6th complication of DM

DM and Periodontal Disease
BDJ Vol 217;433-437;Oct 24 2014

Insulin and DM History:

- 1921 - Insulin was purified and isolated by Frederick Banting and Charles Best from U. of Toronto, Canada.
- August and Marie Krogh - first time Insulin is used on a patient is in Copenhagen in 1923.
- Longer acting Insulin **(NPH)** was made available in 1946 which was a major breakthrough. Hans Christian Hagedorn.*
- NPH is considered the #1 drug needed in a Health System by the WHO

* They form the company
Novo Nordisk

Dr. Priscilla White

- In 1924, White was recruited by Dr. Elliott Joslin to work at the Joslin Clinic at the New England Deaconness Hospital.
- In 1936 Dr. White worked with Dr. Hans Christian Hagadorn and developed PZI (Protamine Zinc Insulin) allowing lower Blood Glucose levels to be maintained up to 24hours. This later became NPH.
- At the start of her career at the Joslin Center the fetal survival rate for diabetic mothers was 54%.

Dr. Priscilla White

- Classification of Diabetes in Pregnancy was her major contribution along with treatment recommendations - based on:
  1) Age of onset of the Diabetes
  2) Duration of the Diabetes and
  3) Presence of Atherosclerotic Disease and
  4) Renal Complications
- Class A - F with different Fetal Survival % in each Class - For example: "B" as T2DM starting over the age of 20 and "D" as age onset under 10 with HTN and "F" as DM with Nephropathy.

Dr. Priscilla White

- In 1968 she added Retinopathy to the criteria.
- This all led to a predictive course for treatment for the diabetic mother.
- She implemented the technique of delivering infants of diabetic women early.
- This brought order to the previously confused literature in the field along with the eventual outcome of a 97% fetal survival rate the year she retired from Joslin, (1975).

Correlated with high CRP

- DM patients have heightened CRP (major inflammatory indicator)
- When pre-treatment CRP is high
- After Perio Treatment and Full Mouth Prophylaxis the CRP can be lowered
- -Loss, J. of Perio, 2000
  -D'Aiuto, J of Dental Research, 2004

Periodontal Changes:

- "Evidence suggests that periodontal changes may be one of the first clinical manifestation of diabetes"
- Lamster, Lalla, **JADA,** Vol 139, Supp 5, Oct **2008** pp19-24
- Since >33% of patients with DM don't know they have it
- More people see their DDS/yr vs. their MD/yr

"Inflammation is a key in the initiation and progression of atherosclerosis"

Arbab-Zadeh, A., Nakano, M., Virmani, R., & Fuster, V. (2012). Acute coronary events. Circulation, 125(9), 1147-1156.

Inflammation has associated elevated levels of:

- Tumor Necrosis Factor-alpha (TNF-alpha)
- Interleukin (IL)-6, IL-1B
- Prostaglandin E2
- C-Reactive Protein (CRP)

Periodontal Disease

- ***Chronic Inflammation*** with bacterial biofilm
- Leads to deep pockets and alveolar bone loss that supports anaerobic flora

Physiologic Chances

- Neutrophils not effective in adherence to Gm - Anaerobes*
- Macrophages will release increased levels of Cytokines like Prostaglandin E2 which increases the production of Collagenase leading to the breakdown of Collagen
- Osteoclastic Activity increases

*Bacteroides, Fusobacterium,

Dr. Marjorie Jeffcoat publication

- American Journal of Preventive Medicine 2014;47(2):166-174
- **"Impact of Periodontal Therapy on General Health"**
- Insurance Claim Date from 338,891 individuals with both Medical and Dental Insurance.

Total patients in study=338,891 of which 112,707 Patients had PD and DM, CVD and/or CAD

Jeffcoat, M. K., et. al. (2014). Impact of Periodontal Therapy on General Health: Evidence from Insurance Data for Five Systemic Conditions. Am J Prev Med. 47(2):166–174

Periodontal Therapy (PD) significantly decreases health care costs in Diabetic and CVD patients:

Evidence indicates that PD is associated with adverse health consequences in diabetics, patients with cerebrovascular disease and cardiovascular disease

Jeffcoat, M. K., et. al. (2014). Impact of Periodontal Therapy on General Health: Evidence from Insurance Data for Five Systemic Conditions. Am J Prev Med. 47(2):166–174

55% male, mean age 48.7

- Grouped into co-morbid conditions and then separated into
- **PD treatment** and no treatment, completed before tabulation of costs for medical treatment

PD treatment = 4 visits during the year 2005*

***This consisted of cleanings, some flap surgeries and mainly scaling and root planning (S & R) treatments**

Jeffcoat, M. K., et. al. (2014). Impact of Periodontal Therapy on General Health: Evidence from Insurance Data for Five Systemic Conditions. Am J Prev Med. 47(2):166–174

- **Primary Outcome**=All medical costs during the years 2006-2009 (Office Visits, Hospital visits, Drugs)
- **Secondary Outcome**=Yearly Hospitalization/1000 patients in years 2006-2009

