

THE
2026-27

Medical-Dental-Legal UPDATE

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



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David R. Victor, JD
CEO

Dear Registrant:

You practice in a dynamic and challenging environment. While keeping clinically current is imperative, it is not enough. You must also develop the skills to manage legal risk, safeguard your professional and personal assets, and adapt to rapid advances in healthcare knowledge and technology. ***The 2026–27 Medical-Dental-Legal Update*** has been designed to assist you in this endeavor.

In a single program you will receive 20 hours of timely instruction from nationally recognized experts in medicine, law, healthcare leadership, public health, finance, and practice management. Their lectures cover a broad array of topics, including updates in chronic disease management, neurologic and metabolic disorders, mental health, and preventive care. You will also hear presentations on emerging pharmacologic therapies, obesity and lifestyle medicine, and the long-term impact of physical activity on health. Beyond the clinical content, the program provides practical insight into malpractice risk, asset protection, practice performance, and the evolving role of artificial intelligence in healthcare. Additional discussions address leadership, public health, and key considerations in today's changing practice environment.

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

As always, I am very interested in your reaction to this year's lecture series. Please take the time to complete the evaluation questions presented on screen for each presentation, and feel free to contact our faculty directly with questions or comments.

Finally, I urge you to take advantage of the diversity of professionals enrolled this week. Your colleagues include physicians, dentists, and attorneys. What better way to broaden your perspective on these multi-faceted issues than to discuss them in real time with participants from different disciplines.

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

Cordially,

AMERICAN EDUCATIONAL INSTITUTE, INC

David R. Victor, Esq
Chief Executive Officer

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Medical-Dental-Legal UPDATE

COURSE OBJECTIVES



After completing *The 2026-27 Medical-Dental-Legal-Update* you should have acquired the knowledge that will better enable you to better:

- Identify key strategies for **managing complex patient interactions** in to improve outcomes and reduce physician stress.
- Recognize the stages of **medical malpractice litigation** and develop strategies to manage risk, documentation, and personal stress during the legal process.
- Understand the pathophysiology, diagnosis, and treatment of **thiamine deficiency** across neurologic and systemic disorders.
- Identify legal strategies to **safeguard personal and business assets** against potential creditor claims.
- Learn to better incorporate updated diagnostic tools and treatment strategies for **Alzheimer's disease** into clinical practice.
- Understand current evidence-based strategies, including lifestyle interventions and pharmacologic therapies, to the **assessment and management of obesity** in clinical practice.
- Apply core ethical principles to the evaluation, deployment, and governance of **artificial intelligence in clinical care**.
- Enhance understanding of the role of **physical activity and cardiorespiratory fitness** in reducing mortality, improving health outcomes, and optimizing long-term disease prevention.
- Better understand how to Integrate validated tools and pharmacologic strategies to improve remission rates in major **depressive disorder**.
- Equip medical professionals with strategies to **safeguard assets, build sustainable wealth, and avoid common business and investment errors** that threaten long-term financial security
- Better understand the latest evidence-based strategies in **preventive cardiology and lifestyle medicine** to reduce cardiovascular disease risk and improve long-term health outcomes.
- Identify strategies for **optimizing revenue cycle management**.
- Apply updated evidence-based strategies to improve diagnosis and long-term **management of gout**.
- Understand the core responsibilities, leadership competencies, and system-level functions of the **Chief Medical Officer** in modern healthcare organizations.
- Understand what **radiologic imaging** to order and why.
- Understand the legal expectations, ethical considerations, and practical preparation required of physicians serving as **medical expert witnesses** or responding to subpoenas and depositions.
- Discuss the epidemiology, prevention and outbreak control of **communicable diseases**.
- Understand the process of transforming clinical observations into **research questions** and designing studies that advance evidence-based medicine.
- Understand the role of **circadian rhythm** in healthy sleep.
- Identify the pros and cons of **private equity practice acquisition**

All learning objectives above address IOM/ACGME core competencies.

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FACULTY DISCLOSURES



The individuals listed below have control over the content of *The 2026-27 Medical Dental Legal Update*. None of them have a financial relationship with an ineligible company.

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Neil Gokal, MD, FAAFP, faculty member, consultant for Exact Sciences.

All lectures presented by speaker with relevant financial relationships have been peer reviewed. All speakers with finance relationships have attested that clinical recommendations they make are evidence-based and free of commercial bias.

All relevant financial relationships have been mitigated prior to the start of this activity in accordance with the ACCME standards.

FACULTY

Louis Kuritzky, MD

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UPDATE

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Navigating Difficult Patient Encounters

Navigating Difficult Patient Encounters

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The Difficult Patient Encounter: Examples

- Drug seeking : Asks for excessive or inappropriate narcotics
- Time demanding : Always exceeds designated time allotment, then is hurt or angry when departure is required
- Seductive : Same or opposite gender
- Noncompliant

Kuritzky, L. Fam Prac Recert 1996;18:2

The Difficult Patient Encounter: Examples

- Self destructive : excess alcohol or tobacco use
- "Oh-by-the-way" patient
- Parent who insists upon accompanying adolescent child
- "Keep looking, I know there's something wrong with me"
- "You are the best and only doctor"

Kuritzky, L. Fam Prac Recert 1996;18:2

The Difficult Patient Encounter: Examples

- "None of these medicines work for my pain"
- A patient who abuses his or her child, spouse, or older family member
- Violent patient
- The family member of a deceased, critically ill, or injured patient
- "Can you do it over the phone?"

Kuritzky, L. Fam Prac Recert 1996;18:2

The Difficult Patient Encounter: Examples

- "Can you give me a work excuse for last week?"
- "I'm angry because you made me wait too long"
- "Could you see the other three little ones while we're here, since they all have the same thing"
- "I am a medical malpractice prosecution lawyer"

Kuritzky, L. Fam Prac Recert 1996;18:2

Difficult Patients: Definition

"Patients become 'problem patients' when they cross a limit that comes into conflict with the judgment, rules, boundaries, anticipated behavior, or expectations of the [clinician]."

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" Patient Care 2006;40(8):41-50

The Difficult Patient : Recognition

- “Difficult patients in whatever guise they present themselves can be consistently described as stressful to the clinician.”

Kuritzky, L. Fam. Prac. Recert 1996;18:2

Prevalence of Difficult Patient Encounters

According to the literature, the percent of visits which physicians describe as ‘difficult patients’ is

- a) <5%
- b) ±10%
- c) ±25%
- d) ±50%

Difficult Patients : How Common?

- “Some authors have suggested that physicians may find as many as 10% of pt interactions to be frustrating.”

THE CONSEQUENCE

- “In addition to the personal stress induced by such difficult relationships, experts believe them to be a significant, direct source of malpractice suits”

Kuritzky, L. Fam. Prac. Recert 1996;18:2

Difficult Patient Encounters : Why Bother?

- ↓ clinician self-confidence
- Disruption and ↓ productivity of involved encounter
- Disruption and ↓ productivity subsequent encounter(s)
- Disruption and ↓ quality dinner/recreation that PM
- Disrupted sleep
- Feelings of self-doubt, inadequacy, resentment

Difficult Patient Encounter: Why Bother?

Physician-Patient Communication

The Relationship With Malpractice Claims Among
Primary Care Physicians and Surgeons

Levinson W, Roter DL, Mullooly JP, et al JAMA 1997;277(7):553-559

Communication and Malpractice

- Objective: “To identify specific communication behaviors associated with malpractice history”
- Design: Comparison of communication behaviors of ‘claims’ vs ‘no-claims’ physicians using audiotapes of 10 routine office visits
- Participants: PCPs (n=59) divided ‘claims’ (≥ 2 lifetime) vs ‘no claims’

Levinson W, Roter DL, Mullooly JP, et al JAMA 1997;277(7):553-559

Communication and Malpractice: Results

"Significant differences in communication behaviors of no-claims and claims physicians were identified in primary care physicians...."

Levinson W, Roter DL, Mullooly JP, et al JAMA 1997;277(7):553-559

Office Interaction Skills of Physicians Who are SUED Less Often

Which of the following physician characteristics during an office visit has NOT been demonstrated to be associated with lower likelihood of lawsuits from patients

- a) Use of humor more often
- b) Use of more facilitation
- c) Use of more statements of orientation
- d) Expedient time utilization (less time spent)

"Compared with Claims PCPs, no-claims PCPS_____"

- Used more statements of orientation
- Used humor more
- Used more facilitation
- Spent more time

Levinson W, Roter DL, Mullooly JP, et al JAMA 1997;277(7):553-559

The No-Claims Advantages: Statements of Orientation

- "educating patients about what to expect and the flow of a visit"

Levinson W, Roter DL, Mullooly JP, et al JAMA 1997;277(7):553-559

The No-Claims Advantages: Humor

- "laughed and used humor more"

Levinson W, Roter DL, Mullooly JP, et al JAMA 1997;277(7):553-559

The No-Claims Advantages: "Tended to Use More Facilitation"

- Soliciting patients' opinions
- Checking understanding
- Encouraging patients to talk

Levinson W, Roter DL, Mullooly JP, et al JAMA 1997;277(7):553-559

The No-Claims Advantages: "Spent Longer..."

- 18.3 vs 15.0 minutes/routine visit

Levinson W, Roter DL, Mullooly JP, et al JAMA 1997;277(7):553-559

Difficult Patient Encounters: Agenda

- Mystery Man
- Percocetisha
- Chopped Liver
- Cleopatra
- Walter Mitty
- Barnacle Bill
- Time Traveler
- Dr. Twilight Zone
- Doorknob Dave

Mystery Man A 36 y.o. with Headache

- CC: headaches X 3 years
- Previous consultants:
 - 3 PCPs
 - 1 Headache specialist
 - 2 chiropractors
 - 1 acupuncturist
- Recent Imaging: Plain films, head CT (2), MRI

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Mystery Man A 36 y.o. with Headache

- Lab: aardvark antibodies-zebra toxin
- Dxs:
 - Tension headache
 - Depression
 - Anxiety
 - Fibromyalgia

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Mystery Man: A 36 y.o. with Headache MEDS in His Possession

- SSRI/SNRI (multiple)
- Carbamazepine
- Topiramate
- Valproic Acid
- Opioid Analgesics
- Riboflavin
- Triptans
- Feverfew
- Dilantin
- Acetaminophen

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Mystery Man The Ball is In Your Court

- Medications work initially, then lose effect
- Opioids for rescue: Lortab 750/500 $\pm$ 10/month
- In response to suggestion for counseling:
 - "This is NOT in my head!"

"What are you going to do now? If you had this burden, wouldn't you expect someone to do something about it?"

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Mystery Man The Problem from HIS Perspective

- It is YOUR responsibility to discover the undiscoverable
- Failure to find 'the answer' is your fault, or due to your inadequacy
- Entered clinical relationship with the EXPECTATION of magical total solution

"Look, I *KNOW* there's something wrong with me. Why can't you find it?"

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Mystery Man The Problem from YOUR Perspective

- I feel intellectually impotent (I *thought* I knew how to manage headache)
- The patient is unhappy with me
- I cannot please this patient
- He might bad-mouth me
- He might sue me
- I feel like I'm in a push-pull contest
- You believe: strong psychogenic component

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Mystery Man: The Solution The Map of his Headache Future

"Mystery Man, let's talk about where we are now. I am really sorry that you are still suffering with these headaches. You've seen many good doctors, and we've done a lot of lab investigation. Let's talk about our choices at this point. The way I see it, there are several possibilities."

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Mystery Man's Map: 1. Maybe I'm Not Smart Enough

"Maybe I'm not smart enough."

I say this because after looking over all the diagnostic possibilities that I know of, I don't see any additional disorders that might be appropriate to consider at this point. It does sometimes happen that 5 doctors will see a patient with a rash, and none of them will know what the rash is, but doctor number 6 will be smart enough to make the diagnosis. You have seen at least 5 doctors, and I can send you to see another, but the ones you have seen are all competent,

so is the problem that your doctors aren't smart enough? Possibly, but I don't think so.

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Mystery Man's Map: 2. Maybe We Haven't Done the Right Test?

"Maybe we haven't done the right test."

The team of clinicians who have provided care for you have looked into all of the disorders that they think might be reasonable causes of your symptoms. Is it possible that if we ordered more tests or did more imaging studies, we'd uncover something that will solve the problem?

Possibly, but I don't think so.

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Mystery Man's Map: 3. Maybe This is an Atypical Presentation?

"Maybe you have a disorder that is presenting in an atypical fashion, and we won't know until the 'typical part' emerges, what has been going on."

For instance, sometimes we see people with arthritis, and can't quite figure out why they have it. Later on--sometimes years later—they come down with psoriasis, and then we look back and say 'You know that arthritis you had years ago? That was probably related to this psoriasis—it must have been psoriatic arthritis' There was no way to easily distinguish psoriatic arthritis initially: we had to wait for the primary disorder to manifest itself. Is that a possibility in your case?

Well, it is possible,

But I don't think so.

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Mystery Man's Map: 4. Maybe You Have a New Disease

"Maybe you have a new disease.

The first people who had Legionnaire's disease, Lyme disease, or even HIV in the 1980s were quite a mystery, and until physicians saw a sufficient number of cases to sort the signs and symptoms into a new diagnosis, nobody really understood what they had.

Could you have a new disease? It's possible, but I don't think so."

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" Patient Care 2006;40(8):41-50

Mystery Man's Map: 5. Is This a Very Rare Serious Disorder?

"Could this be some very rare and serious disorder?

It is always wise to consider whether there is a serious underlying problem that is somehow being missed. I think you should be very reassured, even though you're still troubled with headaches, that all of our investigations have failed to show any sign of serious disorder. If a serious disorder was at hand, it would likely have progressed and made itself known by now. Of course, if new things start to happen, I want to know about it.

So could this be a hidden serious disorder?
It's possible, but I don't think so."

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" Patient Care 2006;40(8):41-50

Mystery Man's Map: 6. Is There an Emotional Component?

"Perhaps there is a much stronger emotional component to these symptoms than we are recognizing.

Certainly we see a number of people who, once depression, anxiety, or areas of conflict in their life are dealt with, tell us that neither we nor they had fully recognized the impact that the emotional disorder was having, until it was resolved.

Is this a possibility for you? Yes, that's a possibility for any of us who are bothered with symptoms for which we can't find another explanation."

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" Patient Care 2006;40(8):41-50

Mystery Man's Response to THE MAP

"So Doc, does this mean you're giving up on me?

CLINICIAN: Not at all, Mystery Man. Let's keep a close watch on these symptoms and I'll see you at regular intervals to keep monitoring for any of those possibilities we just talked about. Let's keep using those NSAIDs and opioids for 'rescue medication', since they do seem to help some, until we have any new information that might change our direction."

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" Patient Care 2006;40(8):41-50

Mystery Man Critical Elements of the Solution

- Advance plan: you're not 'blind-sided'
- Maybe I am not smart enough: nobody knows it all
- Credibility of care team is supported
- Further consultation possibility left open
- Open door: report new findings
- No serious disease
- Possibilities #1-5 NO, possibility #6 (emotional) YES

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" Patient Care 2006;40(8):41-50

Consequences of Opioid Withdrawal

A 32 y.o. new patient comes to your office requesting a refill of Percocet for her chronic LBP. She has received this medication (#120/month) from her specialist in another state for about 5 years. You do not wish to refill her Percocet. She says she has heard of patients dying from abrupt opioid discontinuation. Is she correct?

- a) Yes
- b) No

Percocetisha Chronic Low Back Pain

- **SCENARIO:** It is 4:45 PM Friday, Percocetisha is a 39 y.o. woman who has just moved from another state, and is seeing you for the first time
- **PMH:** MVA 12 years ago → chronic LBP
- **ROS:** LBP → disability. No regular physical activity. Physical therapy: tried it several years ago, "didn't help much"
- **PE:** No focal signs or neurologic deficit. SLR +, but irregular and hyperintense. Palpation → grimacing and pain (hyperintense)

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Percocetisha OPIOID-REQUIRING Low Back Pain

- **CLINICIAN:** What have you been doing for the back pain so far?
- **PERCOCETISHA:** "My doctor in Boston has been prescribing Percocet 10 mg 4 times a day. Usually that controls things pretty well. Nothing else works." She produces a recently filled prescription bottle.
- **ASSESSMENT:** Chronic LBP, no neuro deficit
- **PLAN:** RTC 2 weeks, Medical records request, NSAIDs, use remaining Percocet for 2 weeks

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Percocetisha How satisfied is she?

- **PERCOCETISHA:** "Well, I know that none of these other things work. Are you sure I shouldn't just get a refill of my Percocet?"
- **CLINICIAN:** "There should be enough Percocet left to last until your next visit in 2 weeks. I'd like to get your medical records and see how you're doing then."
- **PERCOCETISHA** (obviously disgruntled): "I know this won't work, but I'll give it a try..."

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Percocetisha Return Visit 2 weeks later

- **CLINICIAN:** "How are things with your back pain?"
- **PERCOCETISHA:** "Well, as long as I use the Percocet, I do OK. I tried that NSAID, and it didn't really do anything."
- **CLINICIAN:** "The records from your physician in Boston came in this week. Fortunately, the MRI and CT didn't show any signs of a serious back disorder, or anything requiring surgery. I'm sorry that the last NSAID we used didn't help. What I'd like to suggest is that we get you enrolled in a course of PT and try a different medication."

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Percocetisha Return Visit 2 weeks later

- **PERCOCETISHA:** (*Obviously annoyed*) "Another NSAID? Doctor, I've tried all of them, and they never work. My doctor in Boston is a back specialist [*translation: He is a much smarter, better, taller, richer, and wiser doctor than you*] and he thinks Percocet is the best thing for me. Why can't you just give me the only medicine that I know works to help my back?"

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Percocetisha: The PROBLEM

Percocetisha likely has a 'drug agenda'

- Disabled for years
- No return to work or activity
 - ? evidence that opioid → functional restoration
- LBP literature does NOT advocate for opioid analgesia in chronic LBP
- Dependency, Addiction or both?

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Percocetisha: Other Problems

- Don't want to discredit Boston physician
- Emotional tone of patient indicates at least disappointment, and possibly anger if opioid not Rx
- Although pt seems overly focused upon opioid, may be premature to diagnose substance abuse
- N Eng J Med: "...until further evidence has demonstrated that long-term narcotic use improves outcomes or functionality in sufferers of LBP, we do not advocate their long-term use.."
- When used, should opioid be rescue or maintenance?

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" Patient Care 2006;40(8):41-50

Percocetisha: Solution

- Validation
- Delineation of the Ethical Contract
- Redirection
- Restructured therapeutic plan

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" Patient Care 2006;40(8):41-50

Percocetisha: Solution

CLINICIAN: "Percocetisha, I am sorry that you continue to have back pain. It must be very trying to have had pain for such a long time.

My responsibility is to offer treatments that provide the best possible balance between improving your ability to function yet avoid adverse effects. The evidence on management of back pain shows That medicines like Percocet have not been proven to improve outcomes over the long term; my advice is that these medicines are used best as 'rescue' medication, not maintenance.

I know you've had NSAIDs that didn't work well for you, but there are some things you haven't yet tried. Most patients can find combinations of NSAIDs, muscle relaxants, and physical therapy that help."

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" Patient Care 2006;40(8):41-50

Percocetisha : Response A



"Well, Doctor, if you really think that's the best, I'm willing to give it a try."

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" Patient Care 2006;40(8):41-50

Percocetisha : Response B



"Look, if I had known that I couldn't get the one medicine that helps my pain, I would never have come here in the first place. How about at least giving me some Lortabs or some SOMA?"

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" Patient Care 2006;40(8):41-50

Percocetisha: Clinician Responses



A: "Good! Let's get started on your physical therapy program right away."



- B: "I'm sorry that we can't agree on the best treatment plan for you. I think you'll need to find a physician who feels differently about the best management of chronic back pain."

Critical Elements of the Solution

- Validation with empathic statement
- No element of distrust conveyed
- No suggestion of abuse, dependency, addiction (yet)
 - Substance users/abusers commonly experience rejection, distrust, dismissal
- No waffling (propoxyphene, codeine)
- Each clinician has the right and responsibility to use and interpret the clinical evidence

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Narcotics : What Role in Chronic LBP?

- Opioid > NSAID for pain relief short term
- Clinical trials: no activity improvement
- "Until further evidence of their safety and efficacy is available from clinical trials, we do not advocate the long-term use of opioids."

Deyo RA, Weinstein JN "Low Back Pain" *N Eng J Med* 2002;344(5):363-370

Chopped Liver

- SETTING: It's Monday morning. Chopped Liver has an appointment for 10:30 AM, and has called at 9:30 AM to confirm his appointment and find out whether things were running reasonably on time. At 9:30 AM, they were.

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Chopped Liver

- CLINICIAN: Good morning, Chop, how are you doing today?"
- Chopped Liver: "Doc, how do you think I could be doing today? I've been waiting over an hour, the parking meter ran out 15 minutes ago, and the last time I came here I waited for over an hour too. I wanted to get this mole removed today, but now who knows if I can make it back to the office in time for my noon meeting....[and so on]"

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Factors That Compound Patient Wait Time

- They don't feel well
- They're anxious about the diagnosis
- The exam room may be too cold
- The exam room may be unequipped with distracting entertainment (magazines, videos)
- Unflattering, cold, modesty-impairing gowns

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Factors That Compound Patient Wait Time

- Doctors' notoriety for making patients wait
- Doctors are at-risk for being considered mercenary because they drive nice cars and make a good salary:
 - "I guess this doctor schedules as many patients as he can, just to make as much money as possible"
 - "This doctor is just like the airlines: overbookings in case of cancellations"

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Factors That Compound Patient Wait Time

- "Maybe the doctor doesn't like me"
- "Maybe the doctor doesn't like my disease"
- "Maybe the doctor prefers patients who are better insured/younger/more upper-class/of a different ethnic group...."
- Maybe the doctor thinks my disease is less important than the others he is seeing today

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" Patient Care 2006;40(8):41-50

Factors That Compound Patient Wait Time

- "Maybe the doctor has forgotten me"
- "Maybe the doctor is visiting with a drug rep"
- "The doctor doesn't value my time the same way as he values his own"
- "If they knew he was running so late, why didn't they let me know!!"

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" Patient Care 2006;40(8):41-50

Patient Wait Time: Considerations

- Patients may not recognize that in every clinical day there is at least one unanticipated, unscheduled demand that requires our urgent attention.
- Even if they do, it may be worth reminding

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" Patient Care 2006;40(8):41-50

Chopped Liver Solution Richmond, Virginia 1971

- CLINICIAN: Hello, Chop. Before we get started with anything today, I want to apologize to you. I know you've had to wait a long time to be seen, and it's not much fun waiting in this cold room. I had only scheduled my regular number of patients but today I had a patient who emergently needed additional time *right now*. My contract with *all* of my patients is that if ever I learn they need my time right now, it is theirs. I want to thank you for allowing me that extra time by waiting for me. I hope you know that same time is there for you, too, if every you need it."

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" Patient Care 2006;40(8):41-50

Chopped Liver Solution: Critical Elements

- It's the TRUTH
- Office delay is most commonly due to unpredictable human need, rather than lack of consideration
- We respect your time, your illness, and you
- We are aware that you have waited and that waiting is not pleasant

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" Patient Care 2006;40(8):41-50

Chopped Liver Solution: Critical Elements

- We thank you for waiting
- Your need of our time is our highest priority
- Those who wait are supplying the time necessary for those who have demands of immediacy

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" Patient Care 2006;40(8):41-50

An Invitation to Dinner

Allison, a patient of yours for the last 3 years, is your last patient of the day. Her visit today is for renewal of a prescription for her well-controlled asthma. At the close of the visit, she asks if you will join her for dinner tonight. You should respond with

- A) I must decline because it is illegal
- B) I must decline because my wife wouldn't like it
- C) I must decline because that would compromise our therapeutic relationship
- D) Steak or Seafood?

Cleopatra

- **SCENARIO:** It is a Friday afternoon, and the last appointment of the day. Cleopatra has asked for the last appointment for each of her last 3 visits. She is coming in for f/u of migraine headaches, which have been recently treated (successfully) with a triptan. Cleopatra comes to the office dressed for a night on the town. She lingers on every word you utter. Many of her communications are embroidered by a gratuitous touch on your arm and a girlish smile.

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Cleopatra

- **CLINICIAN:** "OK, then, Ms. Ptolemy, it looks as if your migraine is under good control. Lets check back again with your next Pap test in 9 months."
- **CLEOPATRA:** "Oh, Doctor, please call me 'Cleo'"
- **CLINICIAN:** "OK, Cleo. Is there anything else you'd like to discuss before we finish?"
- **CLEOPATRA:** "Well there is one other thing, Doctor. I was hoping you'd go out to dinner with me tonight."

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Cleopatra

CLINICIAN:

"Well, uh....I mean...duh, gawrsh...I mean...well, I couldn't do...well, that just wouldn't be OK...well—perhaps you'd better just go out and schedule the next visit with Allison at the front desk...."

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Cleopatra: The Problem

- Whether you are 26 or 86, male or female, beautiful or not, it is likely that some patient(s) some time will find you attractive and want to pursue a personal relationship.
- Patients may be unaware of the 'rules' limiting intimate physician-patient relationships
- Patients may (temporarily) not care about the rules governing patient-physician relationships

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Cleopatra: The Problem

- Lack of advance preparation may catch you off-guard and → inelegant problem resolution
- We don't want to painfully reject Cleopatra
- We don't want to invite further breach of boundaries

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Cleopatra: Critical Elements of Successful Resolution

- Preparedness
- Acknowledgement
- Validation
- Identification and preservation of the Therapeutic Relationship

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Cleopatra: Successful Resolution

CLINICIAN: "Ms. Ptolemy, it is very kind of you to offer to join me for dinner [acknowledgment]. I appreciate your thoughtful invitation [validation]. My responsibility as a physician to every patient is to maintain a Therapeutic Relationship. If a doctor were to establish a personal relationship with a patient, that could compromise the Therapeutic one. I'm sure you understand how important it is to keep the a strong Therapeutic Relationship intact."

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Cleopatra: Successful Resolution

Responses to Avoid

- My wife/partner wouldn't like that (Does that mean I would?)
- My wife/partner wouldn't like that (...if I didn't have a partner, it would be OK?)
- You're too young/too old/too short/too tall/too fat/too skinny/not my type (that shouldn't be the reason)

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Walter Mitty

- **SCENARIO**: Michelle is a 31 y.o with poison ivy dermatitis. Although a recheck wasn't absolutely 'essential', you have scheduled her back for follow-up, just as you did last time when she had bronchitis, 6 months ago. You spent enough time with her at the last visit that your nurse had to prod you along to the next patient. Since you saw her name on the schedule this morning, you have looked forward to her visit as the 'bright' part of your day.

Walter Mitty: What's The Problem?

- A) You're married
- B) She is married
- C) You are too old for her
- D) She is uninsured
- E) None of the above

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Walter Mitty: What's The Problem?

What should clinicians do when they feel attraction to/sexual energy towards a patient?

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Walter Mitty

The American Heritage Dictionary defines a Walter Mitty as “an ordinary, often ineffectual person who indulges in fantastic daydreams of personal triumphs.”

http://en.wikipedia.org/wiki/Walter_Mitty accessed 12/22/2007

Walter Mitty

Walter Mitty is a fictional character in James Thurber's short story “The Secret Life of Walter Mitty”, first published in The New Yorker on March 18, 1939. Mitty is a meek, mild man with a vivid fantasy life: in a few dozen paragraphs he imagines himself a wartime pilot, an emergency-room surgeon, and a devil-may-care killer.

http://en.wikipedia.org/wiki/Walter_Mitty accessed 12/22/2007

Walter Mitty Physician $\Rightarrow$ Patient Sexual Energy

- Normal experiences: at some time in your career, you are likely to experience attraction to a patient.
- The issue is: what to do about it.