Jeffcoat, M. K., et. al. (2014). Impact of Periodontal Therapy on General Health: Evidence from Insurance Data for Five Systemic Conditions. Am J Prev Med. 47(2):166–174

Results: Reduced Costs for Patients Treated with PD:

- **Diabetes (T2DM) = reductions of 40.2%**
- Cerebral Vascular Disease = reductions of 40.9%
- Coronary Artery Disease = reductions of 10.7%
- *Pregnancy = reductions of 73.7%*

Jeffcoat, M. K., et. al. (2014). Impact of Periodontal Therapy on General Health: Evidence from Insurance Data for Five Systemic Conditions. Am J Prev Med. 47(2):166–174

Results: Reduced Hospitalization for Patients Treated with PD

- **39.4% reduction for patients with T2DM**
- 28.6% reduction for patients with CAD
- 21.2% reduction for (CVD) Cerebral Vascular Disease

Jeffcoat, M. K., et. al. (2014). Impact of Periodontal Therapy on General Health: Evidence from Insurance Data for Five Systemic Conditions. Am J Prev Med. 47(2):166–174

Pre-Diabetic state

- Many pre-diabetics are already susceptible to "diabetic conditions". **The Maastricht Study*** (Netherlands)
- ***"Microvascular dysfunction precedes and may therefore contribute to T2DM-associated CVD and other complications,"***

*Circulation. 2016;134:1339-1352. DOI: 10.1161/CIRCULATIONAHA. 116.023446

Pre-Diabetic state

- With the association of: **impaired protein synthesis** and **lowered ability to fight infection** along with a **poorer healing response***, the incidence of Periodontal Disease and other Dental complications associated with diabetes **can occur years before the full expressions of the disease.**

*Unusually poor healing after a simple extraction or periodontal procedure = > IOS

A1c in-office*

- **To Identify patients at high risk for DM and Pre-DM in patients who are not aware of a diagnosis of DM or Pre DM**
- **To follow-up with a Medical Referral**

The ADA suggests that **all adults** who are overweight or obese be tested, along with anyone who has one or more risk factors for diabetes, such as **high blood pressure** or close family members who have diabetes. **At age 45**, all adults should be screened for prediabetes or diabetes, according to the ADA.

Depending on the result:

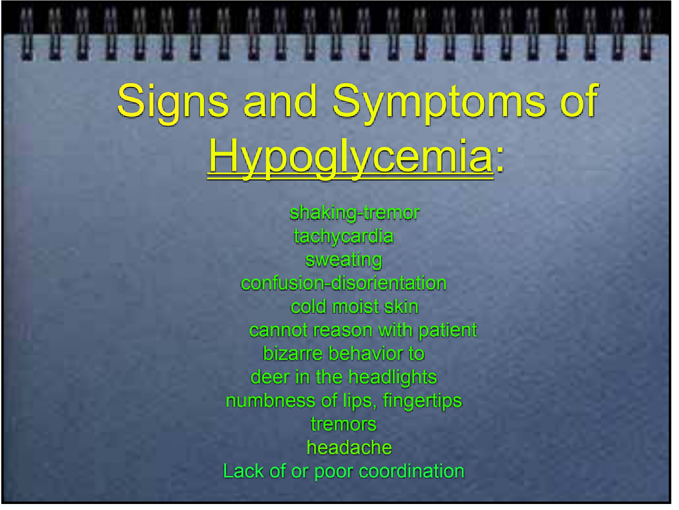
- If an A1c of 6.5% or over - some "enhanced benefit plans" cover "extra" prophylaxis for patients with Diabetes.
- "As necessary for appropriate care" not a number of visits. Could cover up to 6 visits a year for maintenance recall.

Diabetes

- It is no longer a Cardiac Risk Factor it is now a
- Coronary Artery Disease Equavalent
- Up to 10.5%* of U.S. Population of 327 Mill (was 5% just 25 years ago).
- Another 86+ Million are Pre-Diabetic making almost 1/3 of the U.S. Population as Diabetic or Pre-Diabetic.
- Population over 60 = 30% have Type II DM
- 1/3 (33%) are not Dx or treated = 10+ Million - early Dx can lead to a significantly improved life *just updated as of 2/16/17

Joslin Center has shown

- That patients with Diabetes are much more controlled when they have a strict Oral Hygiene regimen
- Frequent visits to the Dentist/Hygienist (every 12 weeks) has been shown to decrease the overall health cost for the complications of Diabetes



Diabetic Patients on Beta Blockers:

Patients who have Diabetes and are also on B Blockers will not necessarily show the shaking and tachycardia and sweating, as the Beta blockers will prevent this and these patients may develop altered consciousness or loss of consciousness without prior warning.

In Our Elderly Population

- UTI is a frequent sign for Altered Consciousness - especially true if the patient is a female Diabetic
- Range is from Confusion to Agitation to Hallucinations to LOC

Hypoglycemia Unawareness

- Patients who have had DM for a long time (especially with frequent Hypoglycemic episodes and/or are on B Blockers) may lose the initial S & S's of Shaking, Tachycardia and Sweating may become…
- Confused, go into Altered Consciousness (even LOC) and/or may have Convulsions* associated with hypoglycemia

Common B Blockers:

- - acebutolol (Sectral, brand discontinued)
- - atenolol (Tenormin)
- - betaxolol (Kerlone, brand discontinued)
- - bisoprolol (Cardicor, Emcor, Zebeta all brands discontinued)
- - metoprolol (Lopressor, Toprol XL)
- - nadolol (Corgard)
- - propranolol (Inderal LA, Inderal XL, Hemangeol, InnoPran XL)
- - timolol ophthalmic solution (Betimol, Istalol, Timoptic)

Causes of Hypoglycemia:

Missed or delayed meals
Excess insulin or oral hypoglycemics
Excessive exercise
Alcohol (with or without food)
Adrenal insufficiency
Other illnesses: hepatic, renal, cardiac failure, sepsis

8 Classes of Oral Meds for Diabetes

- **Alpha-glucosidase inhibitors:** blocks the action of alpha-glucosidase which breaks down carbs like starches and Sucrose to Glucose. *Acarbose* (***Precose***) and *Miglitol* (***Glyset***). This slows down digestion and so glucose passes into the bloodstream slowly and blood glucose levels stay lower after a meal. Side effect is **abdominal discomfort** from the undigested carbs. Often combined with other meds that can cause hypoglycemia ***Do not give sucrose (table sugar or candy) or OJ to correct that - will have little effect. So give Glucose (Dextrose) as tablets or a gel..***

Precose and Glyset

Hypoglycemia - Management

*Acarbose=Precose and Miglitol=Glycet

- For early, mild symptoms
  - Offer liquid glucose or fruit juices (not diet) are preferred - **Note: when on Alpha-glucosadase inhibitors* - to use Pure Glucose**

Hypoglycemia - Management

- For more severe symptoms such as severe drowsiness, convulsions or LOC
  - Glucogon IM, IN can be used = 1 mg for adults.

IV: one ampule IV glucose (50ml of 50% glucose solution)
Recheck blood glucose in 15 minutes

Low Blood Sugar <below 60-70 mg/dl

- Early signs: **Adrenergic Symptoms**
- Sweating and Shaking - then
- Tachycardia, Flushing of face
- Anxiety, Hunger

Very Low Blood Sugar below 40-50 mg/dl

- Late signs: **Neurologic symptoms**
- Headaches — Dizziness
- Numbness of fingers and around mouth
- Confusion
- Difficulty speaking
- Lack of coordination
  ——- LOC—-Seizures —— Coma ——Death

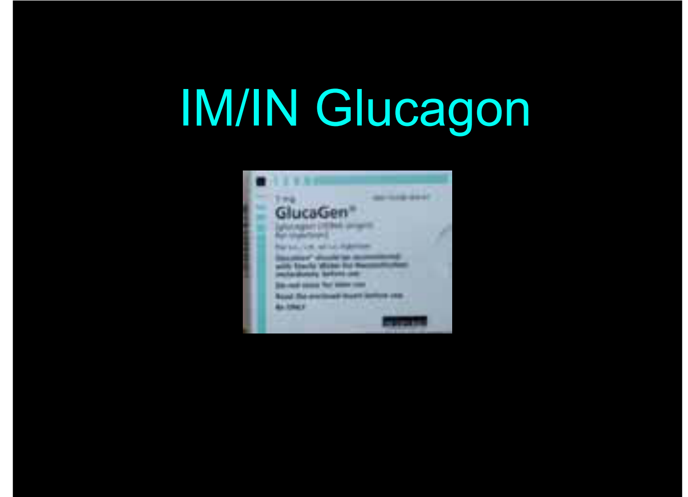
Glucometer in the Healthcare office

Blood glucose results are vital signs – you may save a patient's life!

What is a BSS?

- How do you treat someone with LOC from Hypoglycemia in a BSS?

IM/IN Glucagon



The 6 Complications are:

- **1) Cardiovascular Disease, especially CAD**
- **2) Delayed Wound Healing**
- **3) Diabetic Retinopathy**
  - A) Leading cause of new cases of blindness among adults ages 20 - 74.
  - B) Within 20 years of onset: 100% of Type I Diabetics & 60% of Type II Diabetics have some degree of **Diabetic Retinopathy**

The Maastricht Study

- Demonstrated that in Pre-diabetes there are microvascular changes associated with impaired function in the skin **and vascular impairment in the retina.**

*Circulation. 2016;134:1339-1352. DOI: 10.1161/CIRCULATIONAHA. 116.023446

The 6 Complications are:

- **4) Neuropathy: Altered sensation**

Complications: Nerve damage

- A) Nerve damage causes pain, numbness, tingling or loss of feeling, especially in the lower part of the body along with pain
- B) This numbness can cause injury without knowing it - especially on the lower extremities wounds and slow healing can lead to serious complications.
- C) Bladder dysfunction - leading to loss of sense of urgency, UTI's*

D) Loss of sensory perception for the pain of angina and pain of a Myocardial Infarction - **can lead to MI or UTI without usual S & S's**

E) Sexual Dysfunction

*UTI in elderly female DM patients as a frequent cause of A/C

The 6 Complications are:

- **5) Kidney disease (Diabetic Nephropathy)**
  - Nodular lesions in the glomerular capillaries impair blood flow leading to loss of kidney function **Leading to CKD**
  - Diabetes is the leading cause of End Stage Renal Disease

Link for modification of dosage and/or interval for Rx for patients with CKD

CKD generally become prevalent when eGFR falls below 60 mL/min/1.73 m2 (stage 3 CKD or greater)

http://www.aafp.org/afp/2007/0515/p1487.html#afp20070515p1487-t8

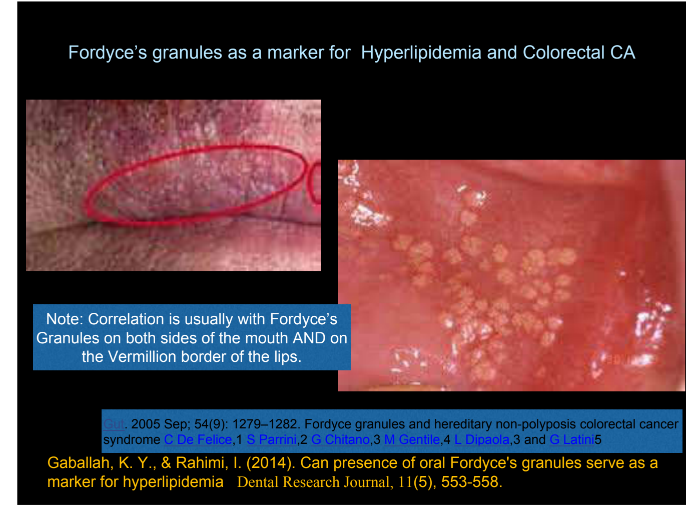
Oral Manifestations..

- 1) Periodontal Disease
- 2) Increased risk of Infections
- 3) Salivary Gland Dysfunction: Hypo-salivation
- 4) Geographic Tongue
- 5) Benign Migratory Glossitis
- 6) Fissured Tongue
- 8) Traumatic Ulcers
- 9) Angular Cheilitis
- 10) Alterations in Taste
- 11) Burning Mouth Syndrome
- 12) Parotid Gland Enlargement
- 13) Lichen Planus (Wickham Striae)

Diabetes – Potential Oral Complications

- Periodontal disease
- **Dental caries**
- **Salivary dysfunction / xerostomia**
- **Oral infections (eg. Candidiasis) Rx:**
- **Oral mucosal disorders:**
  - Burning mouth syndrome
  - Lichen planus
    - Pain management
    - Steroids (topical/systemic)

Fordyce's granules as a marker for Hyperlipidemia and Colorectal CA



Note: Correlation is usually with Fordyce's Granules on both sides of the mouth AND on the Vermillion border of the lips.

Gut. 2005 Sep; 54(9): 1279–1282. Fordyce granules and hereditary non-polyposis colorectal cancer syndrome C De Felice,1 S Parrini,2 G Chitano,3 M Gentile,4 L Dipaola,3 and G Latini5

Gaballah, K. Y., & Rahimi, I. (2014). Can presence of oral Fordyce's granules serve as a marker for hyperlipidemia Dental Research Journal, 11(5), 553-558.

Association of Systemic Conditions with Dental Implant Failure* (% Failure)

-6,358 patients followed from 1983 to 2014
-Study performed at the Mayo Clinic, Rochester, Minnesota, USA

Carr A., Revuru V., JOMI: Vol 32; Number 5, 2017

Diabetic Patients and Implants..

- All recent studies <u>**do not**</u> show a correlation with implant failure and DM Type 1 or Type II however:
- Consideration should be given to allowing a prolonged integration period before restoration to allow for healing

*Eskow CC, Oates TW: ClinImpDentRes:Dec.2016

Diabetic Patients and Implants..

- Consideration to be given to not placing immediate implants or immediately loading protocol
- One common finding with DM patients is an incidence of up to 27% Peri-implantitis*

Use of CGS can lower that to less than 3%, average is 10%

*Eskow CC, Oates TW: ClinImpDentRes:Dec.2016

Finding did show…

- *Presence of Coronary Artery Disease was associated with decreased implant failure*
- A Dx of Diabetes did NOT reduce survival rates for Implants.

Carr A Revuru V, JOMI:Vol 32; Number 5, 2017

JOMI:

Vol 32 Number 3, 2017

- *Efficacy of Local and Systemic Statin Delivery on the Osseointegration of Implants: A Systematic Review*
- Findings: "Results of 18 Studies showed that statin administration enhanced new bone formation around implants and bone/implant contact."