Kuritzky L. “Practical tips for dealing with difficult patients” *FP Recert* 1996;18(2):21-36

Walter Mitty: Critical Transcendence Steps

- Recognition & awareness
- Fantasy designation
- Compartmentalization
- Redirection
- Self monitoring for boundary disruption

Kuritzky L, D'Epiro P “Successful Management of Difficult Patient Encounters” *Patient Care* 2006;40(8):41-50

Walter Mitty: Critical Transcendence Steps

- Recognition & awareness
 - Don't engage in self-deception
 - Longer than necessary visits
 - More than necessary visits
 - Innocent but excessive touch

Kuritzky L, D'Epiro P “Successful Management of Difficult Patient Encounters” *Patient Care* 2006;40(8):41-50

Walter Mitty: Critical Transcendence Steps

- Fantasy designation
 - The ‘car-off-the-bridge’ fantasy

Kuritzky L, D'Epiro P “Successful Management of Difficult Patient Encounters” *Patient Care* 2006;40(8):41-50

Walter Mitty: Critical Transcendence Steps

Compartmentalization & Redirection

- Being your best clinician requires at least 100% of you undivided attention
- Nobody wants their clinician to be a 'dabbler' in medicine
- Recognize need to compartmentalize
- Focus on necessity for single-mindedness

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Walter Mitty: Critical Transcendence Steps

- Recognition & awareness
- Fantasy designation
- Compartmentalization
- Redirection
- Self monitoring for boundary disruption

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Walter Mitty: Critical Transcendence Steps

- Self monitoring for boundary disruption
 - Late appointments
 - Long appointments
 - Unnecessary appointments
- Beyond that?
 - Collegial conversation
 - Consultation

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Barnacle Bill

- SCENARIO: Jennifer is a 16 y.o. girl CC 2 weeks lower abdominal pain. She seems anxious. Her father, Bill, promptly answers or completes answers to anything you ask, even though Jennifer's answers seem adequate. When it's time for gowning and an abdominopelvic examination, you indicate that Bill may wait for you outside while you and the nurse examine his daughter. He is somewhat agitated and clearly doesn't want to comply with your request.

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Barnacle Bill

- CLINICIAN: Well, Bill, if you'll wait outside for a few minutes, Nurse Ratchet and I will examine your daughter
- BARNACLE BILL: What do you mean, wait outside?
- CLINICIAN: Well, Bill, we'd like you to give your daughter some privacy while we can do the necessary exam.
- BARNACLE BILL: Doctor, I know what's best for my daughter—I'm staying!!

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Barnacle Bill: The Problem

- Parents accompanying 'child' are well intended (usually)
- Established pattern is parent + child
- Parental presence precludes privacy, confidentiality, and (sometimes) full disclosure

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Barnacle Bill: The Solution

- **CLINICIAN:** Bill, if you'll briefly wait outside, Nurse Ratchet and I will examine you daughter.
- **BARNACLE BILL:** What do you mean, wait outside?
- **CLINICIAN:** "Bill, it is our office policy that all our young adults have the same privacy and confidentiality as all other adults. So if you don't mind waiting outside for just a few minutes, we will be discussing a few more items with your daughter and will then examine her (showing him to the door).

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Barnacle Solution: Confidentiality

- **CLINICIAN:** (Once parent is out of earshot) Jennifer, before we go any further with your examination, I want to explain your confidentiality and privacy rights in our office. As long as you are our patient, your medical records are confidential from everyone, unless you specifically instruct us to share them with someone. I asked your father to leave because we want every young adult to know that we cannot disclose to parents, without your permission, their son's or daughter's medical information unless this information is life or limb threatening.

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Barnacle Solution: Confidentiality

- **CLINICIAN:** You need to know that you can talk safely and privately here about drugs, sex, birth control, family issues, violence---essentially anything that is concerning you---without worry that it will get back to your parents."

&
ONE MORE THING

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Barnacle Bill: No 'Conspiracies'

- **CLINICIAN:** At the same time, I don't want you to think that we condone any 'conspiracy-type' things here. As a matter of fact, I encourage you to share with your parents as much information as you feel confident to share. I have seen that young adults are often pleasantly surprised at how their parents handle some 'touchy subjects', but I'll leave that completely up to you. I will share with your parents only as much or as little information as you want. We can even invite your father to come back in right now, if you prefer for him to be here during our discussions or your examination.

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Barnacle Bill: No 'Conspiracies'

- **CLINICIAN:** So, before we go on, are there any other concerns you'd like to talk about?
- **JENNIFER:** You're SURE my dad won't find out?
- **CLINICIAN:** Yes, unless you want him to know
- **JENNIFER:** Well, OK. You see, there's this guy at the mall who I've kind of been hanging out with, and this one time the rubber broke, and even though I got my period, I was worried that I might b pregnant, and I'm going to need something better than rubbers....

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Time Traveler

- **SCENARIO:** It's a typical Monday morning in your office. Bill, a 48 y.o. executive is presenting for 'flu'. As you enter the office, this well dressed gentleman looks reassuringly healthy
- **CLINICIAN:** Hello, Bill. How are things going?
- **TIME TRAVELER:** So, Doc, I'm doing OK now, but I had such a bad intestinal flu Thursday and Friday last week that I took off work.

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Time Traveler

- **CLINICIAN:** No Sx now?
- **BILL:** No, I'm pretty much back to normal, and I'm ready to go back to work, but I need a note for last Thursday and Friday.
- **CLINICIAN:** Why didn't you come in then?
- **BILL:** Well, on Thursday, I thought I'd be better the next day; then by the time I called on Friday, it was too late to get in to see you...
- **CLINICIAN:** OK, describe your Sx for me.....

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Time Traveler: The Problem

- The clinician has multiple uncertainties about the illness of Time Traveler
- The clinician tries to keep things honest by re-constructing the illness historically
- If this is a REPEAT experience, other issues:
 - Alcohol abuse
 - Other substance abuse

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Time Traveler: The Solution

- **CLINICIAN:** I'm glad you're better. Let me explain what would be most helpful the next time this kind of thing comes up. Our OFFICE POLICY is to make a TIMELY record of your illness in the chart, even if it's just a telephone communication. That's the best way I can provide what you need.....

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Time Traveler: The Solution

Return to Work Note

- Mr. / Ms -----
was seen in our office on -----TODAY----
and may return to work on ----TODAY-----
- Comments: Mr. Jones REPORTED to me TODAY an illness which kept him from working LAST WEEK. He is now able to resume full normal activities.

Kuritzky L, D'Epiro P "Successful Management of Difficult Patient Encounters" *Patient Care* 2006;40(8):41-50

Dr. Hybrid

- A 49 y.o. man comes to your office with atypical chest pain of 2 days duration. He has a 20 p-y smoking Hx, obesity, and sedentary lifestyle. Lipids, VS, EKG, PE all normal. Last week, he attended the post-MI funeral of his favorite uncle. You should
- Take no chances: by ambulance to the ED
 - Take no chances: Direct admit to the hospital
 - Take a chance: reassure him and send him home
 - Use a Hybrid approach

The HYBRID Approach

Demonstrate 'Due Diligence'
Share Balance of Risks

HYBRID Approach: Due Diligence

"Mr. Jones, I think the likelihood of your symptoms being caused by a heart attack is extremely small. However, because you have risk factors for heart disease and are experiencing chest pain that I *cannot* with certainty determine is 'innocent', I am obligated to tell you that the only certain way to ensure your complete safety is to send you to the ED to make sure you are not having a heart attack"

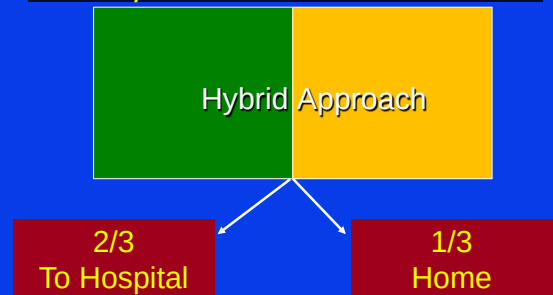
Then, the patient will likely say 1 of 2 things:

- Well, if that's the only way, doc, I guess I gotta go.
- Well, you said you don't think it really looks like a heart attack. Are you sure I really need to go?

HYBRID Approach: Balance of Risks

"Actually, Mr. Jones, if it was me, I wouldn't go, because I really feel like the chances of this being a heart attack are very very slim—but not zero. The difference is, I can take a chance on me, and if I were wrong, I could live with that, but I cannot take a chance on you. That's why I have to advise you the safest thing is to go to the hospital.

Atypical Chest Pain Pts Very Low Likelihood Acute MI



Dave Doorknob

A 58 y.o. man comes in for his annual recheck of well-controlled hypothyroidism. Your hand on the doorknob (minute 14.99/15), he says, 'Oh by the way, doc, could you hook me up with a little Viagra?'

You should

- A) Write a Viagra Rx& talk about it next time
- B) Do a thorough evaluation for sexual dysfunction now
- C) Pretend you didn't hear him
- D) Lend him a few of your own till the next visit
- E) Establish the need for another visit soon

Dave Doorknob Prevention The Target-Centered Introduction

"Well Dave, I see you're back for a recheck of your hypothyroidism. How are things going for you?"

Dave Doorknob Prevention
The Patient-Centered Introduction

“Well Dave, I see you’re back for a recheck of your hypothyroidism. Before we get started, are there ANY OTHER ISSUES YOU’D LIKE TO BRING UP, so we can decide how we’re going to use our time together today?”

SELF EVALUATION

Navigating Difficult Patient Encounters

1. Which of the following best defines a “difficult patient”?
 - a. A patient with multiple chronic conditions
 - b. A patient who frequently visits the clinic
 - c. A patient who crosses a clinician’s boundaries, expectations, or rules
 - d. A patient with poor health literacy
2. T/F - Approximately 25% of patient encounters are considered difficult by physicians.
3. Which physician behavior is associated with a LOWER likelihood of malpractice claims?
 - a. Spending less time with patients
 - b. Using more humor and facilitation
 - c. Limiting patient questions
 - d. Focusing strictly on efficiency
4. T/F - Abrupt discontinuation of opioids is commonly fatal and should always be avoided for that reason.
5. What is the most appropriate response when a patient invites a physician to dinner?
 - a. Accept if the patient insists
 - b. Decline due to personal relationship conflicts
 - c. Decline because it compromises the professional relationship
 - d. Accept but maintain professionalism

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

FACULTY

Kevin Klauer, DO, EJD

Kevin Klauer, DO, EJD, of Winter Park, Florida, is currently the Chief Executive Officer of the American Health Information Management Association and was formerly the System Chief Medical Officer HCA Florida and Ocala hospitals. He formerly served as CEO of the American Osteopathic Association and the Chief Medical Officer and Chief Risk Officer for TeamHealth. He holds the following faculty appointments: Clinical Asst. Professor, Michigan State University College of Osteopathic Medicine; Clinical Asst. Professor, Ohio University Heritage College of Osteopathic Medicine. He is the co-author of five risk management books: *Bouncebacks: Critical Care*, *Bouncebacks: Pediatrics*, *Emergency Medicine*; *Bouncebacks: Medical and Legal* (1st and 2nd Editions) and *Risk Management and the Emergency Department: Executive Leadership for Protecting Patients and Hospitals*. Dr. Klauer also served as the American College of Emergency Physicians Council Speaker and subsequently as a member of their Board of Directors. Dr. Klauer earned his Executive JD, with honors, from Concord Law School in 2011.

You may contact Dr. Klauer with your comments or questions at kevinklauer1@gmail.com.

THE
2026-27

Medical-Dental-Legal
UPDATE

You've Been Named - Navigating the Medical Malpractice Process

Kevin Klauer, DO, EJD

You've Been Named: Navigating the Medical Malpractice Process

Kevin Klauer, DO, EJD, FACEP, FACOEP
Assistant Clinical Professor
Michigan State University College of Osteopathic Medicine
Ohio University Heritage College of Osteopathic Medicine
Orlando College of Osteopathic Medicine

The C



AMA Policy Research Perspectives

José R. Guardado, PhD

Medical liability claim frequency among all physicians
Sued in Career to Date

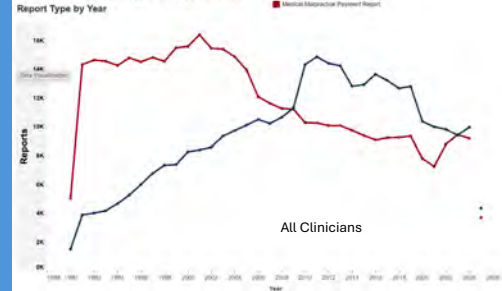
2016	2018	2020	2022
34.0%	32.8%	33.1%	31.2%

Sued in Career to Date
2020-2022

All: 32.1%
Under 40: 9.5%
40-54: 23.8%
55 and Older: 46.8%

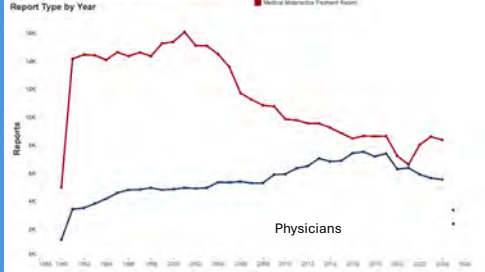
Claims Trended Frequency-NPDB

The data for 2023 only includes reports through June 30th, 2023



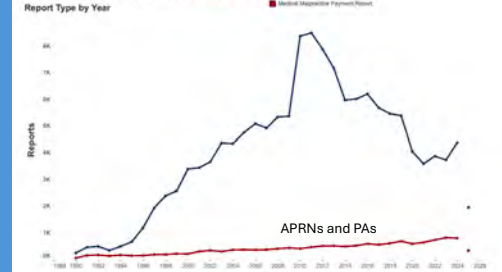
Claims Trended Frequency-NPDB

The data for 2023 only includes reports through June 30th, 2023



Claims Trended Frequency-NPDB

The data for 2023 only includes reports through June 30th, 2023



Cost of Claims

Negligent Action:

Commission or Omission

Special Damages (economic)

- Lifetime disability
- Hospital expenses past / future
- Lost and future earnings

General Damages (non-economic)

- Pain and suffering
- Loss of consortium
- Loss of companionship
- Disfigurement

Punitive Damages

2024 Candello Benchmarking Report

65,359 Closed Claims (2014-2023)

- 58% of documentation cases closed with indemnity paid v. 36%.
- 20% of MPL cases involved documentation failures.
- 140% higher odds of resulting in indemnity payment.
- 50% of documentation cases involved a high-severity injury or death v. 41%.
- 28% of total paid was from documentation cases.
- 54% increase in average total paid.



Discharge Safety Nets



Timed-specific follow up



Addressing abnormalities

Vital signs
Diagnostics



The wrap up visit!



The ambulation test

Essentials of Claims Management



- The Process
- Notice
- Privileged Communication
- Discovery
- Litigation Support

The Hammer Letter-Bad Faith Claims



AMA Policy Research Perspectives

José R. Guardado, PhD

“65 percent of claims that closed between 2016 and 2018 were dropped, dismissed or withdrawn, and out of the 6 percent of claims that were decided by a trial verdict, 89 percent were won by the defendant.”

Studdert DM, Mello MM, Gawande AA, Gandhi TK, Kachalia A, Yoon C, Puopolo AL, Brennan TA. Claims, errors, and compensation payments in medical malpractice litigation. *N Engl J Med*. 2006 May 11;354(19):2024-33. doi: 10.1056/NEJMsa054479. PMID: 16687715.

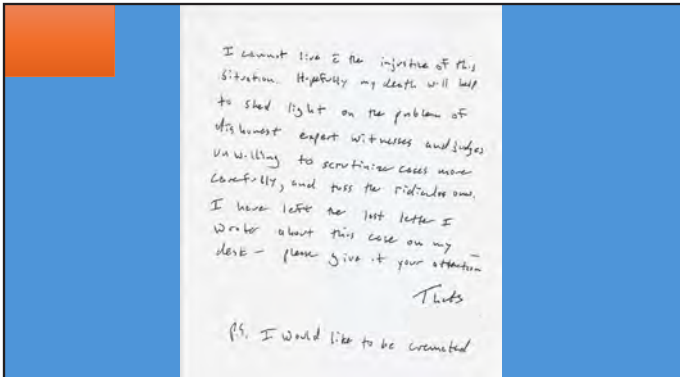
- 1452 closed claims from 5 insurers.
- 37 percent did not involve errors.
- Claims not involving errors accounted for 13 to 16 percent of the system's total monetary costs. For every dollar spent on compensation, 54 cents went to administrative expenses (including those involving lawyers, experts, and courts). Claims involving errors accounted for 78 percent of total administrative costs.



Vanhaecht K, Seys D, Russo S, Strametz R, Mira J, Sigurdsson S, Wu AW, Pollunta K, Popovici DD, Stetou R, Kurt S, Panella M. European Researchers' Network Working on Second Victims (ERNST): An Evidence and Consensus-Based Definition of Second Victim: A Strategic Topic in Healthcare Quality, Patient Safety, Person-Centeredness and Human Resource Management. *Int J Environ Res Public Health*. 2022 Dec 15;19(24):16889. doi: 10.3390/ijerph192416889. PMID: 36554746; PMCID: PMC3773047.



“Any health care worker, directly or indirectly involved in an unanticipated adverse patient event, unintentional healthcare error, or patient injury, and becomes victimized in the sense that also the worker is negatively impacted.”



Litigation Stress Syndrome

"The average physician in the United States will spend 50.7 months, or 11% of a 40-year career, with at least one open, unresolved malpractice claim."

"Physicians experiencing a claim may have strained family relationships, worsening anxiety and depression, and burnout, and have higher rates of medical errors. In such cases, physicians should seek support of their legal counsel and from a licensed professional therapist. Above all, physicians should remember that malpractice claims are an occupational hazard and not a sign that they are a bad physician."

Cocchianale F, Gnatowski M Jr, Pensa G. Medical Malpractice Stress Syndrome. Emerg Med Clin North Am. 2025 Feb;43(1):1-7. doi: 10.1016/j.emc.2024.05.024. Epub 2024 Jul 8. PMID: 39515934.

Madan, R; Das, Nileswari; Pattay, Rahu; Nagpal, Neeraj; Malik, Yogender; Math, Suresh B. Consequences of medical negligence and litigation on health care providers – A narrative review. Indian Journal of Psychiatry 66(4):p 317-325, April 2024. | DOI: 10.4103/indianpsychiatry.indianpsychiatry.799.23



The Stages of Emotional Response

Emotional response in litigation	Description
Shock	- The normal response to litigation when an HCP is confronted. - Manifested as feeling numb, distant or confused. - The worst period for health in distress.
Denial	- HCP may use denial as a defense mechanism to cope with the stress of being sued. - If the medical error was unintentional, they might try to ignore the mistake and believe they did everything to prevent it. - Denial can prevent them from taking responsibility and addressing patient concerns, making the legal process more difficult.
Anger	- Anger may arise from trying to negotiate with the patient or their family to resolve the matter but a way to make sense. - It is essential to recognize that angering is not always a productive or appropriate response to a medical negligence suit. - Anger may also be seen as an admission of fault, which can have legal and professional consequences. - It is characterized by low mood, loss of interest, lack of energy, decreased concentration, loss of appetite, and low self-esteem. - Anger may also be seen as an admission of fault, which can have legal and professional consequences. - The legal process can be lengthy and stressful, and the negative impact on their professional reputation and emotional well-being can be significant.
Depression	- The fear of losing their license or being sued again can lead to persistent anxiety and depression. - Acceptance as the result of medical negligence suits for HCPs can involve acknowledging that a mistake was made and taking responsibility for it. - It can also involve accepting the legal consequences of the litigation, such as accepting a settlement or a ruling against them. - Acceptance can be difficult, but the desired stage to reach. - By accepting the situation and taking steps to learn from it, HCPs can move forward and strive to improve their practice to prevent similar mistakes in the future. - Acceptance can also involve seeking support and coping strategies to manage any ongoing emotional or mental health issues resulting from the experience.

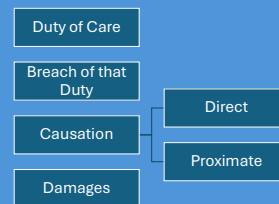
Madan, R; Das, Nileswari; Pattay, Rahu; Nagpal, Neeraj; Malik, Yogender; Math, Suresh B. Consequences of medical negligence and litigation on health care providers – A narrative review. Indian Journal of Psychiatry 66(4):p 317-325, April 2024. | DOI: 10.4103/indianpsychiatry.indianpsychiatry.799.23

Successful Navigation

Phase	Major characteristics	Common questions to ask
Phase 1: Shock and Denial	- Low motivation to respond - Full awareness of legal help - May not be able to control rate of patient - Distraction - Exaggerated sense of victimhood - Relationships may be strained - Exaggerated sense of victimhood	- How did this happen? - Why did this happen? - Why did I do this? - Could this have been prevented?
Phase 2: Denial/Refusal	- Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood	- Why did I do this? - Could this have been prevented? - Why did I do this? - Could this have been prevented? - Why did I do this?
Phase 3: Anger/Depression	- Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood	- Why did I do this? - Could this have been prevented? - Why did I do this? - Could this have been prevented? - Why did I do this?
Phase 4: Seeking the Resolution	- Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood	- Why did I do this? - Could this have been prevented? - Why did I do this? - Could this have been prevented? - Why did I do this?
Phase 5: Seeking the Resolution	- Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood	- Why did I do this? - Could this have been prevented? - Why did I do this? - Could this have been prevented? - Why did I do this?
Phase 6: Seeking the Resolution	- Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood	- Why did I do this? - Could this have been prevented? - Why did I do this? - Could this have been prevented? - Why did I do this?
Phase 7: Seeking the Resolution	- Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood	- Why did I do this? - Could this have been prevented? - Why did I do this? - Could this have been prevented? - Why did I do this?
Phase 8: Seeking the Resolution	- Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood - Exaggerated sense of victimhood	- Why did I do this? - Could this have been prevented? - Why did I do this? - Could this have been prevented? - Why did I do this?

Madan, R; Das, Nileswari; Pattay, Rahu; Nagpal, Neeraj; Malik, Yogender; Math, Suresh B. Consequences of medical negligence and litigation on health care providers – A narrative review. Indian Journal of Psychiatry 66(4):p 317-325, April 2024. | DOI: 10.4103/indianpsychiatry.indianpsychiatry.799.23

Elements of a Lawsuit



Mitigating Risk-This is Not Rocket Surgery

What Works

- Relational
- Caring
- Competent
- Humble

What Doesn't

- Transactional?
- Be Perfect?
- Negligence-Free Practice?
- Predict the Future?
- Be all Things to All People?
- Possess Unlimited Knowledge?

Avoiding Misdiagnoses? A Misdiagnosis of Why Claims Occur

Medical Legal Case

"Hey Doc.....?"

- ED RN Co-worker
- Good working relationship
-Can you write a prescription for my son? I have to work the next couple of days and can't get him to his Dr's office. I know he has another ear infection. Amoxil usually works fine."
- "Sure. No problem."

Follow-Up

- Rx Filled
- Allergic Reaction 24 hours later
- Lawsuit filed 12 months later

Good Samaritan Defense? A Question of Duty



OPINION

Plaintiffs, Darby Thomas and Home Star Bank & Financial Services, as guardian of the estate of Edward Anderson, a disabled person, filed suit against defendants Michael T. Murphy, O.D., and his employer, Emergency Care & Health Organization, Ltd. (ECHO), alleging that Dr. Murphy was negligent in treating Anderson. The circuit court of Cook County concluded that Dr. Murphy was immune from liability pursuant to section 25 of the Good Samaritan Act (the Act) (745 ILCS 49/25 (West 2010)) and granted summary judgment to defendants. Plaintiffs appealed, and the Appellate Court, First District, reversed and remanded. 2012 IL App (1st) 112321. The court held that the Act was meant to apply to volunteers, not to those who treat patients within the scope of their employment and are compensated for doing so. We allowed defendants' petition for leave to appeal and, for the reasons that follow, we affirm the appellate court.

Dumb Samaritan Acts

- No documentation
- Staff favors
- Neighbors/Friends

Action in the Event Tent! Medical-Legal Issues Facing the Volunteer Event Physician

David S. Rose, MD,^{1,2} Alisha Ferguson, PhD,³ and David L. Herbert, JD⁴

Context: Physicians need to consider medical-legal issues when volunteering their time to assist with community mass-participation and athletic events. This article also reviews medical-legal aspects of the volunteer physician's out-of-state practice. Seven cases illustrate the importance of expertise and planning to avoid legal issues for the volunteer event physician.

Evidence Acquisition: Relevant studies, expert opinion, medical legal literature, and medical-legal cases were reviewed.

Results: Physicians typically make 4 common assumptions regarding these types of events: Good Samaritan legislation, event liability insurance, personal liability insurance, and waivers. We discuss the intent of these assumptions and the reality of how, or how not, they provide any protection to the volunteer event physician.

Conclusion: The intent of this article is to make physicians aware of medical-legal issues when volunteering their time for community and athletic events.



- Don't put yourself at risk!
- What does your next career look like?



<https://www.flickr.com/photos/henrythetrouble/1567164749/>

Deposition Disasters

- Not a chance to vindicate yourself
- Friendly ≠ Friendship
- Purpose

Are clinical guidelines authoritative?
Are textbooks reasonably reliable?
You understand and should follow your hospital policies?

Atty: "So, you would consider this an unpredictable event that you could not prevent?"

Dr: "Shit happens."

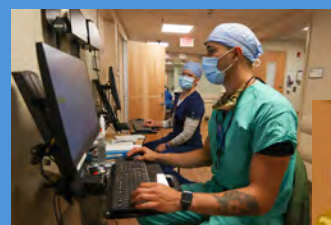


II. Deposition Testimony of Emergency Physician

A. What does the doctor remember, after the fact?

A. I remember having discussions with the patient and family regarding how she was feeling, and I know that midway she was feeling a lot better, and was urging to go home. I remember wanting to give her antibiotics, and she was in a rush, did not want to receive any intravenous dose of antibiotics, because that would take an extra hour. I remember wanting to make sure that the electronic prescription for a medication, I wanted to make sure it went through the pharmacy, and they didn't want to wait, and I urged them to wait, to make sure that it was – it was transferred appropriately.

Documentation: Pay now or Pay later



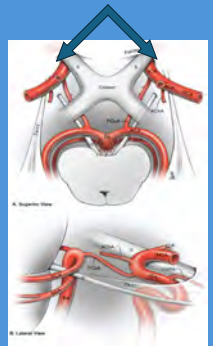
Medical Legal Case: The Telephone Consult

Visit# 1

- September 30
- 47-year-old female presented to the ED
- CC/HPI: She complained of a severe headache, dizziness, nausea, vomiting and photophobia. She denied blurred vision or other neurological complaints. The headache had been intermittent for one month. She rated her pain as a 10 out of 10.
- P.E.: Normal exam

- Tx: Hydromorphone and Ondansetron IV
- Diagnostics
 - Labs: NL
 - CT:

"Sellar/suprasellar mass suspicious for pituitary macroadenoma. Suprasellar component displaces optic chiasm and floor of 3rd ventricle. MRI with dedicated pituitary mass protocol may be helpful in further characterization. No cervical or carotid artery stenosis. Compression of paraclinoid ICA B/L between the mass in the anterior clinoid processes."



Medical Legal Case

- Telephone consult: Neurosurgeon on call
- The report was read to the neurosurgeon
- "Do you want to see her in 1 week."
- Demand: \$35,000,000
Offer: \$100,000
- Patient presented via EMS after being found unresponsive with severe focal neurological deficits
- Dx: Ischemic stroke & Acute adrenal crisis
- Tumor resected
- Permanent, severe neurological sequelae
- She cannot live independently

Making Sense of Med Mal Claims

It's business to everyone other than you and the patient/family.

The number of claims you'll likely receive are far outweighed by the vast majority of patients you've served.

Delivering medial care is a complex process of abductive, deductive and inductive reasoning, often with an incomplete data set. You can expect to "get it wrong" once in a while.

Careers should not be defined by one or two cases, even if there were lessons to learn.

Be kind to yourself as the process may not be.

Thank you!

SELF EVALUATION

You've Been Named: Navigating the Medical Malpractice Process

1. According to AMA data presented in the lecture, approximately what percentage of physicians have been sued at some point in their career?
 - a. 10%
 - b. 20%
 - c. 32%
 - d. 50%
2. T/F - Most malpractice claims result in a trial verdict, and most of those verdicts favor the plaintiff.
3. What proportion of malpractice claims are dropped, dismissed, or withdrawn?
 - a. 25%
 - b. 45%
 - c. 65%
 - d. 80%
4. Which of the following was identified as a major contributor to indemnity payments in malpractice claims?
 - a. Medication errors
 - b. Documentation failures
 - c. Diagnostic imaging delays
 - d. Surgical complications
5. T/F - Malpractice claims are an uncommon event that typically reflects poor physician competence.

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

FACULTY

Michael W. Donnino, MD

Michael W. Donnino, MD, of Suffolk County, Massachusetts, is a Professor of Emergency Medicine at Harvard Medical School, and an attending physician in the Department of Emergency Medicine and Division of Pulmonary/Critical Care Medicine at Beth Israel Deaconess Medical Center. His clinical practice spans both the intensive care unit as well as the emergency department. Dr. Donnino was the first person in the country to train in a 6-year combined emergency medicine, internal medicine, and critical care program leading to board certification in all three areas. Dr. Donnino is also the Director of the Center for Resuscitation Science and Director of Critical Care in Emergency Medicine. Dr. Donnino's research interests include clinical trials and clinical investigations in septic shock and cardiac arrest. In the field of cardiac arrest, Dr. Donnino is the lead investigator of a multi-center clinical trial evaluating the use of steroids in post-arrest shock and a multi-center trial evaluating thiamine as a metabolic resuscitator in septic shock. Other notable studies include an investigation in microcirculatory dysfunction post-arrest, an evaluation of the human metabolome in sepsis and post-cardiac arrest, and severity of illness scoring systems in post-cardiac arrest patients. Dr. Donnino is a member of the Advanced Cardiac Life Support (ACLS) Subcommittee at the American Heart Association and co-author of sections of the 2010 ACLS guidelines.

You may contact Dr. Donnino with your comments or questions at mdonnino@bidmc.harvard.edu.

Thiamine in Neurologic and Systemic Disease

Michael W. Donnino, MD

Thiamine in Neurologic and Systemic Disease

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Disclosures

- Consultant or speaker fees: NONE
- Research Grants: NIH, Foundation, Philanthropy,

Objectives

- Review the pathophysiology, diagnosis, and treatment of neurological manifestations of thiamine deficiency
- Evaluate common misconceptions regarding thiamine deficiency disorders
- Evaluate latest research into thiamine in critically ill populations (i.e., septic shock, cardiac arrest)

Thiamine Deficiency Disorders

- Wernicke's Encephalopathy (Wernicke-Korsakoff)
- Dry Beriberi
- Wet Beriberi
- Gastrointestinal Beriberi
- Lactic Acidosis (lone)

History of Beriberi

Clinical Syndrome - Beriberi

- Sometimes prodrome of fever, URI, or GI symptoms
- Lower extremity weakness
→ Upper extremity
- Paresthesias/pain often in the calves but elsewhere
- Muscle wasting



Clinical Syndrome - Beriberi

- Sometimes prodrome of fever, URI, or GI symptoms
- Lower extremity weakness
→ Upper extremity
- Paresthesias/pain often in the calves but elsewhere
- Muscle wasting
- In some, edema predominates (i.e., wet beriberi)



"Ship" Beriberi

BERI-BERI STRICKEN CREW.

Bark Crescent from Punta Arenas Reports a Fateful Voyage.

The bark Crescent from Punta Arenas reports a sad story occurred here while crew on her just terminated voyage from the above port.

She arrived here yesterday having sailed from Punta Arenas Dec. 24, 1890. She crossed the equator on April 25, 1891.

On May 10 she put in at Barbados for medical assistance, the entire crew being stricken with beri-beri. Before the vessel had reached Barbados three of the crew had already died from the disease and were buried at sea.

Capt. Bartlett and the cook were for several days the only ones able to be on deck, and navigated the ship into that port.

She proceeded from Barbados June 1, having taken eight extra men on board, and had fair weather, excepting a fog in the South channel, until her arrival in this port yesterday forenoon.

STRICKEN WITH DISEASE

Beri-Beri Rages Among the Crew of Greyhound.

Three Men Died and Five Struck Help Part in Serious Condition.

Tragic End to Five Year's Voyages of New Bedford Whaling Bark.

NEW BEDFORD, May 4.—The whaling bark Greyhound, which has been at sea for five years, and which has made a record of 40,000 miles, was yesterday stricken with a terrible disease, which, in its last stages, was known as beri-beri. The crew of the bark, which was composed of 15 men, were all stricken with the disease, and three of them had already died. The remaining 12 men were in a serious condition, and the bark was unable to proceed.

Tragically, Mrs. Elton, wife of the captain, who shared the vessel, also was stricken with the disease, and died yesterday. The vessel was taken to the hospital, and the crew were placed in the hospital. The vessel was unable to proceed, and was forced to return to New Bedford. The disease was a terrible one, and the crew were all stricken with it. The vessel was unable to proceed, and was forced to return to New Bedford. The disease was a terrible one, and the crew were all stricken with it.

Dr. Edward Vedder

DAILY DIET AND HEALTH HINTS
By Dr. T. J. ALLEN, Food Specialist.

BERI-BERI CURED BY CHANGE FROM POLISHED TO UNPOLISHED RICE.

Army surgeons in the Philippines who noticed that the civilian natives who ate only unpolished rice because it was cheaper were free from beri-beri, tried feeding the native soldiers on the unpolished rice and have discovered that the terrible disease then disappears. Attention has frequently been called in these hints to the superiority of unpolished rice. No specific disease has been traced to the white flour, but fresh white bread in combination with flesh is undoubtedly the commonest cause of bowel troubles, especially appendicitis, as such combination tends to induce serious fermentation. When these articles of food are eliminated and the entire grain substituted such diseases will be avoided.

- You cannot conclude that because the disease effects the young and those who appear healthy, that nutritional deprivation is not the origin

Case Presentation

- A 25 year old female who is 13 weeks pregnant presented to the emergency department with intractable vomiting for the past 3-4 weeks
- She was diagnosed with hyperemesis gravidarum and hydrated with IVFs
- After a night of observation, she was discharged with instructions to use phenergan for any continued vomiting and to follow-up with an obstetrician

Case Presentation

- Two days later, the family brought the patient back to the ED with complaint of confusion
- Family relates that the patient took her phenergan as instructed but still had persistent vomiting
- This morning the patient had difficulty getting out of bed - she was unsteady on her feet and the family soon realized that she was very disoriented

PMH: Non-significant

Medications: Phenergan

Allergies: NKDA

Social History: Family reports that patient does not smoke, use illicit drugs, or alcohol.

Family History: Mother - Diabetes

PE: T 36.2 P 110 BP 110/65 R 24 SaO2: 98% RA

General: Awake, alert but confused gravid female

Chest: CTA bilaterally, tachypneic

CV: RRR II/VI SEM; no peripheral edema

Neuro: Alert to self only. Horizontal nystagmus is noted. Other cranial nerves are normal. Motor and sensory examinations are difficult to assess with her decreased mental status but are grossly normal (normal strength). Reflexes +2 bilaterally.

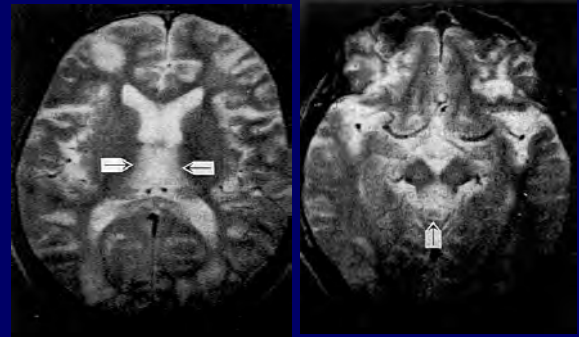
The remainder of the physical exam is normal.

Case Presentation

Laboratory values reveal a hypochloremic, hypokalemic metabolic alkalosis as well as a deficiency in magnesium. A CXR is negative and urinalysis is normal. A non-contrast head CT is performed and does not show acute hemorrhage.

Despite rehydration and supportive care, the patient's condition did not improve over the next three hospital days.

On the third hospital day, a diagnostic test was performed.



Polioencephalitis Haemorrhagica Superioris Carl Wernicke (1881)



(Donnino et al. Myths and Misconceptions of Wernicke' Encephalopathy: What Every Emergency Medicine Physician Should Know. 2007)

- T/F: Wernicke's Encephalopathy is a disease of alcoholics.

- **False: Wernicke's Encephalopathy is a disease of alcoholics.**
- **TRUTH: Wernicke's Encephalopathy is a disease of nutritional deficiency most prevalent in alcoholics.**

Predisposition

- Alcohol Abuse
- AIDS
- Malignancy
- Hyperemesis Gravidarum
- Post-surgical (especially gastric bypass)
- Iatrogenic: Glucose loading in nutritional deprived
- Psychiatric Disorders leading to anorexia
- Other nutritional disorders

- **True/False: The triad elicited by Wernicke (confusion, ophthalmoplegia, ataxia) is almost always present.**

- **FALSE: The triad elicited by Wernicke (confusion, ophthalmoplegia, ataxia) is almost always present.**

- **TRUTH: Retrospective autopsy studies suggest that the triad may be present only in 10% of cases.**

Victor M. Adams RD. The Wernicke-Korsakoff Syndrome and related neurologic disorders due to alcoholism and nutrition. 2nd ed. Philadelphia, PA: FA Davis; 1989

Clinical Presentation

- MENTAL STATUS CHANGES (global confusion, apathetic, somnolent, agitated)
- **OCULAR** abnormalities (nystagmus, ophthalmoplegia, ptosis, abducens palsy, retinal hemorrhages, papilledema)
- ATAXIA and vestibular paresis
- Hypotension
- Hypothermia
- Coma

Victor M. Adams RD. The Wernicke-Korsakoff Syndrome and related neurologic disorders due to alcoholism and nutrition. 2nd ed. Philadelphia, PA: FA Davis; 1989

- **T/F: Wernicke's Encephalopathy is a rare disease.**

- **FALSE: Wernicke's Encephalopathy is a rare disease.**

- **TRUTH: Autopsy studies reveal WE in:**
- **1.5% of hospitalized patients**
- **12.5% of alcoholics¹**
- **10% of AIDS²**

¹Torvik A. Brain lesions in alcoholics. J Neurol Sci 1982;56:233-248

²Boldorini R. Wernicke's Encephalopathy: occurrence and pathological aspects in a series of 400 AIDS patients. Acta Bimed Ateneo Parmense 1992 ;63:43-49

Case 1

- 23 year old female from a local college student presents to the ED confused
- Patient brought in by boyfriend who relates over the past 4 weeks she became weaker and weaker to the point that she could not get out of bed
- Today, she became acutely confused and came to the ED

Case 2

- 43 year old male presents in care of his partner with the chief complaint of confusion
- The patient's partner relates over the last 3-4 weeks he has become weaker and weaker to the point where he can no longer move
- Today, he became acutely confused and came to the ED

Case 3

- 41 year old female presents in care of her 11 year old daughter with the chief complaint of confusion
- The daughter relates over the last 3-4 weeks she has become weaker and weaker to the point where he can no longer get out of bed
- Two days ago, she became acutely confused and after not improving, she came to the ED

On exam...

- All three patients were confused...
- All three patients had nystagmus...
- All three patients were quadraparetic...

On further questioning...

- All three patients were alcoholics...
- All three patients had caregivers continue to provide alcohol despite progressive weakness/paralysis
- All three patients were coherent until 24-48 hours prior to presentation and the reason for presentation was acute confusion

Diagnosis/Outcome

- Diagnosis: Beriberi complicated by Wernicke's Encephalopathy
- After intravenous thiamine, 2/3 patients had resolution of confusion with only mild (if any) Korsakoff syndrome (however 1 maintained persistent symptoms)
- All three patients had gradual but incomplete improvement in weakness prior to being lost to follow-up

Beriberi in and Industrialized Country

- 1) Malnutrition (i.e., alcohol abuse with poor nutrition)
- 2) Access to an enabler (i.e., caregiver to provide alcohol despite progressive paralysis)
- 3) Some sort of "protection" from Wernicke's or perhaps predisposition toward dry beriberi (nutrient driven, genetic, other?)
- 4) Denial and generally failure to seek help

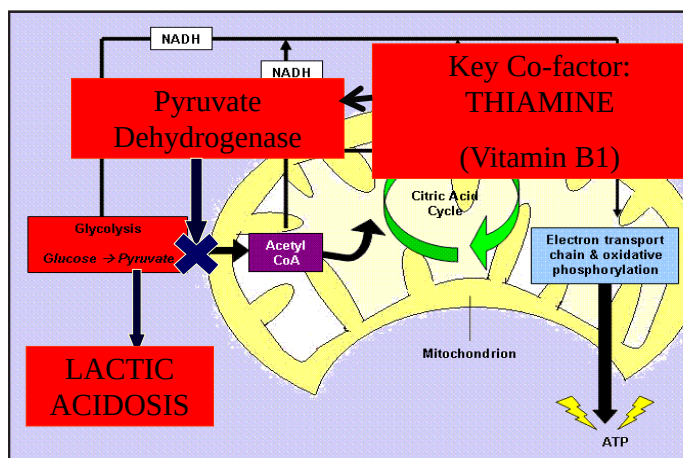
Thiamine Deficiency Disorders

- Wernicke's Encephalopathy (Wernicke-Korsakoff)
- Dry Beriberi
- Wet Beriberi
- Gastrointestinal Beriberi
- Lactic Acidosis (lone)

Pathophysiology

Early Thiamine Deficiency → Biochemical Lesion → Anatomical Lesion

Asymptomatic → Symptomatic but reversible → Irreversible



Distinctive Acid-Base Pattern

Patient	pH	pCO ₂	HCO ₃	Lactate	Anion gap
R.A.	7.48	21	20	7.9	26
A.K.	7.47	17	11	7.4	28
M.K.	7.45	28	17	0.7	21
T.W.	7.42	27	17	5.5	28

Donnino MW, Miller J, Walsh M. Distinctive Acid-Base Pattern in Wernicke's Encephalopathy. Annals of Emergency Medicine (2007)

Case

59 year-old male with unknown past medical history presents with abdominal pain and vomiting. He was found on the street, is confused, and is unable to provide further history.

T 98.6 P 110 BP 84/60 RR 32 Sat 98%
 Gen: Tachypneic, dry mucous membranes
 Chest: CTA bilaterally Heart: S1 S2 reg
 Abd: Soft, mild diffuse tenderness
 Neuro: A & O x 2, no focal neuro findings
 Extrem: Cool, clammy

Case : Labs

Arterial Blood Gas:

pH: 6.9 pCO₂: 10 HCO₂: 3
 pO₂: 80 Sat: 96% Lactate: 27.2 mmol/dl

Complete Blood Count:

White Cell Count: 3.4 Hemoglobin: 8.1
 Platelets: 230

Gastrointestinal Beriberi: An Unrecognized Syndrome?

Patient	Date	pH	pCO2	HCO3	Lactate
LU	03/02	6.82	15	3	27.2
LU	08/02	6.85	14	3	30.0
LU	03/03	6.73	40	5	23.8
MS	03/04	7.06	18	5	18.6

Donnino M. Gastrointestinal Beriberi: A Previously Unrecognized Syndrome. *Annals of Internal Medicine*. (2004) 141 (11): 898-99

Clinical Presentation

- Nutritional predisposition
- Vomiting/abdominal pain
- Lactic Acidosis
- Venous hyperoxia (ScvO₂ > 90%)
- Rapid recovery with thiamine (6- 12 hours)

Donnino M. Gastrointestinal Beriberi: A Previously Unrecognized Syndrome. *Annals of Internal Medicine*. (2004) 141 (11): 898-99

Does Gastrointestinal Beriberi Exist?

- Clinical observation (severe acidosis cases with resolution)
- Observational data from epidemic in Japanese ICUs (33% with abdominal pain prompting ex lap)
- Prospective human data (RD Williams experiments)

Does Gastrointestinal Beriberi Exist?

- Clinical observation (severe acidosis cases with resolution)
- Observational data from epidemic in Japanese ICUs (33% with abdominal pain prompting ex lap)
- Prospective human data (RD Williams experiments)
- Yes, I think there is “GI presentation” but is this really a novel syndrome versus variant presentation

Diagnosis

- Clinical
- Laboratory Measures
 - Thiamine levels
 - Erythrocyte transketolase
- Imaging Studies
 - CT scan → Very poor sensitivity
 - MRI → relatively poor sensitivity (50%) but specific (90%)

- **True/False: The dosage of thiamine is scientifically well established**

- **FALSE: The dosage of thiamine is scientifically well established**
- **TRUTH: No prospective, randomized trials have been performed. Dosages vary greatly in reported cases of WE although majority have used 50-500 mgs in adults...**

Treatment - thiamine

- Route: Intravenous vs. Intramuscular vs. PO
- Dose:
 - Prophylaxis: 100 mgs once per day
 - Treatment: 200 mg – 500 mg 2-3 times/day
- What about other vitamins/electrolytes?

The Association Between Admission Magnesium Concentrations and Lactic Acidosis in Critical Illness

Ari Moskowitz, MD¹, Joon Lee, PhD^{2,3}, Michael W. Donnino, MD^{4,5}, Roger Mark, MD, PhD², Leo Anthony Celi, MD, MS, MPH^{2,4}, and John Danziger, MD, MPH⁶

Abstract

Introduction: Although magnesium plays an important role in aerobic metabolism and magnesium deficiency is a common phenomenon in critical illness, the association between magnesium deficiency and lactic acidosis in the intensive care unit (ICU) has not been defined. **Methods:** This was a retrospective, cross-sectional study conducted at a 77 ICU bed tertiary medical center. Data pertaining to the first unique admission of any ICU patient between 2001 and 2008 were extracted from the Multiparameter Intelligent Monitoring in Intensive Care database. Hypomagnesemia was defined as serum magnesium <1.6 mg/dL. Mild and severe lactic acidosis were defined as lactate concentrations of >2 and >4 mmol/L, respectively. Multivariate modeling was used to explore the association between magnesium and lactate concentrations. **Results:** Of 8922 critically ill patients, 22.6% were hypomagnesemic. Hypomagnesemia was associated with an increased adjusted risk of mild lactic acidosis (odds ratio [OR] 1.71, 95% confidence interval [95%CI] 1.51-1.94, $P < .001$) and severe lactic acidosis (OR 1.56, 95%CI 1.32-1.84, $P < .001$) than the reference quartile. The association between hypomagnesemia and mild lactic acidosis was stronger in those at risk of magnesium deficiency, including diabetics (OR 2.02, 95%CI 1.51-2.72, $P < .001$) and alcoholics (OR 1.92, 95%CI 1.16-3.19, $P = .01$). As an internal model control, hypokalemia was not associated with an increased risk of lactic acidosis. **Conclusions:** Magnesium deficiency is a common finding in patients admitted to the ICU and is associated with lactic acidosis. Our findings support the biologic role of magnesium in metabolism and raise the possibility that hypomagnesemia is a correctable risk factor for lactic acidosis in critical illness.

- **True/False: Thiamine MUST be given BEFORE glucose**

- **Myth: Thiamine MUST be given BEFORE glucose**
- **Myth but some shades of truth...**

Prognosis

- True/False: Thiamine will result in immediate and full recovery in the majority of patients

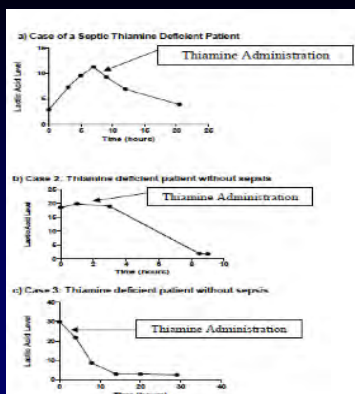
Prognosis

- Myth: Thiamine will result in immediate and full recovery in the majority of patients
- Korsakoff
 - What is this?
 - How often does this occur?
 - After onset, does this ever improve?

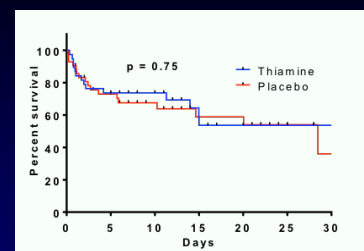
Thiamine Deficiency Disorders

- Wernicke's Encephalopathy (Wernicke-Korsakoff)
- Dry Beriberi
- Wet Beriberi
- Gastrointestinal Beriberi
- Lactic Acidosis (lone)

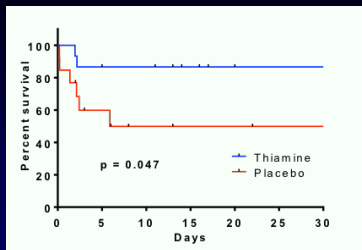
Thiamine Rapidly Reverses Acidosis in Deficient States



Survival - Overall



Survival – Thiamine Deficient



Mortality: Placebo - 46%
Thiamine - 13% $p = 0.13$

Conclusions – Thiamine Def Disorders

- Thiamine deficiency disorders occur in both developing and industrial countries
- Thiamine deficiency disorders include beriberi (wet, dry, gastrointestinal), Wernicke's Encephalopathy, and lactic acidosis
- Metabolic components of beriberi (i.e., lactic acidosis) are relatively rapidly responsive to thiamine (6-12 hours), whereas neurologic components of beriberi and Wernicke's Encephalopathy are slower to respond and may have residual abnormalities

Conclusions – Thiamine Def Disorders

- Thiamine should be given intravenously for deficiency disorders though the exact dosage, frequency, and duration are unclear (suggested regimen provided)
- Thiamine deficiency disorders (especially dry beriberi and possibly Wernicke's) may have a contributory causative component from other B vitamins

END

END END END

Clinical Syndrome - Beriberi

- Sometimes prodrome of fever, URI, or GI symptoms
- Lower extremity weakness
→ Upper extremity
- Paresthesias/pain often in the calves but elsewhere
- Muscle wasting



Background

- Septic Shock affects over 750,000 patients per year with upwards of 215,000 deaths
- Septic shock may be characterized by build-up of pyruvate, lactic acidosis, high metabolic state, refractory shock, and potentially death
- Whether the administration of thiamine in septic shock would enhance aerobic metabolism by increasing activity of pyruvate dehydrogenase remains untested and unknown

Hypothesis

The administration of intravenous thiamine to patients with septic shock will result in attenuation of lactic acidosis and a more rapid reversal of shock

Specific Aims

Specific Aim 1: To determine if the administration of thiamine to critically ill patients with septic shock will improve lactate clearance

Specific Aim 2: To determine whether the administration of thiamine to patients with septic shock improves time to shock reversal

Thiamine Levels in Adult Critically Ill Patients

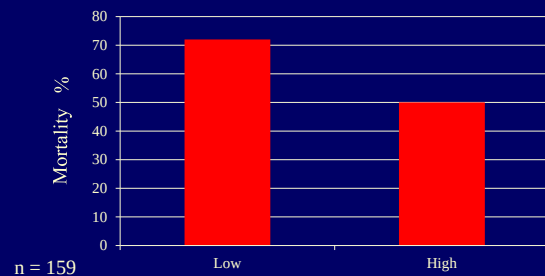
Design: Retrospective

Population: ICU patients on TPN

Assay: Erythrocyte transketolase (indirect assay for thiamine deficiency)

Cruickshank AM, et al. Thiamine deficiency in the critically ill. Intensive Care Med. 1988;14(4):384-7.

Low versus High Levels of Erythrocyte Transketolase (indirect assay for thiamine deficiency)



Cruickshank AM, et al. Thiamine deficiency in the critically ill. Intensive Care Med. 1988;14(4):384-7.

Lactic Acidosis and Thiamine Deficiency

- Causal relation first described in 1950s
- Well-described in cardiac beriberi and TPN-associated beriberi
- Described in patients with Wernicke's Encephalopathy
- Described in gastrointestinal beriberi

Lactic Acidosis in the Critically Ill

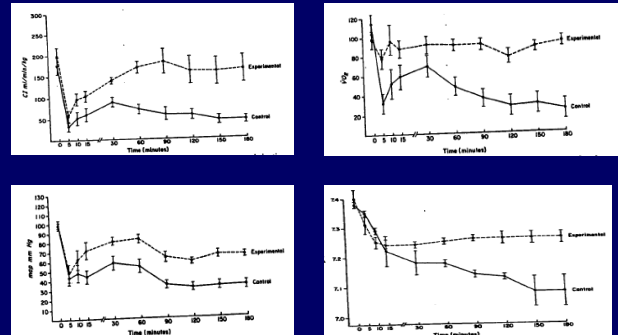
- Might a component of lactic acidosis in the critically ill be related to absolute or relative thiamine deficiency?
- Regardless of a thiamine deficient state, might the provision of thiamine accentuate pyruvate dehydrogenase activity thereby enhancing aerobic metabolism (and decreasing lactic acidosis)?
- Lactate clearance may serve as a surrogate for mortality as well as a marker to validate the proposed mechanism for the effect of intravenous thiamine

Prospective trial of thiamine (v. placebo) in an dog model showed attenuation of acidosis and improved blood pressure

- Design: Prospective, interventional
- Population: Septic dogs (endotoxin model)
- Intervention: Intravenous thiamine (2 g) vs. placebo

Lindenbaum GA, Larrieu AJ, Carroll SF, Kapusnick RA. Effect of cocarboxylase in dogs subjected to experimental septic shock. Crit Care Med. 1989 Oct;17(10):1036-40

Results



Lindenbaum GA, Larrieu AJ, Carroll SF, Kapusnick RA. Effect of cocarboxylase in dogs subjected to experimental septic shock. Crit Care Med. 1989 Oct;17(10):1036-40

Preliminary Data

- Design: Prospective, Observational
- Inclusion: Suspected infection, planned ICU admission (from ED or floor), hypotension requiring vasopressors or lactate > 3 mmol/dl
- Exclusions: Competing reasons for lactic acidosis such as seizures, metformin, linazolid

Donnino M, et al. Thiamine Deficiency in critically ill patients with sepsis. Journal of Critical Care, 2010

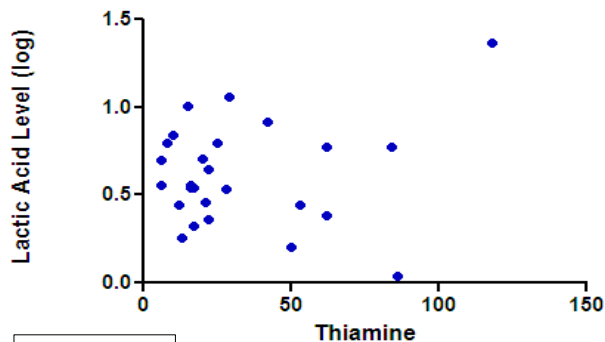
Results

- Upon enrollment: 3/30 (10%) had absolute thiamine deficiency
- Within 72 hours: additional 3 patients (6/30; 20%) developed absolute thiamine deficiency

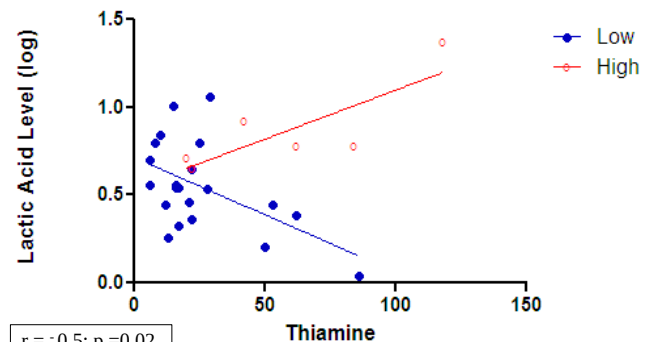
Absolute thiamine deficiency: Less than 9 microliters as defined per Quest Diagnostics standards (based upon normal, healthy population). We measured 30 controls, none of which had absolute thiamine deficiency.