Statins today:

Include:

- Lovastatin (Mevacor)
- Pravastatin (Pravachol)
- Simvastatin (Zocor)
- Fluvastatin (Lescol)
- Atorvastatin (Lipitor)
- Pitivastatin (Livalo)
- Rosuvastatin (Crestor)

Finding did show w/r/t DM..

- Earlier failures and a higher % failure with Immediate Placed Implants and Immediate Loaded Implants than non DM patients.
- Finding of Peri-Implantitis up to 30% in DM patients.

Carr A Revuru V, JOMI:Vol 32; Number 5, 2017

Retrospective Analysis on Survival Rate and Prevalence of Peri-implantitis when using Computer Guided Surgery (Guided Implant Placement)*

- 10 Year follow up with 97.4% Success (694 Implants)
- Previous study with same authors at 7 years shows a 99.1% success rate with Guided Implant Placement**
- Additional finding - Peri-implantitis occurrence of 1.7% - 2.8% at 10 years.

*Tallarico, Meloni,JOMI:Vol 32, Number 5, 2017

**Tallarico,Meloni, JOralImpant,2016; 42:265-271

Medication induced Bone changes

- *PPI's (Proton Pump Inhibitors)
- *Anti Depressants (SSRI's) 11% of people in the U.S. take them = Lexapro, Prozac, Celexa, Zoloft, and Paxil will double the risk of fractures with side effect of Xerostomia plus direct effect on osseointegration
- *Calcium Channel Blockers
- *Statins
- *Immunosuppressants
- Birth Control Meds (DMPA)
- Steroids (for Asthma and COPD)

PPI (Proton Pump Inhibitors)…

- 3559 Implant placed:
- For PPI uses - failure was 12% vs.
- 4.5% failure for non users of PPI
- Hypothesis is that the reduced acidity in the stomach impairs calcium absorption

Chrcanovic, Kish, Albrektsson, JOMI:Vol 32; Number 5, 2017

Common PPI's:

- Nexium
- Protonix
- Prevacid
- Prilosec
- Dexilant
- Kapidex
- Zegerid

5HT-(Serotonin) binds to Htr1b in osteoblasts and inhibits **Creb** (Cyclic AMP response element binding protein) resulting in reduced osteoblast proliferation

Htr1b
Osteoblast
Serotonin
Creb
Decreased osteoblast proliferation
Bone

Calcium Channel Blockers

- Amlodipine (Norvasc)
- Diltiazem (Cardizem, Tiazac, others)
- Felodipine
- Isradipine
- Nicardipine
- Nifedipine (Adalat CC, Afeditab CR, Procardia)
- Nisoldipine (Sular)
- Verapamil (Calan, Verelan)

B Blockers, ACE Inhibitors and Angiotension II Receptor blockers all do not have an effect on mineralization

Major Risk Factors (% Failure)

*Immunosuppressives	13.5%
Bruxism	12.5%
*Proton Pump Inhibitors	12.0%
Smoking	11.6%
Implant length	10.0%
*Antidepressants (SSRI's)	9.3%

Chrcanovic, Kish, Albrektsson, JOMI:Vol 32; Number 5, 2017

Management Considerations for the Dental Patient with Diabetes

- Examinations
  - Collaboration with medical practitioner
    - Refer newly diagnosed patients with diabetes for oral assessment
- As of January 2018: New ADA code: D0411= HbA1c in-office point of service testing- with follow up Medical Referral
- Treatment considerations
  - Patients can respond with improved glycemic control with less complications

Dentists Role

- **Identify patients who are at risk for Diabetes** - Family history, Overweight, Hypertension, Ethnic background, Sedentary lifestyle.
- A1c testing in-office with ADA code: **and the appropriate Medical Referral for these patients.**
- As of January 2018: New ADA code: D0411
- Assist those who have Diabetes to control their A1c with ideal Periodontal Treatment and Maintenance.
- The effect of good oral hygiene and Perio treatment can be equal to not taking an additional medication.

An ideal Periodontal and Maintenance Program

- Can reduce the A1c level by 0.4%* - this can be equal to loosing 20+ lbs and/or reducing the need for an additional medication.

Oral Health is essential to an individuals general health and quality of life.

- ***The United Nations in 2011 recognized that Oral Disease is an integral part of non-communicable diseases.***
- ***Periodontal Disease treatment can impact overall health care costs and hospitalization in a positive manner.***

Glick, M., & Meyer, D. M. (2014). Defining oral health: A prerequisite for any health policy. The Journal of the American Dental Association, 145(6), 519-520.