Donnino M, et al. Thiamine Deficiency in critically ill patients with sepsis. Journal of Critical Care, 2010

Lactate vs. Thiamine

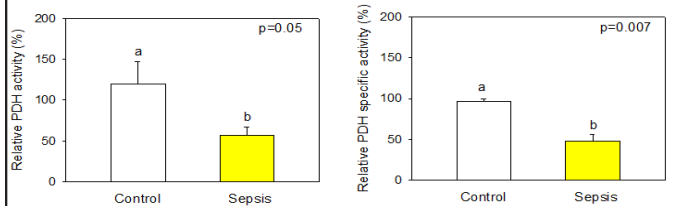


Lactate vs. Thiamine



Low: AST ≤ 240; High: AST > 240

PDH activity is Depressed in Sepsis

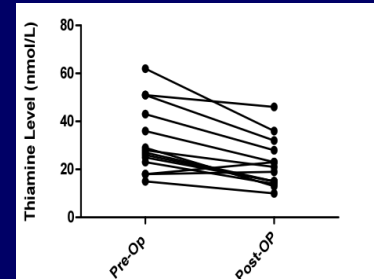


Thiamine levels over time

Design: Prospective, observational study of serial thiamine levels in patients presenting for elective CABG

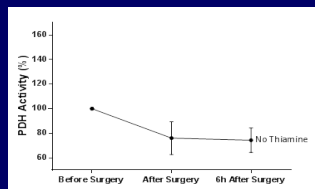
p < 0.05

n = 14



Donnino M, Cocchi M, Carney E, Chou P. Coronary Artery Bypass Depletes Plasma Thiamine Levels. Nutrition. 2010 Jan;26(1):133-6

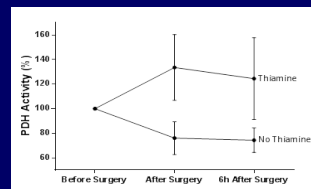
PDH activity in CABG patients



n = 14 patients

Andersen L, Liu X, Peng T, Giberson T, Khabbaz K, Donnino M. Pyruvate dehydrogenase activity and quantity decreases after coronary artery bypass grafting: a prospective observational study. (Shock, In Press)

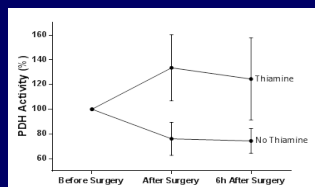
Stimulation of PDH in CABG patients with intravenous thiamine



n = 23 patients (14 non-thiamine, 9 open-label thiamine)

Andersen L, Liu X, Peng T, Giberson T, Khabbaz K, Donnino M. Pyruvate dehydrogenase activity and quantity decreases after coronary artery bypass grafting: a prospective observational study. (Shock, In Press)

Stimulation of PDH in CABG patients with intravenous thiamine



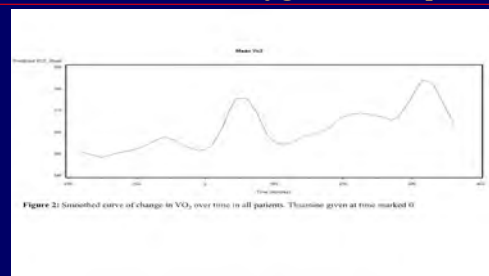
p < 0.05

n = 23 patients (14 non-thiamine, 9 open-label thiamine)

p < 0.05

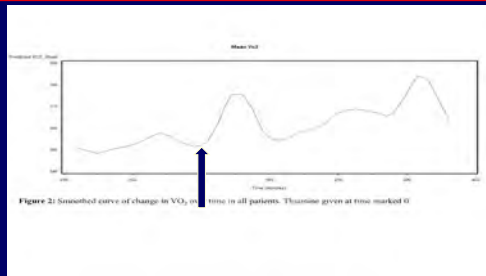
Andersen L, Liu X, Peng T, Giberson T, Khabbaz K, Donnino M. Pyruvate dehydrogenase activity and quantity decreases after coronary artery bypass grafting: a prospective observational study. (Shock, In Press)

Effect of thiamine on oxygen consumption (VO₂)



Berg KM, Gautam S, Saliccioli JD, Giberson T, Saindon B, Donnino M. Intravenous Thiamine is Associated With Increased Oxygen Consumption in Critically Ill Patients with Preserved Cardiac Index. Ann Am Thorac Society (2014)

Effect of thiamine on oxygen consumption (VO_2)



- PDH activity: 0.8 → 1.4
- PDH quantity: 258 → 322
- Ratio: 3.2 → 4.3

The Effect of Thiamine on VO_2

	Avg VO_2 change after thiamine	P-value – adjusted for CO
All patients	16.2ml/min	0.048
Mean CI < 3*	1.5ml/min	0.89
Mean CI > 2.4*	24ml/min	0.026
Mean CI > 3*	71ml/min	<0.0001

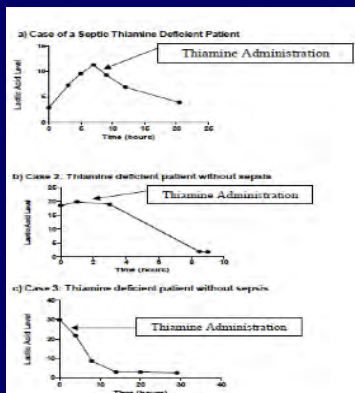
-Baseline VO_2 ranged 175-450 ml/min

-Result driven by positive effect in patients with normal or elevated CI

-No effect in low-CI patients

Berg KM, Gautam S, Saliccioli JD, Giberson T, Saindon B, Donino M. Intravenous Thiamine is Associated With Increased Oxygen Consumption in Critically Ill Patients with Preserved Cardiac Index. Ann Am Thorac Society (2014)

Thiamine Rapidly Reverses Acidosis in Deficient States



Preliminary Data

- Unrecognized thiamine deficiency is prevalent in the septic shock patients
- In patients with normal functioning liver, thiamine levels are negatively associated with lactic acid levels
- Lactate clears very rapidly in thiamine-deficient states when given thiamine
- Stress (CABG) depletes thiamine
- PDH levels and oxygen utilization are decreased in septic shock
- Thiamine increases PDH activity and oxygen utilization even in the absence of deficiency

Thiamine versus Placebo – Septic Shock

- Prospective, double-blind, randomized trial
- Inclusion: Septic Shock (SIRS, vasopressor-dependent, lactate > 3 mmol/L after 2 liters fluid)
- Thiamine 200 mg IV versus Placebo (twice day x 7 days)

Inclusion Criteria

- Adult patients (age > 18 years)
- Suspected or confirmed source of infection
- Hypotension (systolic pressure < 90 mmHg) after a 2 Liter fluid bolus followed by vasopressor-dependence. Vasopressor-dependence will include the continuous infusion of levophed, dopamine (5 mcg/kg/min or greater), or epinephrine. Dobutamine at any dose and physiologic dosages of vasopressin (0.04 Units/min or less) will not be considered vasopressor-dependence.
- Lactic Acidosis > 3 mmol/dl

Exclusion Criteria

- Competing causes of lactic acidosis including:
 - Seizures within 3 hours of enrollment
 - Use of linazolid, metformin, anti-retrovirals at the time of enrollment
 - Carbon monoxide or cyanide poisoning
 - Known mitochondrial disorder including but not limited to Kearns-Sayre syndrome, MELAS, and mitochondrial myopathy
- Liver dysfunction specifically defined as AST or ALT elevation greater than 240 (6 x upper limit of normal)
- Competing indication for thiamine administration as judged by the clinical team managing the patient. Examples include but not limited to a diagnosed thiamine deficiency disorder or alcohol withdrawal

Treatment Protocol

- Patients are administered the study drug (placebo or thiamine 200 mg) intravenously
- Patients receive a twice daily dosage for 7 days or until hospital discharge

Endpoints

- Primary Endpoint: Lactate Clearance at 24 hours (lactate difference at 24 hours)
- Secondary Endpoint: Shock reversal, mortality
- Safety Endpoint: Mortality, Adverse Events (only known adverse reaction from thiamine is allergic reaction)

Statistical Considerations

- Specific Aim 1 (Endpoint: Lactate Clearance)
- Based on the preliminary data, we estimated that the lactate clearance achieved at 24 hours will be 40% SD +/- 28% for the placebo group and 58% SD +/- 28% for the thiamine group
- This effect size of excess risk of 18% can be achieved with a total sample of n=88 subjects, type-I error of 0.05, and power of 0.80. We used the software SAS/STAT (3) procedure POWER to obtain the power estimate for this aim

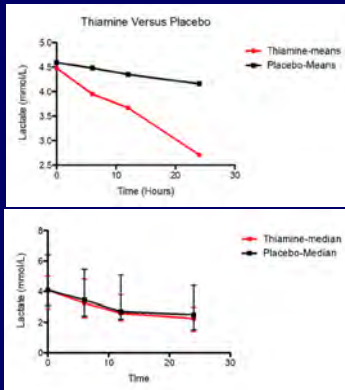
Baseline Characteristics

Characteristic	Thiamine (n = 43)	Placebo (n = 45)
Demographics		
Age – mean years (SD)	72 (34)	65 (37)
Sex – No. female (%)	17 (40)	19 (42)
Race – No. white (%)	36 (84)	40 (89)
Co-morbidities – No. (%)		
Coronary artery disease	10 (23)	11 (24)
Congestive heart failure	5 (12)	5 (11)
Hypertension	21 (49)	20 (44)
Chronic obstructive pulmonary disease	5 (12)	7 (16)
Diabetes	17 (40)	6 (13)
Lactate values		
Lactate – median mmol/L (quartiles)	4.1 (2.9 – 5.0)	4.1 (3.1 – 6.4)
Lactate > 4 mmol/L – No. (%)	25 (60)	23 (52)
Laboratory values at enrollment – median (quartiles)		
White blood count (x10 ³)	14.1 (8.7 – 22.5)	13.1 (4.6 – 39.3)
Hemoglobin (g/dL)	9.9 (8.9 – 12.9)	10.4 (9.3 – 12.5)
Creatinine (mg/dL)	1.8 (1.0 – 2.9)	1.9 (1.4 – 3.3)
Glucose (mg/dL)	145 (91 – 191)	136 (114 – 190)
Mechanical ventilation at time of enrollment	31 (74)	30 (67)
Start of vasopressor(s) to study drug – median hours (quartiles)	11 (4 – 27)	15 (3 – 27)
APACHE II score at enrollment – mean (SD)	25.7 (9.1)	26.5 (9.2)
SOFA score at enrollment – mean (SD)	10.1 (3.7)	10.2 (3.7)

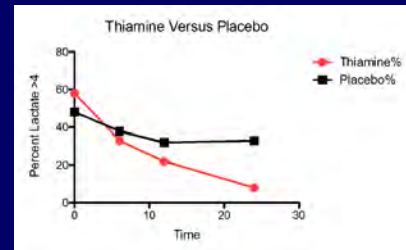
Relative Change in Lactate

- Thiamine: 44% reduction in lactate
- Placebo: 33% reduction in lactate
- p = 0.06

Thiamine Versus Placebo



Thiamine versus Placebo – Septic Shock

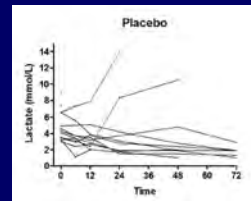


$p = 0.03$

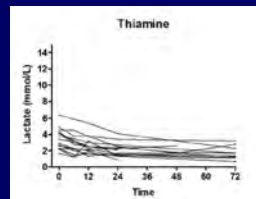
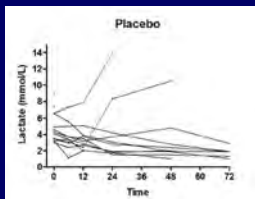
Baseline Characteristics

Characteristic	Thiamine (n = 15)	Placebo (n = 13)
Demographics		
Age – mean years (SD)	69 (19)	61 (14)
Sex – No. female (%)	7 (47)	7 (54)
Race – No. white (%)	12 (80)	11 (85)
Co-morbidities – No. (%)		
Coronary artery disease	3 (20)	0 (0)
Congestive heart failure	0 (0)	0 (0)
Hypertension	9 (60)	7 (54)
Chronic obstructive pulmonary disease	1 (7)	2 (15)
Diabetes	6 (40)	1 (8)
Lactate values		
Lactate – median mmol/L (quartiles)	3.4 (2.3 – 4.3)	4.3 (3.5 – 6.6)
Lactate > 4 mmol/L – No. (%)	6 (40)	8 (62)
Laboratory values at enrollment – median (quartiles)		
White blood count ($\times 10^3$)	10.5 (8.1 – 16.9)	13.2 (4.1 – 17.3)
Hemoglobin (g/dL)	11.3 (9.3 – 13.4)	10.0 (9.4 – 11.8)
Creatinine (mg/dL)	1.6 (0.8 – 3.0)	1.9 (1.5 – 3.0)
Glucose (mg/dL)	145 (111 – 191)	163 (128 – 193)
Mechanical ventilation at time of enrollment	4 (27)	8 (62)
Start of vasopressor(s) to study drug – median hours (quartiles)	24 (4 – 44)	10 (1 – 32)
APACHE II score at enrollment – mean (SD)	22 (19 – 31)	26 (19 – 33)
SOFA score at enrollment – mean (SD)	10 (7 – 13)	9 (7 – 11)

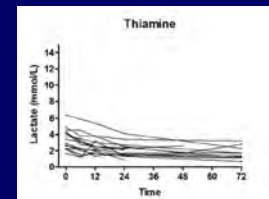
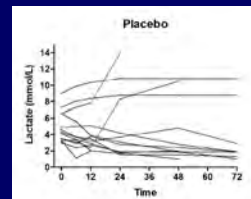
Thiamine Deficient Sub-Group (n=28)



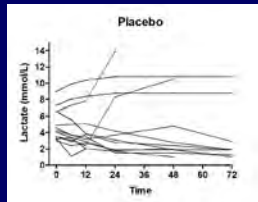
Thiamine Deficient Sub-Group (n=28)



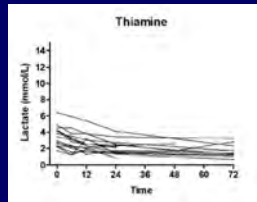
Thiamine Deficient Sub-Group (n=28)



Thiamine Deficient Sub-Group (n=28)



Mortality: 46%



Mortality: 13%

p = 0.13

Conclusions – Septic Shock

- Thiamine deficiency is prevalent in septic shock
- Thiamine did not decrease median lactate at 24 hours or over time but there was a trend in the decrease in mean lactate
- There was a statistically significant reduction in the percent of patients with lactate > 4 mmol/dl at 24 hours
- In the sub-group of thiamine-deficient patients, there was a statistically significant lower lactate in the thiamine group at 24 hours and a trend toward reduction in mortality

Conclusions – thiamine def disorders

- Thiamine deficiency disorders are likely prevalent in both developing and industrial countries
- Thiamine deficiency disorders include beriberi (wet, dry, gastrointestinal), Wernicke's Encephalopathy, and lone lactic acidosis
- Wet beriberi and lactic acidosis are rapidly responsive to thiamine, whereas dry beriberi and Wernicke's Encephalopathy are slower to respond and may have residual abnormalities

Conclusions – thiamine def disorders

- Thiamine should be given intravenously for deficiency disorders though the exact dosage, frequency, and duration are unclear (suggested regimen provided)
- Thiamine deficiency disorders (especially dry beriberi and possibly Wernicke's) may have a contributory causative component from other B vitamins

Other Areas of Research/Interest

- Thiamine deficiency is prevalent in DKA and we are studying thiamine in this setting
- Thiamine may have a role in neuroprotection in cardiac arrest

- | | | |
|---------------------|--------------------|-----------------|
| • Michael Cocchi | • Xiaowen Liu | • Kamal Khabbaz |
| • Kate Berg | • Amy Uber | • Amanda Graver |
| • Maureen Chase | • Howard Smithline | |
| • Shiva Gautam | • David Greenblatt | |
| • Justin Saliccioli | • Erin Carney | |
| • Tyler Giberson | • Ian Barbash | |
| • Brian Saindon | • Nina Joyce N | |
| • Lars Andersen | • Peter Chou | |
| • Julie Mackenhauer | • Long Ngo L | |
| • John Roberts | • Jose Vega | |
| • Ari Moskowitz | • Joseph Miller | |
| • Mark Walsh | • Edward McKee | |
| • Audwin Garcia | • Teng | |

Center for Resuscitation Science

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 - Maureen Chase
 - Katherine Berg
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Francesca Montillo
- **Fellows:**
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 - Ari Moscovitz
 - Brett Carroll
- **Residents:**
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 - Alex Cancellieri
 - Sunil Nair
 - Tristan Kooistra
- **Residents (cont):**
 - David Lam,
 - Erin Nuzzo
 - Sharukh Lockhandwala
 - Bhanu Padibandala
 - Sheeja Thomas
- **Research Assistants/Coordinators:**
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 - Chris Sulmonte,
 - Mary MacDonald
 - Michael Michalczuk
 - Parth Patel
- **Student Interns/volunteers:**
Meredith Hurley (Masters Candidate/BU)

Center for Resuscitation Science - Lab

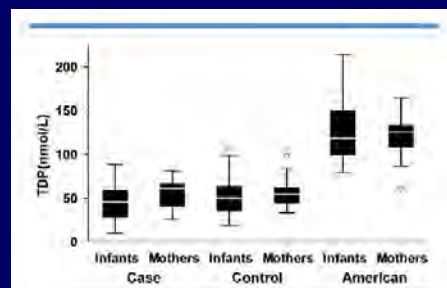
- **Lab Director:** Xiaowen Liu, PhD
- **Fellows:** Hira Pervez
- **Research Technician:** Sophia Montissol
- **Students:** Mathias Holmberg

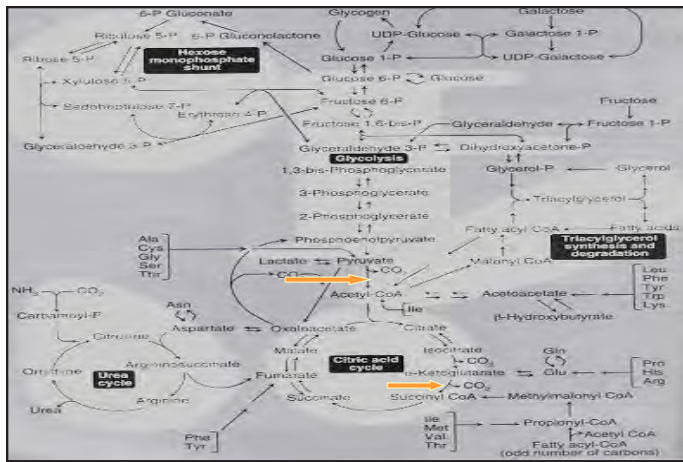


What Vitamins are in Rice?

- Thiamine
- Riboflavin
- Niacin
- Panthothenic Acid (B5)
- Vitamin B6

Thiamine Levels in Beriberi cases/controls





SELF EVALUATION

Thiamine in Neurologic and Systemic Disease

1. T/F - Wernicke's Encephalopathy is primarily a disease of alcoholism.
2. What percentage of patients with Wernicke's Encephalopathy present with the classic triad (confusion, ophthalmoplegia, ataxia)?
 - a. <5%
 - b. ~10%
 - c. ~25%
 - d. >50%
3. Which of the following is a recognized risk factor for thiamine deficiency discussed in the lecture?
 - a. Hypertension
 - b. Hyperemesis gravidarum
 - c. Hyperlipidemia
 - d. Asthma
4. T/F - The optimal dose of thiamine for treating Wernicke's Encephalopathy is well established through randomized controlled trials.
5. Which of the following best describes the response of lactic acidosis to thiamine administration in deficient patients?
 - a. No effect
 - b. Slow improvement over weeks
 - c. Rapid improvement within 6–12 hours
 - d. Only improves with concurrent antibiotics

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

FACULTY

Alan S. Gassman, Esq

Alan S. Gassman, Esq is a Florida attorney specializing in estate planning, asset protection, and advising physicians and healthcare professionals. A partner at Gassman, Denicolo & Ketron, P.A., he has over 40 years of experience helping doctors and business owners navigate legal, tax, and liability challenges. Board Certified in Wills, Trusts & Estates and an Accredited Estate Planner®, he is recognized by Florida Super Lawyers and holds Martindale-Hubbell's AV Preeminent rating. Mr. Gassman is a nationally published author of multiple books and over 200 articles, and he frequently lectures on topics such as medical practice law, creditor protection, and strategies to reduce legal risk for healthcare providers.

You may contact Mr. Gassman with your questions or comments at AGassman@gassmanpa.com.

THE
2026-27

Medical-Dental-Legal
UPDATE

Avoiding Costly Mistakes in Medical Practice Planning

Alan S. Gassman, Esq

3 Things You Want to Get Out of This Workshop

Item	Why is this important?	Next steps forward.
1.		
2.		
3.		

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The Ten Biggest Mistakes That Medical Practices
Make In Their Investment and Business Planning

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Introduction to the Rest of Your Life

MAKING THE MOST OF YOUR INITIAL OPPORTUNITIES

1. You can have a fantastic future. We can talk about that, but also about making sure that you do not make critical errors that would bring your financial future into devastation.
2. The time value of money and savings are amazing things. Start saving as soon as you can. Put your net worth high on the list of scorecards for the sake of mental security, family welfare and future enjoyment.
3. Over time banks will loan you more money than you can repay, and are only concerned about whether you can repay them, and not whether you will then have enough money left over to send your children to college and retire comfortably. Banks make money on interest they charge, not relationships.
4. Do not spend too much money on a house, or the expenses that come with it. Timeshares, vacation homes, and great real estate deals are all things not to rely upon. The appreciation in value may not compensate you for real estate taxes, insurances, maintenance, utilities, and travel expenses to enjoy a property that you may get tired of.
5. Numbers do not lie, but some of the people who use them do, and others are completely misled by their own industries. Be careful. Not everyone is working in your best interests.
6. Use a team of advisors who are independent of each other, who sincerely care about you, and who will debate honestly in order to educate you. Keep the bad apples out of your picnic basket of advisors.
7. Protect your assets from Creditors, and not just malpractice creditors. Car driving, building ownership and signing notes with banks can also be treacherous.
8. Understand how the corporate laws work to limit your liability, and possibly have charging order protection.

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Introduction to the Rest of Your Life

9. Use trusts as an appropriate estate planning mechanism, and on rare occasion as an asset protection mechanism. Most estate plans for doctors are not done correctly. Use a well qualified lawyer for this that is not financially linked to an investment sales organization or arrangement. The goal should be to help you and not sell new products. This includes family members.
10. Cultivate, maintain, and improve on annual and quarterly balanced life goals:
 - a. Your health comes first. This goal will not detract from any others.
 - b. The health and well being of your loved ones comes second. This includes mental health for you and others.
 - c. Your career comes third, but that will be the brightest and loudest stimulus for most of your waking hours. If you do not love it, change it or change how you look at it.
 - d. Saving for retirement comes next. It should be automatic and therefore effortless. If not then see a financial and/or other counselor. If that doesn't work, see a psychiatrist, at least socially!
 - e. Leisure time that enhances Sections a through e comes next. Time to think is important-hunting, fishing, running, boating, and other activities that give you the opportunity to think and take you away from the storm of our hurried existence can have a tremendous benefit.
 - f. Mix in religion, politics, social status and other things as you like, but don't be taken advantage of by yourself or others in the name of any cause that detracts from a through d.
 - g. How many of your actions and decisions are ego-driven? "Give John Smith, M.D. a title and he'll do anything." Don't let others manipulate you in the name of your ego.

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Introduction to the Rest of Your Life

- h. Noise and distraction from the above:
 - i. Here lies John Smith - He died with nothing and left his family destitute, but had great toys along the way- sorry family.
 - ii. Gambling addiction coupled with ego stroking can enable entrepreneurs to use doctor money to build companies that can fail miserably.
 - iii. Investing in real estate beyond your home, your office building, and medical related business that you know can pay rent becomes risky.
 - iv. Loans to family means gifts to family, and it works that way with friends and pseudo-friends. Who are you really helping?
 - v. Divorce can wreck your financial world. A bad relationship can wreck your personal world. If your spouse is not your best friend something is wrong.
 - vi. On the other hand, your children are not your friends. Your job is to make them self-reliant, hard working, confident, but appreciative and self-supporting adults. If you fail, then you will have dependents for life, which is very expensive both from a psychological and financial standpoint.
- i. Good news: There are simple steps to personal success. For example, not much has changed since Benjamin Franklin wrote his autobiography. If you have not read the biography of Benjamin Franklin by Walter Isaacson, start this week. It covers just about everything mentioned in this outline.

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One Step at a Time...

<https://www.youtube.com/watch?v=8cCiqbS39fg>



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Write It Down and It Will Happen – Page 1

If we were having this discussion three years from today, and you were looking back over those three years, what has to have happened in your life, both personally and professionally, for you to feel happy with your progress? - Dan Sullivan

	GOALS	OBSTACLES	SOLUTIONS	ACTIONS TO TAKE
90 Day Goals - Professional	1	1		
	2	2		
	3	3		
90 Day Goals - Personal	1	1		
	2	2		
	3	3		
3 Year Goals - Professional	1	1		
	2	2		
	3	3		
3 Year Goals - Personal	1	1		
	2	2		
	3	3		

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Write It Down and It Will Happen – Page 2

If we were having this discussion three years from today, and you were looking back over those three years, what has to have happened in your life, both personally and professionally, for you to feel happy with your progress? - Dan Sullivan

10 Year Goals - Professional	1	1			
	2	2			
	3	3			
10 Year Goals - Personal	1	1			
	2	2			
	3	3			
Lifetime Goals - Professional	1	1			
	2	2			
	3	3			
Lifetime Goals - Personal	1	1			
	2	2			
	3	3			

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The Ten Biggest Mistakes That Medical Practices Make In Their Investment and Business Planning

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BUILDING YOUR CATHEDRAL – Page 1

TIME DESCRIPTION/ACTIVITY	RATE IMPORTANCE (1-10)	RATE ENJOYMENT (1-10)	RATE EFFICIENCY (1-10)	DELEGABLE (Y/N)	ELIMINATED? (Y/N)	POSSIBLE IDEAS FOR IMPROVEMENT
1 = least – 10 = highest						
If yes, who?						
From waking up, until I leave the house on a weekday.						
1						
2						
3						
4						
5						
6						
7						
8						
From leaving home to arriving at work.						
1						
2						
3						
4						
Morning routine once I arrive at work.						
1						
2						
3						
4						
5						
6						

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BUILDING YOUR CATHEDRAL – Page 2

TIME DESCRIPTION/ACTIVITY	RATE IMPORTANCE (1-10)	RATE ENJOYMENT (1-10)	RATE EFFICIENCY (1-10)	DELEGABLE (Y/N)	ELIMINATED? (Y/N)	POSSIBLE IDEAS FOR IMPROVEMENT
1 = least – 10 = highest						
If yes, who?						
From after morning routine until lunch.						
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
My weekday lunch time routine.						
1						
2						
3						
4						
Post lunch activities.						
1						
2						
3						
4						
5						
6						

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BUILDING YOUR CATHEDRAL – Page 3

TIME DESCRIPTION/ACTIVITY	RATE IMPORTANCE (1-10)	RATE ENJOYMENT (1-10)	RATE EFFICIENCY (1-10)	DELEGABLE (Y/N)	ELIMINATED? (Y/N)	POSSIBLE IDEAS FOR IMPROVEMENT
1 = least – 10 = highest						
If yes, who?						
What I do just before I leave the office.						
1						
2						
3						
4						
5						
6						
What I do on the way home.						
1						
2						
3						
4						
Arriving at home until dinner.						
1						
2						
3						
4						
After dinner until going to sleep						
1						
2						
3						
4						

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BUILDING YOUR CATHEDRAL – Page 4

TIME DESCRIPTION/ACTIVITY	RATE IMPORTANCE (1-10)	RATE ENJOYMENT (1-10)	RATE EFFICIENCY (1-10)	DELEGABLE (Y/N)	ELIMINATED? (Y/N)	POSSIBLE IDEAS FOR IMPROVEMENT
1 = least – 10 = highest						
If yes, who?						
Approximate hours of sleep.						
Exercise ideas.						
1						
2						
3						
4						
Relationship ideas.						
1						
2						
3						
4						
Me time ideas.						
1						
2						
3						
4						
Avoid like the plague?						
1						
2						
3						
4						

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IDEA COLLECTOR

Instructions	1. Personal Improvements, Goals, Activities, and Habits To Work On	2. Personal Work Logistics – Maximizing Use of Your Best Abilities and Effectiveness	3. Team Work – Maximizing Team Coordination and Staff Ideas and Decision Making	4. Marketing and Client Development	5. Unique Process and Office/System Ideas and Improvements	6. Select a Key Client, Problem or Projects
1. List all potential ideas for improvement and actions during the conference.	Idea/Action:	Idea/Action:	Idea/Action:	Idea/Action:	Idea/Action:	Idea/Action:
2. Prioritize under each category at the end of the day.	Idea/Action:	Idea/Action:	Idea/Action:	Idea/Action:	Idea/Action:	Idea/Action:
3. Beginning at page 4, for each category write down the 4 most important ideas.	Idea/Action:	Idea/Action:	Idea/Action:	Idea/Action:	Idea/Action:	Idea/Action:
4. Use the Prioritization Follow-Up system beginning at page 4, to organize thoughts and objectives going into the pocket coach.	Idea/Action:	Idea/Action:	Idea/Action:	Idea/Action:	Idea/Action:	Idea/Action:
5. Review this periodically (at least once a month) assigning grades for progress and reassigning priorities.	Idea/Action:	Idea/Action:	Idea/Action:	Idea/Action:	Idea/Action:	Idea/Action:

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Avoiding Costly Mistakes in Medical Practice Planning

Famous Quotes

"You have to quit something before you can do something else."

- Professor Drucker

"It's the 5% best part of every business that should be accentuated, improved and expanded, and what parts of the 95% can be discontinued or contracted to allow for maximized profitability and enjoyment."

- What David Finkel told Alan Gassman

SWOT – EXAMPLE – FOR A FOUR DOCTOR MEDICAL PRACTICE - ALAN

Use your strengths and opportunities to overcome threats and weaknesses.

STRENGTHS	STRATEGIES	WEAKNESSES	STRATEGIES
Having A Variety Of Specialties		Inability To Attract New Patients	Advertise More
Quality Of Patient Care	Only Retain Physicians Who Provide Excellent Care	Inadequate Human Resources	Out Source To Recruiter
Flexibility		No Growth Within The Practice	Go Back To School & Further Your Education
Control Of Work Environment		Bad Financial Management/ Less Financial Certainty	
Specialty Selection		Start Up Cost	
OPPORTUNITIES	STRATEGIES	THREATS	STRATEGIES
May Attract Quality Physicians, Nurses, And Staff	Provide An Environment Where They Prosper And Feel Comfortable Working	Malpractice	
Expanding To Different Locations	Hire Partners That Work/Run Different Locations	Rivalry Among Competition	Incentives For Patient Referrals
Get More Knowledge Of Running A Business		Dissatisfied Patients	Offer A Gift Card And A Plant On Their Next Visit

SWOT – EXAMPLE – FOR A DOCTOR

Use your strengths and opportunities to overcome threats and weaknesses.

STRENGTHS	STRATEGIES	WEAKNESSES	STRATEGIES
Youth And Energy	Work Efficiently	Lack Of Medical Practice Experience	Mentorship
Trained On Most Recent Technology		Lack Of Business Knowledge	Mentorship
30 Year Work Span	Maximize And Enjoy Career Without Losing Family Experiences	Lack Of Financial Knowledge	Mentorship
Environment Control		Student Loans	Pay Them
Good Health/ Low Health Cost		Possible Spending Habits	Use Earnings To Pay Debt/ Learn To Be Happy With Moderate Spending
		Stress Of New Marriage	See A Counselor
OPPORTUNITIES	STRATEGIES	THREATS	STRATEGIES
Flexibility On Where To Work	Become An Owner To Have A Better Sense Of Control And Satisfaction	Early Burn Out/Poor Decisions	Get Enough Sleep
May Choose Job With Flexible Hours		Malpractice Suits And Guilt	
May Choose Work Model Or Ownership Model		Financial Torture Or Devastation	
May Obtain A Medical Management Degree		Divorce Or Poor Relationship	Have Meaningful Relationships For Proper Support And Mental Wellbeing
May Marry Another Doctor Or Provider		Unhappiness With Profession Or Life	

SWOT – EXAMPLE – FOR A NON-COMPLIANT PATIENT

Use your strengths and opportunities to overcome threats and weaknesses.

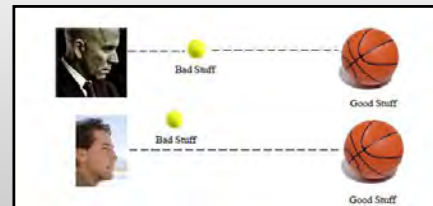
STRENGTHS	STRATEGIES	WEAKNESSES	STRATEGIES
They Can Be Vigilant		Language Barrier	Use A Translator To Best Get Your Message Across
Strong Personality		Lack Of Understanding	Do Your Best To Educate Them
Self Advocate		Mistrust	Build A Relationship With Them
They Have Often Done Research On Their Own	Go Over What They Have Told You And Ensure They Have The Correct Information	Difficulty Managing A Treatment	Attempt To Find The Most Manageable Treatment That Is Time Efficient
OPPORTUNITIES	STRATEGIES	THREATS	STRATEGIES
Document Everything	Make Sure Your Documentation Is Meticulous	They Will Blame You For Their Non-compliance	Have Them Sign An AMA (Against Medical Advice)
Use The Situation As Training For Staff		Risk Of A Lawsuit	Keep Medical Records And Documentation
Set Boundaries And Enforce Them		Decreased Opportunities For Prevention And Ineffective Treatment	

GOAL ACHIEVEMENT/ROAD BLOCK ELIMINATOR

Problem	Causes Resulting From My Actions	Possible Solutions And Actions	A Possible Positive Impact Of Solution (Rated 1-10)	B Ease In Implementation Of Solution (Rated 1-10)	A X B Priority Multiplier (Absolute Necessity = 100)
	1.	1.			
	2.	2.			
	3.	3.			
	4.	4.			
	5.	5.			
Ideal Solution	Causes Resulting From Actions Of Others	Possible Solutions And Actions			
	1.	1.			
	2.	2.			
	3.	3.			
	4.	4.			
	5.	5.			
Awesome Consequences Of Solving The Problem	Causes Resulting From My Perception And The Perception Of Others	Possible Solutions And Actions			
	1.	1.			
	2.	2.			
	3.	3.			
	4.	4.			
	5.	5.			

THE 90/10 RULE HOW TO BE SUCCESSFUL DOING WHAT YOU LOVE, AND LOVING WHAT YOU DO

By Alan S. Gassman and Kristen Sweeney



Imagine holding a basketball out as far as you can from your face with one hand, and a tennis ball out as far as you can from your face with the other. The basketball represents what is good in life, including health, love, prosperity, and ability. The tennis ball represents what is not so great in life. They are in the right perspective, with the good things in life far outweighing the bad. Now move the arm with the tennis ball closer to your face, so the tennis ball blocks the view of the basketball. Now the much smaller tennis ball blocks the view of the basketball almost entirely- the bad things in life seem to be far outweighing the good. This article will help you remember to put that tennis ball back into perspective where it belongs, so you can see and appreciate all the goodness in your life.

Avoiding Costly Mistakes in Medical Practice Planning

THE 90/10 RULE -- HOW TO BE SUCCESSFUL DOING WHAT YOU LOVE, AND LOVING WHAT YOU DO

By Alan S. Gassman and Kristen Sweeney

I had a meeting recently with a 75 year old physician who is still practicing medicine with significant success, energy and enthusiasm. The doctor came jumping out to the lobby with a sprightly greeting, "How you doing? It's great to meet you!" His beautiful wife of over 50 years was there with him. We were there to discuss estate planning, but first he insisted on giving me a tour of his office. He spent 30 minutes with me, going into every room and showing me every piece of art and every piece of equipment in his practice. This man was the chief of staff at one of our local hospitals when I was in school - I am 51, he is 75. He said "Alan, a lot of doctors don't know how good we have it. 90% of my life is fantastic. I am telling the employees what to do, I am helping patients, I am saving their vision, I am important, I have plenty to eat, I have plenty to drink, I have a lovely wife - 90% of life is great. And then 10% of the time there are problems. And so many people take that 10% and put it in front of the 90%. Young doctors come in and say 'they denied my claim for XYZ' and I say 'Who cares, when they paid the other 97 claims!' So maybe we aren't making quite as much now as we used to, maybe this is not the 'golden age'. Instead of focusing on that, we should all be talking about how great 90% of our life is every single day." So before you decide things are so bad you have to sell your practice, or make any other rash decisions, think about that doctor, that 75 year old physician, who is one of the happiest people I know.

That conversation has had a great influence on me and many people that I have shared this story with. It is an excellent reminder that we could all benefit from a little perspective in life- putting the tennis ball back where it belongs. There is no doubt that physicians face hurdles in life. Getting accepted to medical school is only the beginning of a long and difficult road.

MAKING THE BASKETBALL BIGGER

It is vital that whenever you hit a bump in the road, you keep things in perspective, remember why you became a physician in the first place, and hang onto that as the anchor in your daily thoughts. Life never stops challenging us, but remembering why we are here can keep us far more satisfied. Do you love being an obstetrician because you help bring children into this world? An ophthalmologist because you help people regain their sight? An orthopedic surgeon because you help people walk again?



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THE 90/10 RULE -- HOW TO BE SUCCESSFUL DOING WHAT YOU LOVE, AND LOVING WHAT YOU DO

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MAKING THE TENNIS BALL SMALLER - CUTTING YOUR WORRIES IN HALF

Principles from *How to Stop Worrying and Start Living*

The following are "Fundamental Principles for Overcoming Worry" from the incredible book *How to Stop Worrying and Start Living* by Dale Carnegie from 1948!

1. Live in "day-tight compartments."
2. How to face trouble:
 - a. Ask yourself, "What is the worst that can possibly happen?"
 - b. Prepare to accept the worst.
 - c. Try to improve on the worst.
3. Remind yourself of the exorbitant price you can pay for worry in terms of your health.

Basic Techniques in Analyzing Worry

1. Get all the facts.
2. Weigh all the facts - then come to a decision.
3. Once a decision is reached, act!
4. Write out and answer the following questions:
 - a. What is the problem?
 - b. What are the causes of the problem?
 - c. What are the possible solutions?
 - d. What is the best possible solution?

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THE 90/10 RULE -- HOW TO BE SUCCESSFUL DOING WHAT YOU LOVE, AND LOVING WHAT YOU DO

By Alan S. Gassman and Kristen Sweeney

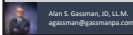
Break the Worry Habit Before it Breaks You

1. Keep busy.
2. Don't fuss about trifles.
3. Use the law of averages to outlaw your worries.
4. Cooperate with the inevitable.
5. Decide how much anxiety a thing may be worth and refuse to give it more.
6. Don't worry about the past.

Cultivate a Mental Attitude that Will Bring You Peace and Happiness

1. Fill your mind with thoughts of peace, courage, health and hope.
2. Never try to get even with your enemies.
3. Expect ingratitude.
4. Count your blessings - not your troubles.
5. Do not imitate others.
6. Try to profit from your losses.
7. Create happiness for others.

Another way of saying all this is to repeat the old adage "You can't see the forest for the trees," meaning to not focus so much on just the details (particularly the negative ones), but instead see the big picture that is your life, and appreciate that the entire forest is infinitely more beautiful than any single tree. It is also important to remember the words, "Why do you see the speck in your brother's eye but fail to notice the beam in your own eye?" Focus on yourself first, appreciate what is great and work on what is not so great, and you will be on the path to success.



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THE 90/10 RULE -- HOW TO BE SUCCESSFUL DOING WHAT YOU LOVE, AND LOVING WHAT YOU DO

By Alan S. Gassman and Kristen Sweeney

"Success is not the key to happiness. Happiness is the key to success. If you love what you are doing, you will be successful."
- Herman Cain

DEVELOPING YOUR UNIQUE ABILITIES

Shick - (Yiddish origin, slang) A characteristic attribute, talent, or trait that is helpful in securing recognition or attention.

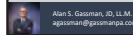
What is a shick? How can you come up with a shick of your own? And how can having and using a shick help bring about success and happiness to your medical practice and your life?

"You gotta getta gimmick if you wanna get ahead."
-Gypsy

Many of the artists, businessmen, and companies that have a lasting impact or prolonged success stick with us because they have something distinctive, something unique that differentiates them from the rest of the crowd. You can tell if someone has shick because it is usually easy to describe them in a few words or phrases - it almost seems that they own certain qualities, because they are so inextricably linked in our minds to a particular individual.

For our first example, we are going to look at a quintessential example of shick in the entertainment industry: the great Charlie Chaplin. Practically anyone who has ever seen a photo of Chaplin can easily identify him by what became his "uniform": "baggy pants, big shoes, a cane and a derby hat.....a small moustache." "I wanted everything to be a contradiction," Chaplin said in his autobiography, "the moment I was dressed, the clothes and makeup made me feel the person [my character] was."

What came to Chaplin as inspiration for one particular character gave life to his on-screen persona; from this film forward, the clownish get-up became his signature, and was forever linked to his style of comedy, largely of the slapstick and mime variety. Chaplin was undoubtedly brilliant, but so were many other performers. Playing the clown, and dressing the part, was his shick, and it made him stand out so much that he created his own genre; comedic bits of clownishness are now referred to as "Chaplin-esque".



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THE 90/10 RULE -- HOW TO BE SUCCESSFUL DOING WHAT YOU LOVE, AND LOVING WHAT YOU DO

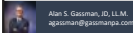
By Alan S. Gassman and Kristen Sweeney

Our second example is a fast-food chain originally founded in 1948. While it has not yet expanded to Florida, In-N-Out Burger has enjoyed fantastic success on the West Coast. The shick of In-N-Out Burger is based on a theory of simplicity: a simple menu and decor that are a throwback to burger joints of the 1950s.

The menu at In-N-Out Burger is focused on doing a few things simply and extremely well. The restaurant sells hamburgers, with the only variations being a cheeseburger and a "double" (double meat, double cheese). They serve hand-cut fries, sodas and milkshakes. Everything is cooked fresh, the meals are simple, and the limited menu allows the food prices to be extremely inexpensive compared to other fast-food chains. The employees wear old-fashioned aprons held together with giant safety pins and paper hats, adding to the old-time feel. The simplicity of the food and atmosphere is the shick; the shick is designed to keep prices down, so the company is successful and customers are happy.

In-N-Out also employs a second shick, the "secret menu". The secret menu is visible online but does not appear anywhere in stores, and allows for such modifications as ordering French fries "well done" to have them cooked extra crispy, or to have a burger served "animal style", which means added mustard, onions, pickles and special sauce. The lure of the secret menu is that you only hear about it by word of mouth, so those who have heard of it feel "in-the-know", and making customers feel special is an excellent way to keep them coming back.

The third example of shick we are going to discuss is actually a widespread movement: the "going green" movement. As we are becoming more ecologically aware and more concerned about our future on this planet, the effort to "go green" has become extremely popular. Large corporations are implementing solar panels or other energy-efficient technologies into their newest buildings, or providing employees with stainless steel reusable bottles instead of disposable plastic water bottles. Some business are trying to move toward a paperless environment or are implementing in-office recycling.



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THE 90/10 RULE -- HOW TO BE SUCCESSFUL DOING WHAT YOU LOVE, AND LOVING WHAT YOU DO

By Alan S. Gassman and Kristen Sweeney

Clothing retailers and food purveyors are placing emphasis on sustainability, which means being able to make products for consumption while maintaining stasis in the environment. Unlike the In-N-Out Burger example, which utilizes its shick to keep prices low, the green/sustainability movement appeals to the moral and ethical sides of consumers. Prices are typically higher for sustainable products, but the idea is that the customer is willing to make this kind of an investment because "it's the right thing to do." It should be noted that the sustainability market is still tenuous as a nationwide shick, experiencing much greater success in some regions than others.

"Everybody's a self-made man; but only the successful ones are ever willing to admit it."
- Anonymous

So now that we understand what a shick is, the next step is finding your own shick, and using it to bring you happiness and success.

Although a shick may imply a certain degree of falseness, of putting on a persona or a character, or embracing a marketing ploy, the best shicks are meaningful at heart to the individuals who employ them.

One of my favorite advisers who passed away recently had hundreds and hundreds of physician clients, just as I do. He always used to say: "You need a shick. Every doctor who does better than most of the others has a shick. Whatever it is - a marketing idea, a platform, or a thing you do for patients that no one else does that causes them to refer, or just something else going on. If you can look for it and find it, find something you love to do that really pays a little better than everyone else, you can increase the profitability and enjoyability of your practice."

This advisor was exactly right. Find out, figure out what is important to you - what you value, your patients (customers) will value, and then find a way to provide that service, perk, or product.

Some of our colleagues are employing these techniques already. An excellent example is the proliferation of "dental spas", which cater to people who are afraid of the dentist by providing a calming environment and relaxing ancillary services while patients are having dental work done. The extra perks keep patients returning because the dental spa stands out among the other practitioners.

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Avoiding Costly Mistakes in Medical Practice Planning

THE 90/10 RULE -- HOW TO BE SUCCESSFUL DOING WHAT YOU LOVE, AND LOVING WHAT YOU DO

By Alan S. Gassman and Kristen Sweeney

Another growing niche market is the concierge doctor, which has gained such popularity that it is even the theme of a popular television show, "Royal Pains". It is thought by some that the concierge market will pick up as healthcare plans pay for less and less. I have quite a few clients who pay \$1,400 a year to a primary care doctor for a 24/7 cell phone, "visit whenever they want" relationship. They do not care if insurance pays for it, they just want someone to call when it hurts.

This system is effective for my clients because the doctor I have used will meet the client the day after we call and immediately write a letter to the healthcare plan medical director, if necessary, saying "I am the new doctor, you don't cover X, Y and Z and I consider that negligence. I want my patient to have these medications and that test, and I am available by phone 24/7. Give me a call." That is worth \$1,400 right there.

So what motivates you, what sparks you that you can add to your practice as that extra something special that you offer? Can you offer early morning and weekend appointments? Do you provide personalized reminders when a patient is due for a check-up? Children's practices may offer a plethora of options, from themed offices to goody bags. Maybe you can offer small prizes for patients who bring in a coupon code found on your website. Maybe your office staff sings. On the luxury end, maybe you provide an extremely private reception area or plush furnishings and a fantastic magazine selection. Do not break the bank investing in perks you cannot afford, but do try to budget in marketing/development funds for the growth of your shtick. There are endless opportunities, and the more creative the better.

"Success: willing to do what the average person is not willing to do."
- Anonymous

Once you have brainstormed about your shtick, come up with an action plan for its implementation. Try it! You and others will like it! Do not be afraid to seek advice outside the realm of the medical world- you are integrating a marketing strategy, and there are experts in this field. If necessary, team up with a trusted advisor in this realm who can offer wisdom and most importantly, will keep the momentum going for integration of your shtick into the daily office routine. It will take effort, it will take time, but that time and effort, and the corresponding results, are exactly how you will set yourself and your practice apart.

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THE 90/10 RULE -- HOW TO BE SUCCESSFUL DOING WHAT YOU LOVE, AND LOVING WHAT YOU DO

By Alan S. Gassman and Kristen Sweeney

If you find a shtick that makes you happy and fulfilled, make it a part of your professional practice. Then success will come, and all that will be left to do is use your newfound perspective to enjoy the happiness and success you have achieved. That basketball will seem bigger than you could have ever imagined.

*"To laugh often and much;
To win the respect of intelligent people and the affection of children;
To earn the approbation of honest critics and endure the betrayal of false friends;
To appreciate beauty;
To find the best in others;
To give of one's self;
To leave the world a bit better, whether by a healthy child, a garden patch, or a redeemed social condition;
To have played and laughed with enthusiasm and sung with exultation;
To know even one life has breathed easier because you have lived ?
This is to have succeeded."*

- Ralph Waldo Emerson

"The person who gets the farthest is generally the one who is willing to do and dare. The sure-thing boat never gets far from shore."
- Dale Carnegie

"The great successful men of the world have used their imagination: they think ahead and create their mental picture in all its details, filling in here, adding a little there, altering this a bit and that a bit, but steadily building - steadily building."
- Robert Collier

"The toughest thing about success is that you've got to keep on being a success. Talent is only a starting point in business. You've got to keep working that talent."
- Irving Berlin

"Success in business implies optimism, mutual confidence, and fair play. A business man must hold a high opinion of the worth of what he has to sell and he must feel that he is a useful public servant." - R.H. Cabell

"The man who will use his skill and constructive imagination to see how much he can give for a dollar, instead of how little he can give for a dollar, is bound to succeed."
- Henry Ford

"No one can possibly achieve any real and lasting success or 'get rich' in business by being a conformist."
- J. Paul Getty

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THE PARETO PRINCIPLE (80/20)

INVENTED BY VILIFREDO PARETO IN 1896

How do I get most of this?	20% of your interactions	80% of your negativity?	Notes of What to Change:
		Ideas and Actions:	

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Don't React Immediately

- Our reptile brain does "flee or fight."
- There is no way to avoid having an emotional response to challenging situations.
- One of the things that our brain does is prompt an immediate reaction to the situation.
- One of the things our reptile brain does "flee or fight" and prehistoric man (and woman) would not have been able to survive if they did not have an immediate response to dangers, challenges, or otherwise.
- Fortunately, we no longer live in caves, and immediate responses by e-mail or in meetings or on the telephone are simply not necessary, or in the best interests of ourselves or our clients if we are having an emotional response.
- Many lawyers and other professionals are quite adept at setting up opponents or even clients to provide an emotional response that they can then take further advantage of.
- Also, e-mails may sometimes appear to be terse and rude, but are instead simply shortened and less eloquent statements made by someone who might not be thinking about how they might be interpreted.
- The adage to "count to ten and take deep breaths" certainly has a great deal of utility to modern man, and cavemen as well. Ask for a minute to think things through. If you like you can use the excuse that you need to make a phone call, go to the bathroom, or check on something.

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Don't React Immediately (Cont'd)

You can get used to saying things like the following when these circumstances apply:

1. I think I understand where you are coming from, but I need to think this through and I will also probably talk it over with _____ and review... and get back with you.
2. Thanks very much for...
3. I'm very surprised that you said that and simple will not respond at this time.

B. But if you "lose it" or say the wrong thing, or realize an hour later that you made a big mistake, apologize immediately and tell the person that they will get a less emotional response from you the next day.

Then talk it over with someone who you trust and come up with the appropriate response to get it off of your list of things to worry about.

The same applies when interacting with office staff and family.

Why come to blows or risk doing something that can cause loss of a good relationship, someone else to be upset, or undermining the ability to have productive team work.

Immediate reprimands work well with children, but not necessarily with employees. Let yourself cool down before deciding exactly how to communicate, unless you have already thought through the response in advance and know that it is appropriate based upon what the person has just done.

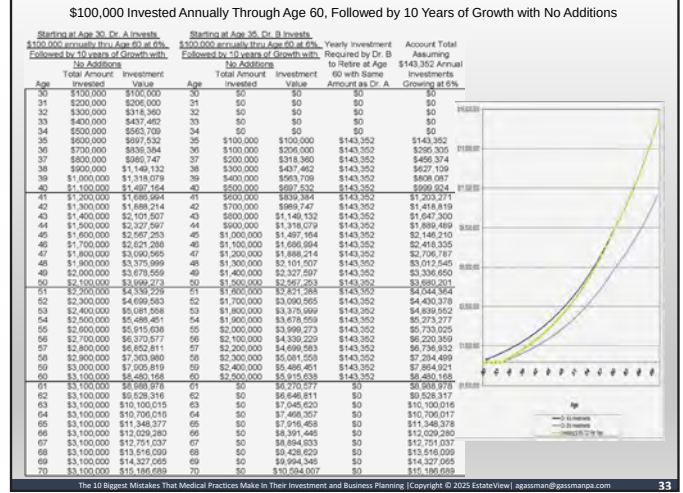
"Ask Me Tomorrow and Hopefully I Will Have an Answer"

Quite often a team member will ask me a question and my answer is "ask me again tomorrow."

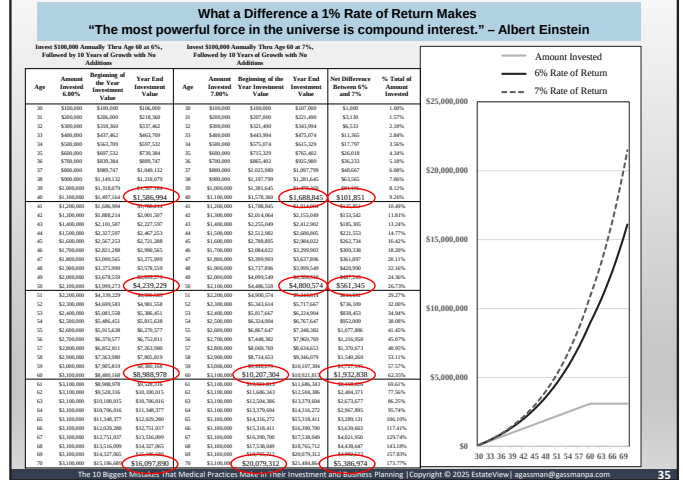
- I will then write the question or matter down to allow my subconscious mind to be activated to begin thinking through what the decision will be.
- The next day, or sometimes the day after ("ask me again tomorrow, okay? I will have an answer - it may come to me subconsciously or while thinking "offline" in the shower, shaving, or otherwise).
- Sometimes I know the reason for the answer I chose, and sometimes my mind has decided this for me.
- And given the choice between (a) making sure that no one has sent you anything on Facebook in the last half hour or (b) picturing yourself in the neatest place you have ever been or want to be with whoever you would prefer to have there with you, which do you choose?

Great ideas typically happen when you are "offline" from work, but not normally while you are plugged into social media activities.

The Mathematics of Investing: START EARLY



Costs Count



SAVE A LOT!! N.E.S.T. Analysis System Copyright © 2013

- 30 year old married couple
- Illustrations show the annual investments needed to achieve \$5,000,000 of inflation-adjusted retirement resources in 25, 30 and 35 years.
- How much would a 30 year old have to invest per year to have \$5,000,000 (in inflation-adjusted money)?
- HINT: Start early!
- Rate of return prior to retirement, 5% rate of return during retirement.