SELF EVALUATION

Diabetes and Its Relationship to Oral Health

1. T/F - 90% of individuals who are pre-diabetic and 33% of Diabetics in the U.S. do not know of their diagnosis.
2. T/F - Most people who have Type I DM know of a family relative with the disease and just 10% of people with Type II DM have a parent or sibling with Type II DM.
3. The most likely association and/or co-morbidities identifying undiagnosed Diabetics Type II would be:
   a. Hypertension
   b. BMI approaching 30 or over
   c. High Triglycerides
   d. Family history of Diabetes
   e. B and D
4. What are the leading causes of death in Diabetic patients?
   a. Myocardial Infarction
   b. Stroke
   c. Cancer
   d. End Stage Renal Disease
   e. All of the above
   f. A and B
5. T/F - Pre-diabetes is often associated clinically with early Periodontal Disease.
6. T/F - The American Diabetes Association (ADA) is now recommending that physicians consider beginning Aspirin Therapy in women over age 50.
7. Diabetics with Renal Disease having a GFR of 60 should have;
   a. daily urinalysis testing
   b. altered doses and/or intervals for prescribed drugs
   c. stress test performed yearly
   d. always have an Insulin pump
8. T/F - Since 1997, the number of people diagnosed with diabetes has increased considerably, rising from 5 percent of Americans to more than 10.5 percent today (2018)
9. Periodontal treatment (conventional non-surgical periodontal therapy) has been associated with improvements in glycemic control in diabetic patients, with reductions in HbA1c of up to-
   a. 0.1%
   b. 0.2%
   c. 0.3%
   d. 0.4%
10. Females and females with Diabetes may experience atypical signs and symptoms with an Acute Myocardial Infarction (AMI)
    a. Unusual fatigue
    b. Acute shortness of breath
    c. Elevated Blood Sugar
    d. No chest pain at all
    e. All of the above

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

Josh Umbehr, MD

Josh Umbehr, MD, of Wichita, Kansas, is a practicing, board-certified family physician. He is the founder and principal of Atlas MD a medical practice utilizing a direct patient care model, a subject on which Dr. Umbehr is a nationally recognized thought leader and presenter having spoken and testified numerous times across the country.

You may contact Dr. Umbehr with your questions and comments at (316) 734-8096, or by email at DrJosh@Atlas.MD.

Starting and Growing a Direct Patient Care Practice
Josh Umbehr, MD

Direct Patient Care Checklist

- **1. Name**
  - ☐ Pick a business name
  - ☐ Check name availability through your state's website > business center > business entity formation
  - ☐ Domain - Enom, Godaddy, Max.d
  - ☐ Domain specific emails - Outlook, Gmail or Other See attached files...
  - ☐ Website - Entermotion, Empoweredmds or Other See attached files...
  - ☐ Social Media - Facebook and Twitter - make sure all info and settings are complete

- **2. Accountant**
  - ☐ Use ours - Reid Hash 785-272-4484 OR r.hash@ssccpas.com
  - ☐ Find Local

- **3. Lawyer**
  - ☐ Use ours - Luanne Leeds See attached files...
  - ☐ Find Local
  - ☐ Create Patient Agreement
  - ☐ Create Privacy Policy >> https://termsfeed.com/privacy-policy/generator/?utm_expid=97203325-254.cWlbs1lcQzO_5W3XmaVodA.0&utm_referrer=https%3A%2F%2Ftermsfeed.com%2Findex2

- **4. ESTABLISH BUSINESS ENTITY**
  - ☐ a. Become certified with your State Medical Board http://www.fsmb.org/state-medical-boards/contacts
  - ☐ Check state regulation if CLIA certification is required > http://www.kdheks.gov/lipo/clia_survey_and_cert.htm
  - ☐ b. Apply for business structure LLC vs PLLC vs S Corp vs C Corp
  - ☐ c. Apply for Federal Tax ID
  - ☐ d. Apply for State ID
  - ☐ Consider completing a small business workshop. Our local college offers a 4 week course for $75. Show the bank a certificate of completion of that course to lower your risk and get better rates, etc.

Direct Patient Care Checklist

- 5. Insurance Contracts
  - ☐ Cancel Medicare See attached files...
  - ☐ Cancel Private Plans
- 6. Location
  - ☐ Rent, own or lease
  - ☐ Add yourself to www.iamdirectcare.com and iwantdirectcare.com maps
- 7. Coversion
  - ☐ Determine Schedule - 4/8/12 week timeline
  - ☐ Letters - 1st, 2nd, 3rd See attached files...
  - ☐ Town Halls - Timing, set up, cost
- 8. Marketing
  - ☐ Word of Mouth
  - ☐ Flyers See attached files...
  - ☐ Radio
  - ☐ Facebook - check the "services" tab to publish specific posts for visitors
  - ☐ Twitter - tips for beginners https://medium.com/@buffer/twitter-tips-for-beginners-everything-i-wish-i-knew-about-twitter-when-i-started-a716e70276c
  - ☐ Press release about the launch of your DPC practice http://www.bizjournals.com/wichita/blog/2014/12/atlas-md-adding-second-wichita-location.html
  - ☐ Sample Press Release See attached files...
  - ☐ Meet with local SHRM - society of human resource management http://goo.gl/pGtbn2
  - ☐ Find retiring physicians See attached files...
- 9. Pricing Structure for Patients
  - ☐ Age Based - Set ages
  - ☐ Not Age Based - set prices
  - ☐ Patient Enrollment form See attached files...
  - ☐ Release of Records See attached files...
  - ☐ Patient History Form See attached files...