INVESTMENT GROWTH	8% GROWTH PER YEAR	5% GROWTH PER YEAR
55 Years Old		
Annual Investments Required:	\$193,631.94	\$142,625.75
60 Years Old		
Annual Investments Required:	\$130,374.38	\$107,835.79
65 Years Old		
Annual Investments Required:	\$90,807.66	\$82,749.90

N.E.S.T. Analysis

Need Estimated Savings Tabulation

Enter all information in the colored boxes:

Initial Set-up

Age: Husband 40, Wife 37

Years to Run: 25, 30, 35

Ending Year: 2017

Number of Children: 3

Needs:

Column 1 (i): Name Line 1, Name Line 2, Inflation Rate: 2.5%, Starting Value: \$1,200,000.00

Column 2 (ii): Name Line 1, Name Line 2, Inflation Rate: 2.5%, Starting Value: \$1,200,000.00

Column 3 (iii): Name Line 1, Name Line 2, Inflation Rate: 2.5%, Starting Value: \$1,200,000.00

Column 4 (iv): Name Line 1, Name Line 2, Inflation Rate: 2.5%, Starting Value: \$1,200,000.00

Column 5 (v): Name Line 1, Name Line 2, Inflation Rate: 2.5%, Starting Value: \$1,200,000.00

Column 6 (vi): Name Line 1, Name Line 2, Inflation Rate: 2.5%, Starting Value: \$1,200,000.00

Column 7 (vii): Name Line 1, Name Line 2, Inflation Rate: 2.5%, Starting Value: \$1,200,000.00

Column 8 (viii): Name Line 1, Name Line 2, Inflation Rate: 2.5%, Starting Value: \$1,200,000.00

Column 9 (ix): Name Line 1, Name Line 2, Inflation Rate: 2.5%, Starting Value: \$1,200,000.00

Column 10 (x): Name Line 1, Name Line 2, Inflation Rate: 2.5%, Starting Value: \$1,200,000.00

Annual Savings Calculation

Refer to Step 45 on instruction sheet

Future Amount: \$1,200,000.00

Avoiding Costly Mistakes in Medical Practice Planning

NEST Analysis Needs/Estimated Savings Tabulation

- Only enter information in "Data Input" page except for the client's name and number of years.
- Save as another file before entering ANY information whatsoever.
- Only type in shaded spaces on input page.

- Starting under *Initial Set-Up*, enter the age of the husband and wife as well as the number of years until your planned retirement and your needs reduction percentage for life insurance. Also include the actual amount of life insurance you have.
- Filling in Needs:
 - Names: In the green spaces, enter the name of your need. The green spaces are the exact size of the column on the presentation. For a better appearance, if a title is only one line, place it on line 2 rather than line 1. Suggested names are in place.
 - Inflation Rate: Enter in the percentage (up to two decimal places) of inflation on each need. If a need depreciates, simply add a hyphen in front of the number. The percentage sign will appear automatically.
 - Starting Value: Enter the Starting (year 1) value of each need. The dollar sign and two decimal places will appear automatically.
 - If you have fewer needs than the space that is given, simply leave each column blank. This will show zeros on the presentation.
 - Columns 4 and 5 have an extra entry box called *Year Expensed*. This space is used if a cost is only expended for a certain number of years (such as college). To use this function, enter in the last year the cost will be accrued.
- Filling in Resources:
 - Names: In the green spaces, enter the name of your resource. The green spaces are the exact size of the column on the presentation. For a better appearance, if a title is only one line, place it on line 2 rather than line 1. Note that column 1 is already filling in for you as Present Investments.

NEST Analysis Needs/Estimated Savings Tabulation

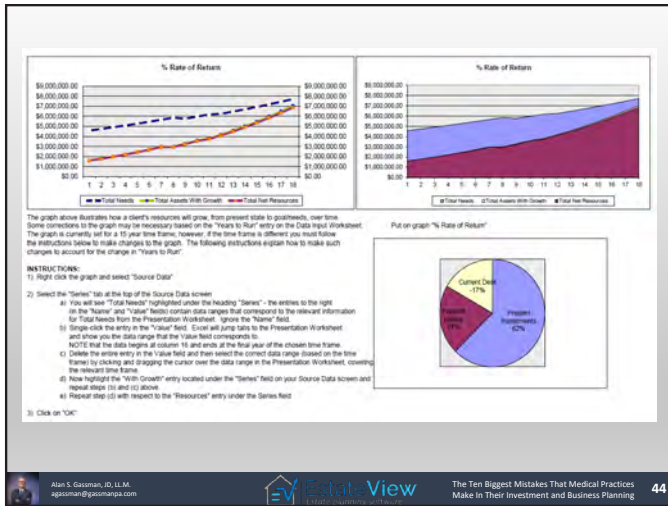
- Growth Rate: Enter in the percentage (up to two decimal places) of inflation on each resource. If a resource depreciates, simply add a hyphen in front of the number. The percentage sign will appear automatically. For the present investments column, enter the starting growth rate (the actual growth rate), and for the retirement growth rate enter in the starting growth rate minus the percentage of investments planned to be used each year after retirement.
- Starting Value: Enter in the Starting (year 1) value of each resource. The dollar sign and two decimal places will automatically appear.
- Column 5 is used to show debt that the client may have. Enter in the interest rate, debt amount, and the target year to pay off debt. If there is no debt, make sure there is still a target year. The target year with no debt amount will not affect the chart, and the chart will not function properly without it. To see how the debt is amortized, click on the purple tab that says "Debt Amortization". This shows the balances, interest amounts and principle.
- If you have fewer resources than the space that is given, simply leave a column blank. This will show as zeros on the presentation.
- Once the ages, needs and resources are entered, click the green Presentation tab. This will take you to a partially filled out spreadsheet. Check to make sure your information is properly entered. Everything up to Column 13 should be filled out at this point. You may find it helpful to hold in the row corresponding with the year you are reaching for at this point. This will be the year to reach your retirement goal.
- Calculating your Annual Addition to Investments:
 - Write down the dark red number in column 13 that is in your boldfaced target year.
 - Now return to the blue Data Input tab, and manually type in that number in the light blue space provided. The dollar sign will automatically appear.
 - On the presentation tab, there should now be a number repeating through all of the column 14 up to your target year. This number represents how much you will need to save each year in an effort to have enough money in your retirement year. The next column shows your savings growing with the same growth rate used by your Present Assets. Each year that savings number is added to that total. Your target year should match the red number in that column, and the next column should show \$0.00 as the difference in what you need and what you have.

- Printing and Sending: For best results print to Adobe as a PDF. Go to page set-up and set the chart to fit on 8.5 x 11 page. This will reduce the size of the chart and make it easier to send through mail or PDF. Be sure to print in color, the explanation letter uses colors to help the client quickly recognize columns.

N.E.S.T. Analysis Copyright 2015
Needs/Estimated Savings Tabulation

Year	Husband Age	Wife Age	1 Present Investments	2 Retirement Savings	3 Future Value	4 College	5 Wesleyan	6 Total Needs
1	52	52	\$1,350,000.00	\$750,000.00	\$2,100,000.00	\$250,000.00	\$100,000.00	\$2,450,000.00
2	53	53	\$1,365,000.00	\$765,000.00	\$2,121,000.00	\$250,000.00	\$100,000.00	\$2,471,000.00
3	54	54	\$1,380,000.00	\$780,000.00	\$2,142,000.00	\$250,000.00	\$100,000.00	\$2,492,000.00
4	55	55	\$1,395,000.00	\$795,000.00	\$2,163,000.00	\$250,000.00	\$100,000.00	\$2,513,000.00
5	56	56	\$1,410,000.00	\$810,000.00	\$2,184,000.00	\$250,000.00	\$100,000.00	\$2,534,000.00
6	57	57	\$1,425,000.00	\$825,000.00	\$2,205,000.00	\$250,000.00	\$100,000.00	\$2,555,000.00
7	58	58	\$1,440,000.00	\$840,000.00	\$2,226,000.00	\$250,000.00	\$100,000.00	\$2,576,000.00
8	59	59	\$1,455,000.00	\$855,000.00	\$2,247,000.00	\$250,000.00	\$100,000.00	\$2,597,000.00
9	60	60	\$1,470,000.00	\$870,000.00	\$2,268,000.00	\$250,000.00	\$100,000.00	\$2,618,000.00
10	61	61	\$1,485,000.00	\$885,000.00	\$2,289,000.00	\$250,000.00	\$100,000.00	\$2,639,000.00
11	62	62	\$1,500,000.00	\$900,000.00	\$2,310,000.00	\$250,000.00	\$100,000.00	\$2,660,000.00
12	63	63	\$1,515,000.00	\$915,000.00	\$2,331,000.00	\$250,000.00	\$100,000.00	\$2,681,000.00
13	64	64	\$1,530,000.00	\$930,000.00	\$2,352,000.00	\$250,000.00	\$100,000.00	\$2,702,000.00
14	65	65	\$1,545,000.00	\$945,000.00	\$2,373,000.00	\$250,000.00	\$100,000.00	\$2,723,000.00
15	66	66	\$1,560,000.00	\$960,000.00	\$2,394,000.00	\$250,000.00	\$100,000.00	\$2,744,000.00
16	67	67	\$1,575,000.00	\$975,000.00	\$2,415,000.00	\$250,000.00	\$100,000.00	\$2,765,000.00
17	68	68	\$1,590,000.00	\$990,000.00	\$2,436,000.00	\$250,000.00	\$100,000.00	\$2,786,000.00
18	69	69	\$1,605,000.00	\$1,005,000.00	\$2,457,000.00	\$250,000.00	\$100,000.00	\$2,807,000.00
19	70	70	\$1,620,000.00	\$1,020,000.00	\$2,478,000.00	\$250,000.00	\$100,000.00	\$2,828,000.00
20	71	71	\$1,635,000.00	\$1,035,000.00	\$2,499,000.00	\$250,000.00	\$100,000.00	\$2,849,000.00
21	72	72	\$1,650,000.00	\$1,050,000.00	\$2,520,000.00	\$250,000.00	\$100,000.00	\$2,870,000.00
22	73	73	\$1,665,000.00	\$1,065,000.00	\$2,541,000.00	\$250,000.00	\$100,000.00	\$2,891,000.00
23	74	74	\$1,680,000.00	\$1,080,000.00	\$2,562,000.00	\$250,000.00	\$100,000.00	\$2,912,000.00
24	75	75	\$1,695,000.00	\$1,095,000.00	\$2,583,000.00	\$250,000.00	\$100,000.00	\$2,933,000.00
25	76	76	\$1,710,000.00	\$1,110,000.00	\$2,604,000.00	\$250,000.00	\$100,000.00	\$2,954,000.00
26	77	77	\$1,725,000.00	\$1,125,000.00	\$2,625,000.00	\$250,000.00	\$100,000.00	\$2,975,000.00
27	78	78	\$1,740,000.00	\$1,140,000.00	\$2,646,000.00	\$250,000.00	\$100,000.00	\$2,996,000.00
28	79	79	\$1,755,000.00	\$1,155,000.00	\$2,667,000.00	\$250,000.00	\$100,000.00	\$3,017,000.00
29	80	80	\$1,770,000.00	\$1,170,000.00	\$2,688,000.00	\$250,000.00	\$100,000.00	\$3,038,000.00
30	81	81	\$1,785,000.00	\$1,185,000.00	\$2,709,000.00	\$250,000.00	\$100,000.00	\$3,059,000.00
31	82	82	\$1,800,000.00	\$1,200,000.00	\$2,730,000.00	\$250,000.00	\$100,000.00	\$3,080,000.00
32	83	83	\$1,815,000.00	\$1,215,000.00	\$2,751,000.00	\$250,000.00	\$100,000.00	\$3,101,000.00
33	84	84	\$1,830,000.00	\$1,230,000.00	\$2,772,000.00	\$250,000.00	\$100,000.00	\$3,122,000.00
34	85	85	\$1,845,000.00	\$1,245,000.00	\$2,793,000.00	\$250,000.00	\$100,000.00	\$3,143,000.00
35	86	86	\$1,860,000.00	\$1,260,000.00	\$2,814,000.00	\$250,000.00	\$100,000.00	\$3,164,000.00
36	87	87	\$1,875,000.00	\$1,275,000.00	\$2,835,000.00	\$250,000.00	\$100,000.00	\$3,185,000.00
37	88	88	\$1,890,000.00	\$1,290,000.00	\$2,856,000.00	\$250,000.00	\$100,000.00	\$3,206,000.00
38	89	89	\$1,905,000.00	\$1,305,000.00	\$2,877,000.00	\$250,000.00	\$100,000.00	\$3,227,000.00
39	90	90	\$1,920,000.00	\$1,320,000.00	\$2,898,000.00	\$250,000.00	\$100,000.00	\$3,248,000.00
40	91	91	\$1,935,000.00	\$1,335,000.00	\$2,919,000.00	\$250,000.00	\$100,000.00	\$3,269,000.00
41	92	92	\$1,950,000.00	\$1,350,000.00	\$2,940,000.00	\$250,000.00	\$100,000.00	\$3,290,000.00
42	93	93	\$1,965,000.00	\$1,365,000.00	\$2,961,000.00	\$250,000.00	\$100,000.00	\$3,311,000.00
43	94	94	\$1,980,000.00	\$1,380,000.00	\$2,982,000.00	\$250,000.00	\$100,000.00	\$3,332,000.00
44	95	95	\$1,995,000.00	\$1,395,000.00	\$3,003,000.00	\$250,000.00	\$100,000.00	\$3,353,000.00
45	96	96	\$2,010,000.00	\$1,410,000.00	\$3,024,000.00	\$250,000.00	\$100,000.00	\$3,374,000.00
46	97	97	\$2,025,000.00	\$1,425,000.00	\$3,045,000.00	\$250,000.00	\$100,000.00	\$3,395,000.00
47	98	98	\$2,040,000.00	\$1,440,000.00	\$3,066,000.00	\$250,000.00	\$100,000.00	\$3,416,000.00
48	99	99	\$2,055,000.00	\$1,455,000.00	\$3,087,000.00	\$250,000.00	\$100,000.00	\$3,437,000.00
49	100	100	\$2,070,000.00	\$1,470,000.00	\$3,108,000.00	\$250,000.00	\$100,000.00	\$3,458,000.00
50	101	101	\$2,085,000.00	\$1,485,000.00	\$3,129,000.00	\$250,000.00	\$100,000.00	\$3,479,000.00

Notes: 1. All values are in US Dollars. 2. All values are rounded to the nearest dollar. 3. All values are based on a 7.00% interest rate. 4. All values are based on a 7.00% inflation rate. 5. All values are based on a 7.00% growth rate. 6. All values are based on a 7.00% depreciation rate. 7. All values are based on a 7.00% amortization rate. 8. All values are based on a 7.00% annuity rate. 9. All values are based on a 7.00% bond rate. 10. All values are based on a 7.00% stock rate. 11. All values are based on a 7.00% real estate rate. 12. All values are based on a 7.00% private equity rate. 13. All values are based on a 7.00% hedge fund rate. 14. All values are based on a 7.00% venture capital rate. 15. All values are based on a 7.00% private debt rate. 16. All values are based on a 7.00% public debt rate. 17. All values are based on a 7.00% public equity rate. 18. All values are based on a 7.00% private equity rate. 19. All values are based on a 7.00% private debt rate. 20. 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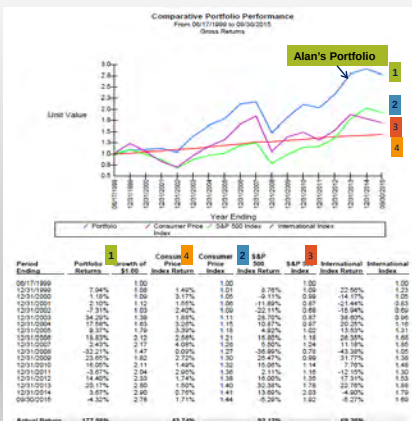


Go for Singles and Doubles, Not Home Runs!

- Beware of any investment opportunity you hear about in the doctor's lounge.
- Beware of the doctors who brag about their investments – the author knows that these are usually the doctors who lose the most money.

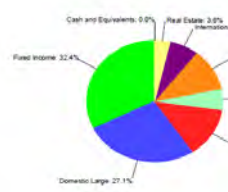
The Importance of Asset Allocation

SAMPLE PENSION REPORT



Portfolio Allocation and Statement

As of 09/30/2015



Asset	Description	Quantity	Current Price	Current Value
Cash and Equivalents	Schwab Money Market Fund			313.75
Fixed Income				
10.0%	DFA One Year Fixed Income	28,888.087	10.330	277,247.70
10.0%	DFA Ten Year Global FI	9,940	9.940	98,591.16
10.0%	Vanguard ST Bond Index Admiral	28,252.238	10.940	275,668.45
32.4%				834,997.34
Domestic Large				
13.3%	DFA U.S. Large Cap Value RI	15,734.461	22.190	347,791.72
13.3%	Vanguard Total Stock Mkt Adm	7,309.629	49.070	360,224.67
27.1%				608,006.57
Domestic Small				
8.6%	DFA U.S. Small Cap Value	4,816.145	26.430	125,509.81
8.6%	DFA U.S. Small Cap Value	5,329.23	31.430	165,811.01
13.3%				342,120.12
Emerging Markets				
8.6%	DFA Emerging Markets Core	6,970.402	15.990	142,829.39

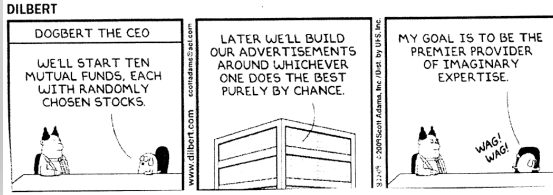
Portfolio Allocation and Statement

As of 09/30/2015

Weight	Description	Quantity	Current Price	Current Value
International Large				
6.0%	DFA International Value III	12,581.097	13.610	171,228.73
4.0%	Vanguard Developed Mkts Admiral	10,280.878	11.440	117,727.64
11.2%				288,956.37
International Small				
3.2%	DFA Intl Small Cap Value	4,616.312	18.470	83,453.22
3.6%	DFA Intl Small Co	5,519.804	16.930	93,450.28
6.9%				176,903.50
Real Estate				
3.6%	Vanguard REIT Index Admiral	879.146	107.020	94,086.20
100.0%				2,578,963.24

FORGET ABOUT TIMING THE MARKET OR FINDING A FUND THAT WILL OUTPERFORM OTHERS

"The Market Timers Hall of Fame is an empty room – the vast majority of investors who try to time the market lose significant value – the average mutual fund increases by 7% a year, but the average mutual fund investor earns only 2% a year."



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The New York Times | http://nyti.ms/WqKHP

YOUR MONEY

Who Routinely Trounces the Stock Market? Try 2 Out of 2,862 Funds

JULY 19, 2014

Strategies

By JEFF SOMMER

When the stock market rose 30 percent in 2013, plenty of fund managers had a triumphant year.

Almost anyone can post good numbers in a bull market, though. It's like sprinting downhill with the wind at your back: The chances are good that you'll be pleased with your own performance.

Outperforming most other people consistently, year in and year out, is obviously a much more difficult feat, in any competition. But how rare is it, exactly, for stock market investing?

A new study by S&P. Dow Jones Indices has some fresh and startling answers. The study, "Does Past Performance Matter? The Persistence Scorecard," provides new arguments for investing in passively managed index funds — those that merely try to match market returns, not beat them.

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Yet it won't end the debate over active versus passive investing, because it also shows that a small number of active investors do manage to turn in remarkably good streaks for fairly long periods.

The study examined mutual fund performance in recent years. It found that very few funds have been consistently outstanding performers, and it corroborated the adage that past performance doesn't guarantee future returns.

The S&P. Dow Jones team looked at 2,862 mutual funds that had been operating for at least 12 months as of March 2010. Those funds were all broad, actively managed domestic stock funds. (The study excluded narrowly focused sector funds and leveraged funds that, essentially, used borrowed money to magnify their returns.)

The team selected the 25 percent of funds with the best performance over the 12 months through March 2010. Then the analysts asked how many of those funds — those in the top quarter for the original 12-month period — actually remained in the top quarter for the four succeeding 12-month periods through March 2014.

The answer was a vanishingly small number. Just 0.07 percent of the initial 2,862 funds managed to achieve top-quartile performance for those five successive years. If you do the math, that works out to just two funds. Put another way, 99.93 percent, or 2,860 of the 2,862 funds, failed the test.

The study sliced and diced the mutual fund universe in a number of other ways, too, each time finding the same core truth: Very few funds achieved consistent and persistent outperformance. Furthermore, sustained outperformance declined rapidly over time. And the report said, "The data shows a likelihood for the best-performing funds to become the worst-performing funds and vice versa."

What should investors make of these findings? There is one clear implication, said Keith Loggie, senior director of global research and design at S&P. Dow Jones Indices.

"It is very difficult for active fund managers to consistently outperform their peers and remain in the top quartile of performance over long periods of time," he said. "There is no evidence that a fund that outperforms in one period, or even over several consecutive periods, has any greater likelihood than other funds of outperforming in the future."

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This seems to bolster the case for index-fund investing. After all, if a fund manager with a great year can't be counted on to outperform other fund managers later, it's reasonable to ask: Why bother trying to beat the market at all?

A separate series of annual S&P. Dow Jones studies has found that over extended periods, the average actively managed fund lags the average index fund. All of this may be enough to persuade you to abandon actively managed funds entirely.

But the story is more complex than that: The study also demonstrates that active managers can actually beat the market. Remember those two funds that did so consistently over the five years through March? The study didn't identify them, but at my request Mr. Loggie did.

They were the Hodges Small Cap fund and the AMG SouthernSun Small Cap fund, which were also the top two general domestic funds over the last five years through June, according to Morningstar performance rankings conducted recently for The New York Times.

Each fund has rewarded shareholders spectacularly, turning a \$10,000 investment to \$35,000 over those five years, the Morningstar data shows. By contrast, the same investment in a Standard & Poor's 500-stock index fund would have become more than \$23,000. While hardly shabby, that's not nearly as good.

I called the managers of the two funds. Both had good things to say about index funds, and about their own brand of investing.

Craig Hodges, manager of the family-run Hodges Small Cap fund, said that index funds are fine for many people, but that the intensive scrutiny his team applies to the often-neglected small- and midcap parts of the market should enable the fund to outperform the overall market in the future. "We won't do it all the time, of course," he said. "We'll have bad times. We'll make mistakes. But over the long run, I think we can keep doing very well."

Michael W. Cook, the lead manager of the SouthernSun Small Cap fund and the founder of the firm that runs it, had a similarly nuanced view.

Index funds deserve to be core holdings for many investors, he said, and despite his own fund's exceptional record, it may not be a good choice for everyone.

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"One thing you don't want to do is just read about performance numbers — ours or anybody else's — and put money into an investment," he said. "Chasing past returns doesn't make sense."

Asset allocation is crucial, Mr. Cook said. Before putting money into a fund like his, he said, ask yourself: Do you really need more small-cap stocks in your portfolio? These smaller companies can be volatile, and they may well decline in price. Janet L. Yellen, the Federal Reserve chairwoman, warned last week of "stretched" valuations for small-cap stocks.

That said, Mr. Cook spoke with the conviction of a true believer about patient, shoe-leather stock-picking discipline. He looks to buy shares in "businesses that we can own for a lifetime," he said. "We spend a lot of time understanding businesses we buy. And we keep checking them and their competitors and their industries. We need to really understand them."

Mr. Cook has closed his fund to new investors so that he can maintain control over the portfolio's quality, he said. If the fund eventually reopens, and you want to consider investing in it, he said, "You shouldn't expect that we'll perform at the very top every quarter — we won't do that, I'm pretty sure." He said that he was happy about the last five years, but that they didn't prove much.

Over the long haul, which is probably 50 years or more, he said, he will look back at his fund's track record, and he hopes he will be able to conclude: "We had a good approach. We worked hard and we did well for investors."

In the meantime, though, past performance doesn't guarantee future returns.

A version of this article appears in print on July 20, 2014, on page B6 of the New York edition with the headline: Who Routinely Trounces the Market? Try 2 Out of 2,862.

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Does Past Performance Matter? The Persistence Scorecard

Summary of Results

- Very few funds can consistently stay at the top. Out of the 667 funds that were in the top quartile as of March 2012, only 3.78% managed to stay there by the end of March 2014. Further, 1.50% of the large-cap funds, 3.16% of the mid-cap funds and 4.11% of the small-cap funds remain in the top quartile.
- For the three years ended March 2014, 14.10% of large-cap funds, 16.32% of mid-cap funds and 25.00% of small-cap funds maintained a top-half ranking over three consecutive 12-month periods. Random expectations would suggest a rate of 25%.
- An inverse relationship exists between the measurement time horizon and the ability of top-performing funds to maintain their status. It is worth noting that no large-cap or mid-cap funds managed to remain in the top quartile at the end of the five-year measurement period. The figures paint a poor picture of the lack of long-term persistence in mutual fund returns.
- Similarly, only 3.09% of large-cap funds, 3.0% of mid-cap funds and 5.48% of small-cap funds maintained top-half performance over five consecutive 12-month periods. Random expectations would suggest a repeat rate of 6.25%.
- The transition matrices track the performance of top and bottom quartile performers over subsequent time periods. The data shows a likelihood for the best-performing funds to become the worst-performing funds and vice versa. Of 420 funds that were in the bottom quartile, 26.64% moved to the top quartile over the five-year horizon, while 28.57% of those top-quartile funds moved into the bottom quartile during the same period.
- Our research also finds that there is consistency in the death rate of bottom-quartile funds. Across all market cap categories and all periods studied, fourth-quartile funds had a much higher rate of being merged or liquidated. The five-year transition matrix illustrates that 38.31% of large-cap, 39.13% of mid-cap and 45.54% of small-cap fourth-quartile funds disappeared.

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Avoiding Costly Mistakes in Medical Practice Planning

Does Past Performance Matter? The Persistence Scorecard June 2014

About the Persistence Scorecard

The phrase "past performance is not an indicator of future outcomes" (or some variation thereof) can be found in the fine print of most mutual fund literature. Yet due to either force of habit or conviction, investors and advisers consider past performance and related metrics to be important factors in fund selection. So does past performance really matter?

To answer this question on a continuous basis, the S&P Persistence Scorecard, released twice per year, tracks the consistency of top performers over yearly consecutive periods and measures performance persistence through transition matrices. As in our widely followed SPVAT Scorecards, the University of Chicago's Center for Research in Security Prices (CRSP) Survivorship Bias Free Mutual Fund Database serves as our underlying data source.

S&P Dow Jones Indices is one of the world's leading index providers, maintaining a wide variety of investable and benchmark indices to meet an array of investor needs. Our Index Research & Design team is dedicated to conducting unbiased, in-depth analysis on a broad range of topics and issues facing investors in today's marketplace. This scorecard highlights performance persistence over three- and five-year consecutive 12-month periods and two non-overlapping three- and five-year periods.

Key features of the S&P Persistence Scorecard include:

- Historical rankings without survivorship bias: For anyone making an investment decision, all funds available at the time of that decision are part of the initial opportunity set. Nevertheless, in their persistence calculations, analysts often limit their sample to funds that continue to exist over the complete time period examined, ranking only the survivors. If that happens, funds that liquidate or merge during a period of study are disregarded, biasing measurements of persistence. Using the University of Chicago's CRSP Survivorship Bias Free Mutual Fund Database, the S&P Persistence Scorecard ranks all funds available at each point in time and tracks the top-quartile and top-half performing throughout the time period. This approach accounts for all initially available funds.
- Clean universe: The mutual fund universe used in these reports comprises actively managed domestic U.S. equity funds, index funds, sector funds and index-based dynamic (bull/bear) funds are excluded from the sample. To avoid double-counting multiple share classes, only the largest share class of a fund is used.
- Transition matrices: Transition matrices show the movements between quartiles and halves over two non-overlapping three- and five-year periods. They also track the percentage of funds that have merged or liquidated. In addition, we monitor movements between capitalization levels. This helps us capture, for example, the conversion of some large-cap funds to mid- and small-cap funds.
- Tracking reports of top performers: The tracking reports show the percentages of funds that remain in the top-quartile or top-half rankings over three- and five-consecutive-year periods.

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Real Estate

- Leveraged real estate for your own office may be a fantastic investment if you do not overpay.
- Getting into real estate deals with other people who are not shoulder to shoulder in income, net worth, and ethics is almost always a bad idea. Never get into a multiple party deal without careful and thoughtful legal and business counseling.

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Partnership v. S Corporation- Which is Better to Hold Real Estate?

PARTNERSHIP	S CORPORATION
Advantages 😊	and Disadvantages 😞
Partners receive basis for indebtedness incurred by the partnership 😊	DOI income insolvency exclusion is determined at the corporate level. 😊
On the death of a partner, the partnership's (inside) tax basis of its assets can receive a step-up in income tax basis, if a Section 754 election is in place for the partnership 😊	No similar basis adjustment mechanism applies to S corporations. 😞
When a new partner buys into a partnership corporation, their depreciation write-off and underlying basis in their partnership interest will be based upon the price that they pay. 😊	When a new shareholder buys into an S corporation, their depreciation write-off and underlying basis if and when the real estate is ever sold has to be based upon the historic basis and depreciation taken, versus being based upon the price they pay. 😞
Appreciated real property can generally be distributed from the partnership tax-free to the partners. 😊	Distributions of appreciated real property to the shareholders are treated as if the property was sold at its fair market value to the shareholders. 😞
No restrictions apply as to who can own partnership interests. 😊	S corporations can only be owned by certain individuals and trusts, and cannot be owned non-resident aliens, corporations or partnerships 😞
Partnerships can have more than one class of stock, and income and distribution preferences can be drafted in virtually any manner, so long as they have substantial economic effect 😊	S corporations cannot have a "second class of stock," and income allocation and distribution rights must be pro rata to ownership 😞
DOI income insolvency exclusion is determined at each partner's level. 😞	Shareholders do not receive basis for indebtedness incurred by the corporate, unless the loan is made by such shareholder. 😞

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WISDOM ABOUT YOUR HOME

- Buying a completed home from a reputable contractor or builder with excellent warranties, after close inspection, is acceptable.
- Buying a home that you will remodel anytime soon, or building your own home, can be a much more expensive, unpredictable and stressful experience.
- Buying a used home with close inspection that includes review for mold and Chinese wallpaper is normally the best move.
- Please see a psychologist before concluding that you need more than 3,500 square feet to live a comfortable life with your family. Anything over 3,500 square feet is luxury or for in-laws or more than two children.
- One of the best things about any house is who the neighbors are. It may be a great strategy to raise your children in an upper middle class environment, and not in a "rich people only" gated community.
- Your home will grow in value at less than average, because your home is one year older every year.

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WISDOM ABOUT YOUR HOME, CONTINUED

- 1 divided by 60 years is 1.667% depreciation per year. If houses are going up by 4% a year, then your house is going up in value by 2.33% a year, and you have to maintain it!
- If acquisition and selling costs are 10%, then you have to live in the home 4.3 years on average to recoup the cost of buying and selling it.
- "I would rather rent than own" is not a bad conclusion if you would otherwise buy a house that is too small or not where you will eventually settle.
- Statistically speaking, there is as much chance of losing money as there is in making money if you will hold a house for less than 4 years.
- The money you set aside for your future "dream home" in ten years will hopefully grow at a much higher rate than 2.33% per year. A long term conservatively allocated stock and bond or mutual fund equivalent portfolio may average 10% over ten or twenty years by comparison, and doesn't leak when it rains, develop mold, or need to be repainted or redecorated.

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The Ten Biggest Mistakes That Medical Practices Make In Their Investment and Business Planning 60

If It's Too Good To Be True, It Probably Is

Do Not Be a “Gambleaholic”

- Gauge whether you or a family member has a gambling addiction – the need to invest often and to try to get high rates of return triggers dopamine and merits therapy to avoid repeated bankruptcy's.
- “Spendaholism” is related to this.
- Cultivate the dopamine hit that you can derive from a high savings rate. Are you tracking your monthly spending and savings?
- Shopaholism works the same way...as does “Look at what I have!” – I can't feel important without it.

ADVERTISING and THE END OF THE WORLD

Sit down with your family and watch the YouTube video by Professor Sut Jhally of the University of Michigan by the above title. Do you buy what you want, or what advertisers told you that you want.

See also – *Killing Us Softly* - by Professor Jean Kilbourne

Do Not Set Up a Non-Medical Related Business

Do not let your spouse or significant other open up a business unless it pays for itself just about from the beginning. Even a break-even business will take a tremendous psychological and financial toll on a family and a relationship.

Life Insurance Investments and Savings



Buying Term Insurance

- You can ask an independent agent who writes for many carriers to have the client take the physical so that they can get quotes from several carriers.
- You can ask that all results and quotes be confidential and not given to the bureau that all carriers belong to and share information with. Once a carrier turns the client down or “rates” the client all other carriers know.
- This is called an “informal application” and then the carriers can each give informal quotes for term coverage. If the client likes the quote then he or she can buy it.
- You might spread this among 2 or 3 carriers in case one goes under.
- Better to buy 6 \$500,000 policies than one \$3,000,000 policy- with separate carriers for financial security. You can't reduce the amount of coverage in a life insurance policy once purchased, but you can terminate smaller policies to adjust coverage downward when appropriate.
- Sample term rates for “preferred”, “standard” and “standard smoker” individuals are as follows:

BUYING TERM INSURANCE

AGE 30						
	PREFERRED		STANDARD		STANDARD SMOKER	
	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE
10 Year Term	\$378	\$328	\$658	\$518	\$1,548	\$1,218
15 Year Term	\$458	\$398	\$768	\$688	\$1,918	\$1,438
20 Year Term	\$608	\$478	\$968	\$738	\$2,278	\$1,638
30 Year Term	\$938	\$768	\$1,518	\$1,218	\$3,908	\$3,018

35 Year Old (Per \$1,000,000 of Coverage)

AGE 35						
	PREFERRED		STANDARD		STANDARD SMOKER	
	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE
10 Year Term	\$375	\$345	\$735	\$565	\$1,685	\$1,345
15 Year Term	\$515	\$415	\$915	\$805	\$2,135	\$1,775
20 Year Term	\$665	\$565	\$1,105	\$945	\$2,885	\$2,265
30 Year Term	\$1,015	\$825	\$1,735	\$1,375	\$4,705	\$3,555

Avoiding Costly Mistakes in Medical Practice Planning

BUYING TERM INSURANCE

AGE 40

	PREFERRED		STANDARD		STANDARD SMOKER	
	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE
10 Year Term	\$505	\$435	\$925	\$785	\$2,405	\$2,005
15 Year Term	\$655	\$575	\$1,215	\$1,035	\$3,125	\$2,485
20 Year Term	\$865	\$745	\$1,505	\$1,255	\$4,345	\$3,185
30 Year Term	\$1,495	\$1,135	\$2,465	\$1,985	\$7,175	\$5,275

AGE 50

	PREFERRED		STANDARD		STANDARD SMOKER	
	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE
10 Year Term	\$1,235	\$1,025	\$2,145	\$1,625	\$6,435	\$4,295
15 Year Term	\$1,785	\$1,235	\$2,805	\$2,065	\$7,825	\$5,725
20 Year Term	\$2,225	\$1,625	\$3,425	\$2,715	\$10,425	\$6,865
30 Year Term	\$4,025	\$2,645	\$6,245	\$4,785	\$13,715	\$10,109

AGE 60

	PREFERRED		STANDARD		STANDARD SMOKER	
	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE
10 Year Term	\$3,098	\$2,198	\$4,808	\$3,278	\$13,028	\$8,308
15 Year Term	\$4,488	\$3,048	\$7,088	\$5,218	\$17,658	\$12,978
20 Year Term	\$5,798	\$4,078	\$9,488	\$6,668	\$22,048	\$15,058
30 Year Term	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available

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The Ten Biggest Mistakes That Medical Practices Make In Their Investment and Business Planning

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Ultra Plus Flexible Premium Adjustable Life Insurance (Form UL0700 Series)

LINCOLN BENEFIT LIFE AN ALLSTATE COMPANY

Prepared For:
Valued Client
Male, Age 50
Preferred Life

Plan Details:
Initial Face Amount: \$1,000,000
Initial Death Benefit Option: 1
Initial Premium Outlay: \$5,785.78

Yr. Age	Annual Premium Outlay	Net Distr.	Guaranteed Values		Non-Guaranteed Values	
			Policy Value	Net Surrender Value	Policy Value	Net Surrender Value
1	5,786	0	4,430	0	1,000,000	4,508
2	5,786	0	8,430	0	1,000,000	9,238
3	5,786	0	12,430	0	1,000,000	14,180
4	5,786	0	17,352	5,202	1,000,000	19,357
5	5,786	0	21,986	9,836	1,000,000	24,809
6	5,786	0	26,716	15,417	1,000,000	30,481
7	5,786	0	31,910	21,340	1,000,000	36,822
8	5,786	0	37,198	27,478	1,000,000	43,476
9	5,786	0	42,564	33,694	1,000,000	50,439
10	5,786	0	48,021	39,881	1,000,000	58,023
11	5,786	0	53,544	46,254	1,000,000	66,011
12	5,786	0	59,118	52,798	1,000,000	74,413
13	5,786	0	64,717	59,006	1,000,000	83,254
14	5,786	0	70,315	65,455	1,000,000	92,536
15	5,786	0	75,895	71,886	1,000,000	102,293
16	5,786	0	81,442	78,162	1,000,000	112,518
17	5,786	0	86,956	84,526	1,000,000	123,250
18	5,786	0	92,477	90,897	1,000,000	134,535
19	5,786	0	98,041	97,191	1,000,000	146,430
20	5,786	0	103,618	103,618	1,000,000	158,940
21	5,786	0	109,312	109,312	1,000,000	166,097
22	5,786	0	115,032	115,032	1,000,000	173,518
23	5,786	0	120,778	120,778	1,000,000	181,253
24	5,786	0	126,549	126,549	1,000,000	189,246
25	5,786	0	132,345	132,345	1,000,000	197,492
26	5,786	0	138,166	138,166	1,000,000	206,321
27	5,786	0	144,012	144,012	1,000,000	215,470
28	5,786	0	149,883	149,883	1,000,000	224,923
29	5,786	0	155,779	155,779	1,000,000	234,772
30	5,786	0	161,699	161,699	1,000,000	244,980

This Illustration is for illustrative purposes only; nothing herein is a contractual obligation.

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LHL 7300

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The Ten Biggest Mistakes That Medical Practices Make In Their Investment and Business Planning

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Ultra Plus Flexible Premium Adjustable Life Insurance (Form UL0700 Series)

LINCOLN BENEFIT LIFE AN ALLSTATE COMPANY

Prepared For:
Valued Client
Male, Age 50
Preferred Life

Plan Details:
Initial Face Amount: \$1,000,000
Initial Death Benefit Option: 1
Initial Premium Outlay: \$5,785.78

Yr. Age	Annual Premium Outlay	Net Distr.	Guaranteed Values		Non-Guaranteed Values	
			Policy Value	Net Surrender Value	Policy Value	Net Surrender Value
31	0	0	65,211	65,211	1,000,000	266,487
32	0	0	65,211	65,211	1,000,000	277,742
33	0	0	65,211	65,211	1,000,000	289,271
34	0	0	65,211	65,211	1,000,000	301,165
35	0	0	65,211	65,211	1,000,000	313,373
36	0	0	65,211	65,211	1,000,000	325,918
37	0	0	65,211	65,211	1,000,000	338,829
38	0	0	65,211	65,211	1,000,000	352,122
39	0	0	65,211	65,211	1,000,000	365,810
40	0	0	65,211	65,211	1,000,000	379,865
41	0	0	65,211	65,211	1,000,000	394,261
42	0	0	65,211	65,211	1,000,000	408,963
43	0	0	65,211	65,211	1,000,000	423,982
44	0	0	65,211	65,211	1,000,000	439,359
45	0	0	65,211	65,211	1,000,000	455,143
46	0	0	65,211	65,211	1,000,000	471,373
47	0	0	65,211	65,211	1,000,000	488,087
48	0	0	65,211	65,211	1,000,000	505,321
49	0	0	65,211	65,211	1,000,000	523,111
50	0	0	65,211	65,211	1,000,000	541,493
51	0	0	65,211	65,211	1,000,000	560,507
52	0	0	65,211	65,211	1,000,000	580,186
53	0	0	65,211	65,211	1,000,000	600,569
54	0	0	65,211	65,211	1,000,000	621,696
55	0	0	65,211	65,211	1,000,000	643,597
56	0	0	65,211	65,211	1,000,000	666,304
57	0	0	65,211	65,211	1,000,000	689,848
58	0	0	65,211	65,211	1,000,000	714,269
59	0	0	65,211	65,211	1,000,000	739,597
60	0	0	65,211	65,211	1,000,000	765,863

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The Ten Biggest Mistakes That Medical Practices Make In Their Investment and Business Planning

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Buy Term; Invest the Rest

Age	Total Universal Life Premiums Paid	Total Term Premiums Paid	Yearly Amount Invested	Cumulative Amount Invested	Annual Net Difference Invested at 8%	Annual Net Difference Invested at 8%	Guaranteed Net Surrender Value	Non-Guaranteed Net Surrender Value	Savings at 8% if Projections Pan Out
31	\$5,786	\$700	\$5,086	\$5,086	\$5,340	\$0	\$0	\$0	\$5,493
32	\$11,572	\$1,400	\$10,172	\$11,215	\$11,865	\$0	\$0	\$0	\$11,865
33	\$17,358	\$2,100	\$15,258	\$17,383	\$18,746	\$887	\$2,030	\$18,716	\$18,716
34	\$23,144	\$2,800	\$20,344	\$23,869	\$26,178	\$5,202	\$7,207	\$18,971	\$18,971
35	\$28,930	\$3,500	\$25,430	\$30,659	\$34,205	\$9,836	\$12,659	\$21,546	\$21,546
36	\$34,716	\$4,200	\$30,516	\$37,800	\$42,873	\$15,417	\$19,182	\$24,691	\$24,691
37	\$40,502	\$4,900	\$35,602	\$44,297	\$52,236	\$21,340	\$26,252	\$28,584	\$28,584
38	\$46,288	\$5,600	\$40,688	\$50,985	\$62,347	\$27,478	\$33,756	\$32,591	\$32,591
39	\$52,074	\$6,300	\$45,774	\$57,435	\$73,287	\$33,694	\$41,570	\$36,697	\$36,697
40	\$57,860	\$7,000	\$50,860	\$64,698	\$84,986	\$39,881	\$49,881	\$40,881	\$40,881
41	\$63,646	\$7,700	\$55,946	\$72,227	\$97,798	\$46,254	\$58,721	\$47,721	\$47,721
42	\$69,432	\$8,400	\$60,032	\$80,795	\$111,554	\$52,798	\$68,011	\$53,798	\$53,798
43	\$75,218	\$9,100	\$65,118	\$89,643	\$126,410	\$59,006	\$77,544	\$60,244	\$60,244
44	\$81,004	\$9,800	\$71,204	\$98,963	\$142,455	\$65,455	\$87,679	\$66,779	\$66,779
45	\$86,790	\$10,500	\$76,290	\$109,060	\$159,784	\$71,886	\$98,284	\$72,784	\$72,784
46	\$92,576	\$11,200	\$81,376	\$120,000	\$178,499	\$78,162	\$109,234	\$79,234	\$79,234
47	\$98,362	\$11,900	\$86,462	\$131,312	\$198,711	\$84,526	\$120,587	\$85,587	\$85,587
48	\$104,148	\$12,600	\$91,548	\$143,135	\$220,541	\$90,897	\$132,556	\$91,556	\$91,556
49	\$109,934	\$13,300	\$96,634	\$155,599	\$244,116	\$97,191	\$145,589	\$97,889	\$97,889
50	\$115,720	\$14,000	\$101,720	\$168,699	\$269,578	\$103,618	\$159,246	\$104,246	\$104,246
51	\$121,506	\$14,700	\$106,806	\$182,405	\$296,923	\$110,312	\$174,518	\$110,518	\$110,518
52	\$127,292	\$15,400	\$111,892	\$196,817	\$325,269	\$117,518	\$190,804	\$117,804	\$117,804
53	\$133,078	\$16,100	\$117,978	\$211,935	\$354,626	\$124,923	\$208,129	\$125,129	\$125,129
54	\$138,864	\$16,800	\$122,064	\$227,765	\$385,003	\$132,742	\$226,584	\$132,784	\$132,784
55	\$144,650	\$17,500	\$127,150	\$243,335	\$416,409	\$140,861	\$246,189	\$140,861	\$140,861
56	\$150,436	\$18,200	\$132,236	\$259,767	\$448,854	\$149,284	\$266,944	\$149,284	\$149,284
57	\$156,222	\$18,900	\$137,322	\$276,969	\$482,349	\$158,011	\$288,859	\$158,011	\$158,011
58	\$162,008	\$19,600	\$142,408	\$294,937	\$516,894	\$167,046	\$311,924	\$167,046	\$167,046
59	\$167,794	\$20,300	\$147,494	\$313,767	\$552,509	\$176,393	\$337,259	\$176,393	\$176,393
60	\$173,580	\$21,000	\$152,580	\$333,347	\$589,194	\$186,046	\$363,804	\$186,046	\$186,046

* Note - Term life insurance lapses after age 60 leaving dollar unearned

Illustrations show a 20-Pay universal life policy, along with a 30-year term life policy on a 30 year old healthy, non-smoking male

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The Ten Biggest Mistakes That Medical Practices Make In Their Investment and Business Planning

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Disability Statistics

- A disability can happen to anyone...at any time.
- In 2007, 12.8% of people between the ages of 21-64 surveyed have a disabling illness. (U.S. Census Bureau)
- You have a 1 in 21 chance that you will have a disabling accident. (2005 Field Guide to Estate Planning)
- In the last 10 minutes, 498 Americans became disabled. (2008 National Safety Council Injury Facts)
- Almost 3 in 10 workers entering the workforce today will become disabled before retirement. (2007 Social Security Administration Fact Sheet)
- Over 85% of disabling accidents and illnesses are not work related. (2008 National Safety Council Injury Facts)
- Stroke is the leading cause for long-term disability. (2007 Centers for Disease Control)

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Individual Disability Insurance The most flexible and reliable source of coverage is an individual disability insurance policy you purchase on your own. A privately owned policy is portable, meaning you won't have to worry about losing coverage if you change jobs. Generally, most individual policies pay between 40% to 65% of your pre-disability gross salary. When paid with after-tax dollars, benefits are received income tax free.

KEY TERMS

When considering your disability insurance needs, you should be familiar with the following:

Benefit level and period Disability policies usually pay from 40% to 65% of your pre-disability earnings at the time of purchase for a specified period of time. That period may run from one to five years, until age 65, or in some cases, for life.

Elimination period There usually is a waiting period, known as an elimination period, before benefits kick in. It's typically 30 days, 90 days or six months after a disability occurs. You can select the waiting period when you buy your policy. Opting for a longer waiting period reduces the premium cost.

Definition of disability Some policies pay if you're unable to perform the duties of your own occupation; others pay only if you can't work at any occupation for which you're reasonably qualified. In addition, some policies pay only for disabilities arising from an accident.

Extent of disability Some policies pay only if you are totally disabled. Others may cover partial disability for a limited time, but only when it follows a period of total disability for the same cause.

Residual benefits If you're unable to perform some aspects of your job, residual benefits allow partial disability payments based on the amount of your lost income.

Guaranteed renewable One of two major types of disability policies, it means your policy can't be cancelled as long as the premiums are paid. Premiums can be raised for an entire class of policyholders but not for reasons related to your individual circumstances.

Non-cancelable The other major type of disability policy, these policies can never be cancelled as long as premiums are paid, and premiums are guaranteed not to increase.

Inflation protection You can typically add a cost-of-living adjustment rider to an individual disability insurance policy that increases benefits by a specified percentage after each year of disability. Though expensive, this option can be vital to maintaining your standard of living if you're out of work for an extended period of time.

SAVINGS WILL NOT SEE MOST WORKERS THROUGH A DISABILITY FOR LONG

Average Savings in Months of Pre-Disability Income

Source: U.S. Census Bureau, Income, Program and Participation

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How Much is Enough?

Will you be able to maintain your current standard of living if you become disabled? This essential tool to answer that question is to add up your monthly living expenses and compare them with the income you could expect from your existing disability coverage, plus any income you count on from other sources, such as personal savings. If your income from all sources won't be enough to support you and your family, consider buying additional disability insurance—either through work or on your own—to make up the difference.

Use our Disability Insurance Needs Worksheet as a starting point for your calculations. Some things to keep in mind when going through the numbers:

- Employee-paid disability benefits are typically taxable. Estimate the after-tax amount of these benefits when assessing your level of income.
- Benefits from your employer's group plan or a personal disability policy may be reduced by the amount of Social Security or other government benefits you're receiving.
- You may be eligible for disability payments from other sources, such as Veterans Administration, civil service benefits or your union's group disability plan. In addition, some auto insurance policies cover disability resulting from an auto accident. Some lenders also offer insurance that takes care of your loan payments if you become disabled.

DISABILITY INSURANCE NEEDS WORKSHEET

This simple worksheet lets you assess the income needed to sustain your current standard of living should you become disabled or a qualified insurance professional.

Monthly Income Available

Income from current group disability coverage	\$ _____
Income from current individual disability coverage	\$ _____
Income from spouse and/or other family members	\$ _____
Monthly investment income	\$ _____
TOTAL MONTHLY INCOME AVAILABLE*	\$ _____

Monthly Expenses

Mortgage (including property tax) or rent	\$ _____
Homeowner's or renter's insurance	\$ _____
Car payments and insurance	\$ _____
Utilities	\$ _____
Food and clothing	\$ _____
Child care expenses	\$ _____
Health and dental care	\$ _____
Medical expenses	\$ _____
Health (including personal)	\$ _____
Insurance premiums (life, disability, dental, etc.)	\$ _____
Savings, investment and retirement contributions	\$ _____
Home maintenance costs	\$ _____
Other (education, entertainment, etc.)	\$ _____
TOTAL MONTHLY EXPENSES*	\$ _____

INCOME - EXPENSES

Result for additional income replacement due to a disability

* Does not include 40% of your net change premium.
* Does not include 40% of your net change premium.
* Does not include 40% of your net change premium.
* Does not include 40% of your net change premium.

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NEW & NEWSWORTHY

Disability Income

MetLife Disability Income Underwriting Guidelines for Physicians & Dentists

MetLife Disability Income (DI) wants to help you grow your business and provide your clients with the right amount of coverage. To that end, we have introduced new, higher, issue and participation limits for physicians and dentists.

These enhancements apply to the 4M and 5I occupational classes. The table below also includes limits for the 5S and 5D occupational classes.

OCCUPATIONAL CLASS	AGE	ISSUE & PARTICIPATION LIMITS
Occupations with Non-Exempt Duties	35	Male Issue: \$10,000/mo. + Female Issue: \$10,000/mo. +
		Male Issue: \$10,000/mo. + Female Issue: \$10,000/mo. +
Occupations with Exempt Duties	35	Male Issue: \$10,000/mo. + Female Issue: \$10,000/mo. +
		Male Issue: \$10,000/mo. + Female Issue: \$10,000/mo. +
Occupations with Exempt Duties	45	Male Issue: \$10,000/mo. + Female Issue: \$10,000/mo. +
		Male Issue: \$10,000/mo. + Female Issue: \$10,000/mo. +
Occupations with Exempt Duties	55	Male Issue: \$10,000/mo. + Female Issue: \$10,000/mo. +
		Male Issue: \$10,000/mo. + Female Issue: \$10,000/mo. +

Physician Occupational Class Information: For some medical occupations, a factor in determining the appropriate occupational class is whether or not the individual is performing invasive, interventional or surgical duties. The reverse side provides a description of the terms used by MetLife's DI Underwriting Department to determine the extent of a client's invasive, interventional or surgical duties.

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How to Find a Good Financial Planner

- Do not use the ones who approach you.
- Life insurance people are compensated differently.
- Consider a low cost "fee for service" program or trust company program where the advisor and firm is paid based upon a percentage of assets, without incentive to make decisions based upon how they are compensated or a long term hold advisor.
- In Europe commissions have to be disclosed up front. In the United States commissions do not have to be disclosed up front, and will probably never be illegal.
- Any fee for service relationship must be absolute – the person and company must agree not to accept a commission on any product, or a kickback or remuneration on any life insurance, annuity, or other commission-based product that they may be asked to opine on.

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Use an Independent Qualified CPA

- Stay away from CPA firms that sell investments or that are "pushy" about having you attend seminars or getting introduced to specific products that they derive commissions from or have cross-referral relationships that "necessitate" pushing clients into higher cost investments.
- "I used to work for the IRS" is not necessarily a good thing to hear.

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Qualifications of the Lawyer Who Helps You

We have a bias with respect to selection of legal counsel for practicing physicians, but also a rationale and track history to back this up. In our opinion, the vast majority of physicians are best served by having a qualified tax lawyer who understands estate planning, business law, creditor protection rules, and when other specialist lawyers are needed.

While there are creditor protection lawyers who can put together solid plans for a practicing physician, "creditor protection" is not a recognized legal specialty among board certification, law school curricula, or established and well-respected academics and other organizations. The bankruptcy law organizations are firmly established and respectable, but bankruptcy lawyers have no special background or training on how income tax, estate planning, and business structures are to work from a corporate compliance, tax, or healthcare law standpoint.

The typical tax lawyer has special training that often will include a one year post-law degree in taxation or estate planning. This is called an LL.M. (Master of Laws) degree, and the vast majority of lawyers do not have one. Many of the LL.M. schools are very selective, and according to most reports (including the U.S. News Law School Reports), the very best LL.M. schools for tax lawyers are (1) New York University, (2) University of Florida, and (3) Georgetown University. It is possible for a lawyer to be well qualified in the above areas without having an LL.M. degree, but this is increasingly rare, given the time demands on graduating lawyers and the continued acceleration of complexity in these areas.

Estate planning, tax, and creditor protection continuing education programs simply do not provide the depth of a graduate law school program, so it is unusual, though not unheard of, for a lawyer without an educational tax background to have mastered the appropriate areas.

Most lawyers will not be able to become tax lawyers because of the detailed nature of the tax law, which is considered by many to be mundane and beyond comprehension (while some of us are nerdy/studious enough to make it not only our profession but also a hobby).

Many physicians have excellent attorneys who know almost nothing about taxation, estate planning, and creditor protection. If those lawyers are willing and able to work closely with a qualified lawyer who knows and understands these areas, the clients will be fine.

Often, however, we find that lawyers do not have a good sense of "knowing what they don't know." This often catches doctors off guard and can cause the loss of precious assets, not to mention precious sleep.

Further discussion on advisor coordination and common mistakes made with respect to the use of (or abuse by) advisors can be found in our book *The Florida Physician's Guide to Creditor Protection*, which can be found on amazon.com and can be downloaded to your iPad, Kindle, Nook or other favorite device.

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OPTIMIZE QUALIFIED PLAN CONTRIBUTIONS

Confer with a Good Actuary

- Quite often clients are underserved with respect to retirement planning. This is often the result of product or general brokerage houses and banks that sponsor simple retirement plans without extensively trained planned design and maintenance personnel.
- One example is the possible use of a 401(k) plan that uses the 3% safe harbor. Such a plan can be set up so that the 3% contribution is not required. The client can decide before the end of each year whether the safe harbor contribution will be made for the year, and must give notice to all participants by the end of November stating whether or not the 3% contribution will be made. This is often known as the "flexible safe harbor" or "maybe safe harbor" or "wait and see safe harbor plan." Many physician groups should be checking with their pension advisors to see if their plan has the flexible safe harbor feature. A plan with a required safe harbor match cannot be managed on a flexible basis.
- Appropriate pension planning can also include cross-testing and defined benefit planning.



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[illegible]

Optimize Qualified Plan Contributions

(courtesy of Jim Feutz, Suncoast Pension & Benefits Group, Inc.)

- On the following page, we have an example of an allocation of benefits as provided by a physician, his spouse who is the account manager for the practice, and 4 employees, using a flexible 401(k) plan.
- This client had been told that “all that they could do economically” was a SIMPLE IRA Plan because the client has four other full time employees.
- As shown on the following page, the physician and his wife would benefit from 89% of the plan contributions, with the four other employees sharing 11%, part of which is subject to vesting requirements of 20% per year over 5 years. Most physician groups would not be aware of this type of opportunity.