- **10. Medications**
  - ☐ Set up andameds.com account See attached files...
  - ☐ Pill counter from rxcount.com
  - ☐ Order bottles/lids
  - ☐ Labels
  - ☐ Printers - Dymo See attached files...
  - ☐ Shipping Bags
  - ☐ Pharmacy bags - custom or generic
  - ☐ Inventory See attached files...
  - ☐ Script Paper See attached files...
- **11. Medical Supplies**
  - ☐ Andameds See attached files...
  - ☐ Other Reps
  - ☐ IRS Eligible Medical Expenses See attached files...
  - ☐ Cheap insulin/steroid inhalers See attached files...
  - ☐ Cheap othro glass https://goo.gl/omd5Q3
- **12. Labs**
  - ☐ Labcorp
  - ☐ Quest See attached files...
  - ☐ Local
- **13. Imaging and X-Rays**
  - ☐ Imaging Prices See attached files...
  - ☐ X-Ray Prices See attached files...
- **14. Radiology**
  - ☐ Use our prices to find local deals
- **15. Pathology**
  - ☐ Use our prices to find local deals
- **16. Staff**
  - ☐ No staff
  - ☐ Small Staff - RN or LPN or MA

- **17. Office Management**
  - ☐ OSHA www.stericycle.com
  - ☐ Hipaa www.stericycle.com
  - ☐ Bio hazard waste removal www.stericycle.com
  - ☐ Bookkeeper/HR/payroll - Quickbooks, freshbooks, Xero See attached files...
  - ☐ Employee Benefits - medical, dental, vision, life, disability, retirement
  - ☐ Credit Card Billing Auth See attached files...
- **18. Office Based Technology**
  - ☐ Mobile - iOS or Android
  - ☐ Office Computers See attached files...
  - ☐ Printers for Office
  - ☐ Printers for RX labels, lab labels, shipping
  - ☐ Create RingCentral account for efax http://refer.ringcentral.com/USCA/accept-prospect/?EID=6e405a8f-dfea-4fd5-bf30-f91d69e94f71&type=ShareUrl
  - ☐ Create Dropbox account > link to emr
    - DeleteEdit

  ☐ Add digital signature to Adobe for easy electronic signing of documents

  Unassigned
  - ☐ Phones - Standard line OR ringcentral OR grasshopper VOIP type
  - ☐ Greeting cards - http://emilymcdowell.com
- **19. Master Checklist**
  - ☐ DPC Practice See attached files...

Direct Patient Care Practice Checklist				
Waiting Room	**Doctors Rooms**	**Pharmacy**	**Lab**	**Office**
Furniture	Exam Table	Pill Counter	Urinalysis Machine	Xerox Machine
Trash Can	Tissue Paper Rolls	Rx Bottles	Urine Dip Sticks	Dymo 4X6
Music	Speculums	Dymo Printer	Autoclave	Dymo 4X6
Coffee Machine	Chucks	4X2 Dymo Labels	Autoclave Bags	Mail Scale
Coffee Cups	Furniture	Rx Cabinet	Bacterial Test Kit	Trashcan
Ipads	Cotton Balls	Poly Mailer Bags	Clia-Waived Tests	Phones
Art Work	Alcohol Pads	Drug Store Rx Bags	1Cc Syringe	Interet
Blinds	Tongue Depressors	Www.Practrx.Com Account	3Cc Syringe	Free Wifi
Sink	Ear Cannulas	Rx Basins	10Cc Syringe	Secure Wifi
Trash Bags	Ky Lube		18 G Needle 1”	Money Box
Magazines	Kleenex		18 G Needle 1.5”	Secure Rx Paper
Kleenex	Paper Towels		22 G Needle 1.5	Paper
Paper Towels	Sink		25 G Needle 1.5”	Stationary - Letter Head
Coffee Cup Sleeves	Clean Wipes		31 G Needle 1”	Stationary - Envelopes
Sweet & Low	Bandaids		4X4 Gauze	
Creamer	Otoscope		Alcohol Pads	
Sugar	Opthalmoscope		Iodine Pads	
Straws	Emesis Basins		Trash	
Coffee Table	Trash		Biohazard Trash	
	Biohazard Trash		Sharps Container	
	Soap Dispenser		Suture	
	Coat Rack		Scapels	
	Art Work		Ear Wash Kit	
	Iodine Pads		Eye Wash Attachment For Facuet	
	Sharps Container		Cleaning Supplies	
	Ekg Pads		Surgical Tools	
	Gowns		Electrocautery	
	Stethoscopes		Microscope	
	Baby Plankets		Glass Slides	
	Baby Scale		Refrigerator	
	Head Circumference		Refrigerator Thermometer	
	Eye Chart		Refrigerator Thermometer	
	Scale		Punch Biopsies	
	Height		Lidocaine	
	Vitals Machine		Lidocaine With Epi	
	Morgan Lens Kit		Iv Fluid	
			Iv Supplies	
			Urine Containers	
			Emesis Basins	
			Spill Powder	
			Osha Labels	
			Msds Sheets	
			Woods Lamp	
			Protest Biological Test - Autoclave	

Direct Patient Care Practice Checklist				
Break Room	**Procedures**	**Compliance**	**Dme**	**Business**
Osha Signs	Ekg	Osha	Crutches	Accountant
Refrigerator	Spirometry	Hipaa	Post Op Shoes	Payroll
Table	Urinalysis	Fire Plan	Cam Walkers	Hr
Chairs	Clia-Waived Tests	Fire Extinquishers	Cock Up Wrist Splints	Vacation Days
Cups	Cautery	Crash Cart	Rib Belt	Holidays
Plates	Ultrasound	Defibrilator	Knee Immobilizer	Rent
Silverware	Ultrasound Gel	Wheelchair	Shouler Slings	Utilities
Wire Shelves		Policies & Procedures	Ace Wraps	Quaterly Taxes
		Laundry Service	Kurlex	
		Biohazard Service	Speculums	
			Speculum Lights	
			Biohazard Bags	
			Trash Bags	

Direct Patient Care Practice Clinical Forms			
Membership Forms	Marketing	Website	Clinical
Agreement	Flyers	Online Enrollment	Pdq-9
CMS Waiver	Price List	Faq	Adhd Screen
HIPAA Waiver	Business Cards	Hours	Epworth Sleepiness Scale
Release Of Records	Letterhead	Price	
CC Billing Auth	Envelopes	Doctor Bio	
Pt Hx Form		Directions	
		Mobile Friendly	

IWantDirectCare survey

Direct Care is a retainer-based, insurance-free primary care model that's actually affordable and actually effective. Help us gauge the local demand for direct care by completing our survey.

PLEASE INDICATE IF YOU AGREE OR DISAGREE WITH THE FOLLOWING STATEMENTS

[SD: strongly disagree, D: disagree, N: neutral, A: agree, SA]

Statement	SD	D	N	A	SA
+ I will ignore a pressing medical issue to save money.	○	○	○	○	○
+ I will avoid follow-up visits with a physician to save money.	○	○	○	○	○
+ I have had trouble scheduling an appointment with a provider when it was urgent.	○	○	○	○	○
+ I am satisfied with my current healthcare plan.	○	○	○	○	○
+ I understand what I am paying for when I receive a medical bill.	○	○	○	○	○
+ I have experienced "sticker shock" after reviewing my medical bill.	○	○	○	○	○
+ Last year, I clearly recall meeting my health insurance deductible.	○	○	○	○	○
+ I understand my current health insurance plan (i.e. deductibles, copays, in-network vs. out-of-network costs, etc.)	○	○	○	○	○
+ The media is fairly covering stories of cash-only doctors (Direct Care, Concierge Medicine, etc.)	○	○	○	○	○
+ I would like to lower my monthly health insurance premium.	○	○	○	○	○
+ I would pay upfront for unlimited, 24/7 access to a qualified physician with $0 copays.	○	○	○	○	○
+ I would buy wholesale prescriptions out-of-pocket if the prices were lower than my copay.	○	○	○	○	○
+ I would pay a yearly fee for access to a personal physician who would handle my non-life-threatening ER/Urgent Care needs.	○	○	○	○	○
+ I would like it if a doctor could negotiate steep discounts on services like MRIs and CT-Scans.	○	○	○	○	○
+ I want to know what I'm actually paying for when I receive a medical bill.	○	○	○	○	○
+ I would gladly consult a doctor in lieu of scheduling a full appointment.	○	○	○	○	○
+ I would like to text my family doctor if I have questions regarding a recent diagnosis and treatment.	○	○	○	○	○
+ I am familiar with "wrap-around" insurance plans (also called "catastrophic care" plans)	○	○	○	○	○
+ I understand the difference between concierge medicine and Direct Care.	○	○	○	○	○
+ I am interested in learning more about the Direct Care model of primary care.	○	○	○	○	○
+ I know how to find practitioners offering Direct Care services.	○	○	○	○	○

THANKS FOR COMPLETING THE SURVEY!

By cutting out the insurance middleman, doctors can skip the bureaucracy and spend time caring for patients. And patients can lower their overall medical expenses by paying only for what they need. However, it'll take ingenious doctors and smart patients to turn common sense into the status quo for primary care.

SELF EVALUATION

Starting and Growing a Direct Patient Care Practice

True/False

1. Direct primary care has bipartisan support.

2. Insurance companies are very supportive of the insurance free model.

3. I can't afford my insurance PLUS a DPC membership.

4. The best way to grow quickly is to have a large marketing campaign.

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