Optimize Qualified Plan Contributions

(courtesy of Jim Feutz, Suncoast Pension & Benefits Group, Inc.)

Flexible 401(k) Plan for Charles Allen, M.D., P.A.

Name	Position	Earnings	Age	Employee Deferrals	Profit Sharing	Total to Employee	Employer CostX	% of Total
Charles Allen	Owner	250,000	46	17,000	33,000	50,000	50,000	62.7
Ann Allen	Mgr	82,000	46	17,000	4,100	21,100	21,100	26.5
Sub-Total		332,000		34,000	37,100	71,100	71,100	89.2
Jan Brown	Staff	76,267	47	763	3,813	4,576	3,813	4.8
Mindy Garcia	Staff	24,980	43	250	1,249	1,499	1,249	1.6
Alice Jenkins	Staff	39,503	29	395	1,975	2,370	1,975	2.5
Sue Mayfair	Staff	18,960	40	190	1,555	1,745	1,555	1.9
Sub-Total		159,710		1,598	8,592	10,190	8,592	10.8
Total		491,710		35,598	45,692	81,290	79,692	100.0

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Optimize Qualified Plan Contributions

(courtesy of Jim Feutz, Suncoast Pension & Benefits Group, Inc.)

- The following page is an example where the owner employs her son. Note that the physician is able to get the maximum \$55,500 (since she is over 50) even though she only takes compensation of \$130,000.
- The plan also covers Ann Mitchell, a highly compensated assistant, who is not an owner. If desired the plan could totally exclude Mitchell which would reduce the contribution by \$3,630.

Optimize Qualified Plan Contributions

(courtesy of Jim Feutz, Suncoast Pension & Benefits Group, Inc.)

Flexible 401(k) Plan for Mary Johnson, M.D., P.A.

Name	Position	Earnings	Age	Employee Deferrals	Profit Sharing	Total to Employee	Employer Cost	% of Total
Mary Johnson	Owner	130,000	61	22,500	33,000	55,500	55,500	60.5
Ron Johnson	Mgr	70,000	36	17,000	5,250	22,250	22,250	24.2
Sub-Total		200,000		39,500	38,250	77,750	77,750	84.7
Susan Brown	Staff	39,000	61	1,000	1,950	2,950	1,950	2.1
Bill Castor	Staff	43,000	32	1,000	2,150	3,150	2,150	2.3
Sally Martin	Staff	47,000	31	1,000	2,350	3,350	2,350	2.6
Amy Truax	Staff	40,000	30	1,000	2,000	3,000	2,000	2.2
Julia Wilde	Staff	39,000	42	1,000	1,950	2,950	1,950	2.1
Ann Mitchell	Tech	121,000	53	2,000	3,630	5,630	3,630	4.0
Sub-Total		329,000		7,000	14,030	21,030	14,030	15.3
Total		529,000		46,500	52,280	98,780	91,780	100.0

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Optimize Qualified Plan Contributions (courtesy of Jim Feutz, Suncoast Pension & Benefits Group, Inc.)

Flexible 401(k) Plan for Smith & Jones, M.D.'s, P.A.

Name	Position	Earnings	Age	Employee Deferrals	Profit Sharing	Total to Employee	Employer Cost	% of Total
Art Jones	Owner	200,000	56	22,500	33,000	55,500	55,500	42.9
Bill Smith	Owner	200,000	50	22,500	33,000	55,500	55,500	42.9
Sub-Total		400,000		45,000	66,000	111,000	111,000	85.8
Nan Andrews	Staff	33,000	28	1,000	1,650	2,650	1,650	1.3
Ali Connors	Staff	26,000	29	1,000	1,300	2,300	1,300	1.0
Beth Davis	Staff	36,000	51	1,000	1,800	2,800	1,800	1.4
Gwen Garner	Staff	90,000	39	3,000	4,500	7,500	4,500	3.4
Mary Howell	Staff	52,000	32	1,000	2,600	3,600	2,600	2.0
Deb Randall	Staff	96,000	49	3,000	4,800	7,800	4,800	3.7
Ann Thomas	Staff	36,000	67	1,000	1,800	2,800	1,800	1.4
Sub-Total		369,000		11,000	18,450	29,450	18,450	14.2
Total		769,000		56,000	84,450	140,450	129,450	100.0

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Choices and Factors with Respect to Allocation & Payment of Medical Practice Income for the Practitioner

PAYEE	CREDITOR PROTECTED IN FLORIDA?	Current Taxes/Expenses	Tax Cuts and Jobs Act
Pension Plans	Yes	Costs for staff and to maintain plan – spouse on payroll to justify additional contribution. Highest tax – 39.6%. Nonqualified plans subject to 3.8% Medicare tax	Highest tax bracket is 37%.
Children on the Payroll	Yes – If goes to Roth IRA in the name of the child.	Child in lower rate (lowest bracket – 10%) but 15.3% employment taxes apply.	Lowest bracket will be 10%. Standard Deduction = \$12,000 Single or \$24,000 MFJ
Wages paid to Doctor	If Head of Household, Florida Statute 222 may apply – deposit directly into protected account.	15.3% employment taxes on first \$127,200, and then 2.9% over \$127,200 plus .3% tax on wages exceeding \$200,000 for single person and \$250,000 for married joint filers.	Repeal of additional 0.9% tax not mentioned in new Act
Dividends to owner of entity.	Only if owner is protected – such as tenants by the entirety or a family limited partnership owning the entity.	Not subject to payroll taxes – but could be recharacterized by IRS, and not subject to the 3.8% Medicare tax unless distributions represent income from passive sources.	Business Income Deduction of 20% of Qualified Income Repeal of 3.8% Medicare tax not mentioned in new Act
Spouse on payroll.	Yes, if spouse is safe.	15.3% employment taxes on first \$127,200, and then 2.9% over \$127,200 plus .3% tax on wages exceeding \$200,000 for single person and \$250,000 for married joint filers.	Repeal of additional 0.9% tax not mentioned in new Act
Rent	Yes, if renting entity is protected. They protect PA assets if landlord has lien to enforce rent on long-term lease.	6.8% sales tax Subject to the 3.8% Medicare tax for single taxpayers with MAGI over \$200,000 and MFJ taxpayers with MAGI over \$250,000.	Repeal of 3.8% Medicare tax not mentioned in new Act State sales tax is reduced to 5.8% on commercial real property rentals
Interest owed to related parties.	If related party is protected.	Deductible as interest – receding party pays interest income.	Interest expense not eliminated.

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PRACTICE AND BUSINESS ENTITIES AND HOW THEY CAN BE TAXED

REGULAR CORPORATION OR PROFESSIONAL ASSOCIATION	LLC OR LP OR LIMITED PARTNERSHIP (LP) OR LLP	GENERAL PARTNERSHIP OR LIMITED LIABILITY PARTNERSHIP (LLP)
1. Taxed as S corporation or C corporation. 2. S corporations pay no tax unless they used to be a C corporation and certain circumstances exist. The income and deductions of an S corporation flow through to the shareholders pro rata to ownership. 3. A C corporation is taxed as a separate entity and if it is a professional service company, all net income is taxed at the highest bracket (21%). 4. No charging order protection. Florida Fee: \$35 filing fee \$150 annual report fee	1. Only 1 member for tax purposes - disregarded for federal income tax purposes. But may have a Taxpayer Identification Number. 2. If 2 or more members for tax purposes – taxed as a partnership. A partnership is taxed in a manner similar to an S corporation, but with major differences. 3. Can elect to be taxed as an S corporation or a C corporation for federal income tax purposes. To have corporate tax treatment a Form 8832 must be filed with the IRS. Florida Fee: \$125 LLC filing fee \$138.75 LLC annual report fee \$1,000 LP/LLP filing fee \$500 LP/LLP annual report fee	1. Can be disregarded if considered to have one member (such as if an individual owns 50% and his or her revocable trust owns 50%). 2. Taxed as a partnership if 2 or more members. 3. No charging order protection. No filing required for general partnership. Florida Fee: \$50 LLP filing fee \$25 LLP annual report fee

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BASIC INCOME TAX OPERATION OF EACH TYPE OF ENTITY

Shareholder (Dividends are taxed)	Shareholder (Dividends are not taxed)	Partners (Individuals, S corporations or otherwise) (Distributions are not taxed)	
C CORP TAXED ENTITY	S CORP TAXED ENTITY	PARTNERSHIP TAXED ENTITY	PROPRIETORSHIP
Corporate level tax – revenues minus deductible expenses. Dividends are not deductible expenses. May deduct healthcare and disability insurance expenses under certain circumstances. In the highest individual tax bracket on the first dollar of income if this is a personal service company.	Income and deductions are computed and then go on income tax returns of owners by K-1 reporting. There can only be one class of stock, but voting/non-voting is permitted. Contribution of appreciated assets can trigger tax unless the 80% rule is followed under IRC Section 351. Income is triggered if an appreciated asset or accounts receivable are transferred from the S corporation to shareholders unless it is deductible compensation. Special rules apply if an S corporation used to be a C corporation. This can cause double tax. Shareholder might be afforded the benefit of the 20% Section 199A deduction.	Income and deductions are computed and then go on income tax returns of owners by K-1 reporting – no entity level tax. Distributions to partners are usually subject to employment taxes. Compensation paid to partners is often called “guaranteed payments” and reduces partnership income. Typically no income tax is triggered when appreciated assets are contributed to the partnership in exchange for a partnership interest. Typically no gain is triggered when the partnership transfers appreciated assets to its partners to redeem their ownership interests. Partner might be afforded the benefit of the 20% Section 199A deduction.	All income and deductions are shown on individual's Form 1040 Schedule C – subject to employment taxes of 12.4% on the first \$128,400 of income, plus the 2.9% Medicare tax, making for a 15.3% tax thereon, plus the 2.9% Medicare tax on income from \$128,400 and an additional 0.9% Medicare tax to the extent of self-employment income that exceeds \$200,000 for a single taxpayer and \$250,000 for a married taxpayer. Owner might be afforded the benefit of the 20% Section 199A deduction.

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Partners Are Responsible For Each Others Actions

Partners are responsible for each other's actions and for the actions of the partnership, unless it is a limited partnership (“LP”) or a limited liability partnership (“LLP”).

- An informal “partnership” or “joint venture” can cause liability, even where there is no formal Partnership Agreement.
- For example, doctors working at a hospital are often determined by juries to be “ostensible employees or partners”, and hospital is responsible for their actions.

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Do Not Get Divorced or Live Miserably

- Read “Medical Marriage” and try not to lose one-half of your assets plus one-third of your future income (and sanity) to a divorce.
- Get counseling to make your marriage work, or if there is a good chance your marriage will not work, get divorced before you have children, and/or before you have permanent alimony and more assets to divide equally.
- Consider whether your children will be better off in a happier household.
- “If your spouse is not your best friend something is wrong.” – Gus Stavros
- You cannot afford to be married to an uncontrolled “spend-a-holic” (or to be one).
- Other great books: (1) *It is Mostly His Fault*; (2) *The Female Brain*; (3) *The Male Brain* – a much shorter book than *The Female Brain*; and (4) *Dale Carnegie – How to Win Friends and Influence People*.

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The Five Love Languages

From Wikipedia, the free encyclopedia

The Five Love Languages: How to Express Heartfelt Commitment to Your Mate is a 1995 book by Gary Chapman.^[1] It outlines five ways to express and experience love that Chapman calls "love languages": gifts, quality time, words of affirmation, acts of service, and physical touch.^[2] Chapman's book claims that the list of five love languages is exhaustive.^[3] Chapman argues that, emotionally, people need to receive love.^[4] He also writes that people should not use the love languages that they like the most but rather the love languages that their loved ones can receive.^[5] Since 1995, Chapman has written several books related to *The Five Love Languages*, including *The Five Love Languages of Children* in 1997 and *The Five Love Languages for Singles* in 2004.^[6] Andy Andrews called Chapman's book "amazing" and credited *The Five Love Languages* with inspiring a portion of his own book *The Noticer*.^[7]

The Five Love Languages

Author	Gary Chapman
Country	United States
Language	English
Subject	Intimate relationships
Publisher	Northfield Publishing
Publication date	1995
ISBN	1081273156

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Categories: 1995 books | American non-fiction books | English-language books | 20th-century Christian texts | Faith-based literature | Inspirational literature | Book stubs

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Make Your Children Self-Supporting

- Your children and their children will often be your primary financial enemy. Sometimes the remora is bigger than the shark!
- Make them self-supporting. Save mid-life and retirement years money by making your children self-supporting.
- Do not neglect your children or allow your children to be raised improperly. Take the time and effort to figure out what it means to raise a child to be self-supporting, responsible, and without a sense of entitlement or an inability to work. It is easy to spoil a child, but more difficult to be a responsible parent.
- Do not create a child who was "born on third base and thinks he or she hit a triple.
- "Don't handicap your children by making their lives easier." – Robert Heinlein

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Unspoiled Children, No Rod Needed

How Parents Can Be Generous Without Turning Children Into Entitled Little Terrors
By Veronica Dagher, July 13, 2014, *Wall Street Journal*

You want to give your children everything. But sometimes you can go too far and create a spoiled, entitled brat. The consequences can be severe: In addition to acting like whiny complainers now, spoiled children are more likely to grow into financially dependent, irresponsible adults plagued by overspending and debt. "Some parents want their children to have everything for free," says Katherine Dean, managing director of wealth planning at Wells Fargo Private Bank in San Francisco. "But the real world doesn't work that way." Financial advisers and therapists suggest various ways to avoid spoiling your children. A few:

1. Understand Yourself

Ask yourself, "Why am I inclined to indulge my children?" says Susan Newman, a social psychologist in Metuchen, N.J. It might be to gain their approval, to relieve your sense of guilt for the limited time you spend with them, to make up for things you didn't have growing up, or your need to keep up with friends and neighbors, Dr. Newman says. Understanding your own motives can help you break the habit and take a different approach, she says. If you feel guilty about working so much, plan a time to take your child to the park or cook a meal together instead of giving into the impulse to buy a new toy. "Buying them a gift won't make up for lost time and have a lasting impact on their happiness," says Nathan Dungan, owner of Share Save Spend in Minneapolis.

2. Talk About Money

A big mistake parents make is not talking about money with their children, fearful they'll become overly focused on money, says Ann Freil, a family-education expert at Northern Trust Wealth Management in Chicago. But children notice early on if a friend's house is bigger than theirs. And they'll certainly notice if you evaluate the people inside it based on the disparity, she says. In turn, it's important to speak about your own family's money values. If you believe "things don't equal love," share that with your children and reinforce it by talking about what you value more than money, Ms. Freil says. One parent Ms. Freil works with regularly points out to his children the qualities he respects in his colleagues, friends and neighbors: their intelligence, kindness, sense of humor and integrity. "He'll emphasize that he doesn't care how much or little someone has financially," says Ms. Freil. "If these things aren't present, he doesn't hold that person in high regard."

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Diet and Weight

Thinner people live longer.

There are hard ways to diet and easy ways to diet.

Is it a myth that it is unhealthy to not eat carbohydrates?

Weight Watchers can work wonders. Take someone you love there, and lose weight yourself!

Write down everything you eat and you will eat less and healthier.

Try the Rise App.

The older you get, the more challenging this is, but good habits can override weight issues.



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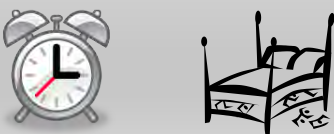
Early to Bed, Early to Rise Makes a Person, Healthy, Wealthy and Wise

- Ben Franklin

In the early hours you can be uninterrupted, your brain is well-rested, and your staff can come in and work on what you do in the early morning so that you can proofread it through the afternoon and get home at a decent hour.

Does it make sense to do your uninterrupted, concentrated work in the evening, when you have already been at it for 10 hours?

Better to do the mental lifting in the morning, and the social interaction in the afternoon.



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3. Educate Your Children

If you're concerned that your child isn't getting a realistic sense of how to set financial priorities, speak to them about real-life money decisions where trade-offs are required, Ms. Freil says. You can involve them in household finances from middle school onward without opening your financial books to them, she says. For example, you can show them a line-item budget for monthly household expenses with percentages rather than dollar amounts. "Ask them how they might make choices and trade-offs if one of the household expenses went up dramatically," she says. Prepaid minutes are a great way to limit your adolescent's phone use and teach budgeting, says Brad Klontz, a financial psychologist in Kapaa, Hawaii. In the first month, they are likely to blow through their minutes in a few days. "Resist the urge to bail them out, and make them wait until next month," he says. After a few trials they'll learn about budgeting and delayed gratification, two keys to future financial success, he says.

4. Set an Example

"Kids develop attitudes about money by observing their parents' day-to-day actions more than anything else," says Ms. Freil. Shopping to relieve tension, for example, might seem harmless if you can afford it. But it can also communicate to your children that material goods alleviate emotional pain and longing, Ms. Freil says. Likewise, your tipping practices, charitable giving and the way you treat your belongings will demonstrate your money values to your children, Ms. Freil says. Instead of impulsively buying a new car, speak to your children about how you're saving each month for it and maybe even taking on extra work to afford it. Involve them in comparison shopping, either in stores or online. "Even if you can afford not to, cut coupons with your children and take them to the store when you use them," Dr. Klontz says.

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5. Learn to Say 'No'

The simple way to avoid spoiling your kids is to make sure it's OK to say "no." It isn't always easy, says Thomas Henske, partner at Lenox Advisors in New York. If your 10-year-old son pleads for \$240 soccer cleats, you might ask him why he wants a pair that might be double the price of some other brand, Mr. Henske says. This can start a conversation about relative value and comparison shopping, he says. If your son doesn't conclude on his own that the cleats are too pricey, you can explain that in your house "you live on a budget and don't spend an unlimited amount of money on things we need." Explain that the family budget for cleats is say, \$100, and that your son has to come up with the extra \$140 if he wants the pricier pair, Mr. Henske says. Yet sometimes you just need to say no. On those occasions, be sure you and your spouse are delivering the same message. "Do not allow the children to pit one parent, or grandparents, against each other when it comes to money," says Neale Godfrey, president of the Children's Financial Network in Chester, N.J. "Decide the rules together and stick to them."

6. Make Them Work

"Start by teaching them the only way to get money is to earn it," says Mr. Godfrey. You might pay them for doing age-appropriate chores. For older children, you might set expectations such as "if you go to college, you will work during the summer to earn some of the money for your expenses," she says. Have them work to help pay for something special, such as a summer trip to a foreign country, says Andy McVay, a Laguna Hills, Calif., financial adviser. Having "skin in the game" by paying for things with money they worked for teaches children to set financial goals and prioritize, he says.

7. Teach Them to Give Back

Volunteer as a family, and when your children are old enough, encourage them to volunteer for causes they care about, Dr. Newman says. Families should have a mandatory "giveaway rule," she says. Twice a year, before birthdays or big holidays, ask your children (help the younger ones) to look through their clothing and toys and determine what they can give to a charity. When a tragedy such as a hurricane or a tornado strikes elsewhere, have a discussion about ways your family might help those in need, she says. Encourage your older children to create a list of possible recipients and let them decide where their donations go, whether it's a children's ward at a hospital or a homeless shelter, she says.

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Having Spouses or Others Involved in Multiple Member Medical Practices

(This sometimes works, but not always.)

7.10 Nepotism and Spousal or Significant Other Involvement. It shall be a policy of the Company and its Members to forbid personal romantic or physical relationships between Named Physicians and any other employees, independent contractors, or agents of the Company. Further, no spouse, significant other, or relative of any Named Physician shall have physical access to any Company office or professional, formal, or informal interaction in the office or in a business setting with any employee or independent contractor thereof without advanced written consent provided by all Members. The term "significant other" shall refer to an individual who has a romantic relationship with a Named Physician, such as a steady girlfriend or boyfriend, or a spouse.

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THE BIGGEST MISTAKES THAT DOCTORS MAKE WITH RESPECT TO MANAGING THEIR MEDICAL PRACTICES AND INVESTMENTS

By Alan S. Gassman, J.D., LL.M.

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Alan Gassman, a partner in Gassman, Bates & Associates, P.A., and a frequent LISI commentator, has represented several hundred medical practices through the years. Alan practices business, estate planning and tax law in Clearwater, Florida.

A thriving and successful medical practice can quickly be pulled under by one catastrophic incident that destroys its financial solvency, its credibility, or both. How and why do such catastrophes occur, and what are their most common forms?

EXECUTIVE SUMMARY:

This commentary reviews ten avoidable mistakes that can be the cause of fatal errors for medical practices and investment portfolios.

COMMENT:

While different physicians and groups of physicians tend to make more mistakes in one area than another, each common mistake area should be reviewed and understood with appropriate advisors. These common errors, which are described in more detail below, are as follows:

1. Failure to Maintain and Appropriately Use Independent Professional Advisors.
2. Failure to Maintain Medical Law Compliance.
3. Failure to Maintain Proper Malpractice Insurance.
4. Failure of Multiple Physician-Owned Practices to Have Appropriate Buy-Sell and/or Shareholder Agreements in place.
5. Failure to Procure and Maintain Proper Insurances.
6. Failure to Make the Medical Practice and Doctor Judgment-Proof.
7. Failure to Theft-Proof the Practice's Monies and Accounts Receivable.
8. Using Greedy Investment Advisors.
9. Unbalanced Investment Portfolio.
10. Doing Business With the Wrong People.
11. Failure to Have Anyone in the Practice Pay Attention to Contracts with Third Parties.

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1. **Failure to Maintain and Appropriately Use Independent Professional Advisors.** Many of the calamities described below will be avoided if a medical practice has experienced advisors on board. The practice should consult with its advisors when making major practice decisions, and also periodically confirm that appropriate procedures and safeguards are in place.

(a) CPA: Quite often the quarterback of the advisor team will be a good, caring Certified Public Accountant who does extensive medical practice work. CPA's are often well versed in investments, business matters, and methods of theft-proofing a medical practice from a financial standpoint.

CPAs should prepare quarterly or monthly financial statements for the medical practice; these statements should involve a review of accounts receivable, cash flow and general practice financial information.

(b) Attorney: An experienced lawyer who represents a number of medical practices should have sufficient experience to help physicians avoid terrible problems before they occur.

Just as physicians advise patients to have an annual check-up, and may wisely require this before prescriptions are renewed beyond 12 months, a medical practice client should confer with its lawyer on a periodic basis. Commonly the primary lawyer for the practice will refer matters to appropriate sub-specialist attorneys in a number of different areas. Often this happens in conjunction with a CPA meeting.

(c) Other Advisors: Other advisors commonly and appropriately used by a medical practice group will include (i) a qualified pension plan advisor, who is also preferably an actuary, as well as (ii) a banker who is knowledgeable as to practical business expense and loan-associated planning, and (iii) a reputable and conservative financial advisor or advisors who assist with pension planning, various insurances, and other practice-associated financial instruments.

Good advisors should be honest and always let the physician and the rest of the team know about questions, concerns, or the need to bring in additional experts to handle any particular matter or situation. Advisors who show up to sell a single product or scheme commonly cause problems, as described in below.

2. **Failure to Maintain Medical Law Compliance.** A great many physicians are annihilated financially when Medicare and/or private insurance carriers request hundreds of thousands of dollars in refunds because the physician has used inappropriate billing practices or financial arrangements with third parties. In many cases these problems are reported to the government by employees who can earn a 15% "whistle-blower fee."

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Many physician clients simply do not realize that they use improper coding, do not maintain sufficient patient file back-up, or bill for items that are inappropriately unbundled or altogether un-billable.

Several years ago, the concept of a "medical practice compliance audit" was in vogue, and many professionals, in the opinion of the author, significantly over-charged physician groups for "practice audits." Such audits extended far beyond a reasonable review of billing, patient file documentation, and third-party financial arrangement review.

Reasonable and periodic practice maintenance and reviewed by trusted medical consultant advisors eliminates the need for such a costly venture. In the author's experience, most medical practices benefit from hiring an independent consultant to come into the practice, perhaps annually, to spend a day randomly reviewing patient charts and the billing and collection processes associated therewith.

Quite often a good consultant can spot billing opportunities where the practice is undercharging or not knowing to charge for certain services. An independent consultant can also be a tactful go-between to let certain members of a medical practice know that their file documentation is not sufficient. Such corrections are best conveyed by a neutral third party.

Consultants should be hired by a lawyer on behalf of the medical practice so that any problems they may discover can stay confidential under the attorney-client privilege to the extent possible.

If and when the government criticizes a medical practice's coding, file documentation or other billing procedures, it is very helpful to be able to show that the practice conscientiously hired and followed the advice of a reputable billing and coding consultant on a periodic basis.

Many physician groups are also unfamiliar with or intentionally disregard rules relating to arms length leases, compensation arrangements, and also the ability to refer tests within a group medical practice only if certain rules are followed. The author has had law-abiding and well-meaning physician clients arrested in their lobbies by the FBI as a result of being in business with the wrong people at the wrong time.

Doctors can rest assured that any "scaudrel" that they have legitimate or questionable business relationships with will turn them in to get amnesty if and when approached by law enforcement, even if the doctor did nothing wrong. When law enforcement comes knocking the doctor should immediately have appropriate sub-specialty lawyers contact law enforcement on his or her behalf. Neither the doctor nor his or her staff should directly speak with any law enforcement officers at any time on any topic.

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3. **Failure to Maintain Proper Malpractice Insurance.** While malpractice insurance is not inexpensive, it is necessary in order to protect physicians from the significant legal fees, expert witness costs, and liability exposure associated with defending lawsuits. The proliferation of the personal injury lawyer industry shows no sign of slowing down, and a sympathetic jury system, coupled with experts willing to testify that a doctor committed malpractice under complicated circumstances that a jury can never understand provides good cause for maintaining appropriate malpractice insurance coverage.

Many advisors and clients believe that a practice need only maintain the lowest limits of liability coverage because "they will always settle for your limits," but the author has found that in many cases plaintiffs will not settle for low limits of medical malpractice insurance liability where there are other significant assets exposed. Physician clients will sleep better and have a greater sense of financial security, as well as significantly less personal exposure, when they have higher levels of liability insurance than the legally required minimum.

Many physicians will obtain malpractice insurance coverage from low-cost carriers that turn out to be infirm and go bankrupt, leaving doctors high and dry to defend their own claims and without any coverage whatsoever for legal and expert expenses.

Any opportunity to pay significantly less than the going rate for malpractice coverage should be reviewed carefully with the above concerns in mind.

Also, the income tax laws permit a medical group to form its own "captive insurance carrier" and deduct premiums paid to the carrier company. Under the tax law the carrier company may not have to include premiums received as income unless or until it is determined what portion of the premiums will be used to pay claims as expenses and what portion of the premiums will be profits. Profits taken out later may be taxed at favorable capital gains rates.

Nevertheless, there is a significant economic risk taken since the carrier could "go under" if there are extensive claims, and when there are multiple doctors being insured by the carrier, one or two doctors who make a lot of mistakes could cost all of the equity for the other doctors.

Further, unlike conventional malpractice insurance, which requires a carrier to offer tail malpractice insurance coverage at the request of each doctor, captive insurance carrier reinsurance contracts will commonly not bind the reinsurance company to even renew the coverage, let alone provide a tail policy on termination, leaving an entire group of doctors without any coverage whatsoever. Successor carriers will not provide tail coverage for periods of time that no other carrier is on the hook for.

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Avoiding Costly Mistakes in Medical Practice Planning

The laws of most states require that malpractice insurance be provided by a state-registered carrier. Doctors who have malpractice insurance furnished by an unregistered carrier may be considered to be "going bare" under state law, and may therefore have to notify patients that the doctor is "bare." A possible loss of license can occur if a doctor cannot satisfy a claim by reason of not having malpractice insurance or the financial wherewithal to pay a claim.

Many doctors are not aware that for a small additional premium they can have a separate "corporate" malpractice insurance policy issued by the same carrier that provides individual policies that covers the medical practice company in order to effectively double the limits of malpractice insurance that would be available to pay on a claim, and to assure that the company will have coverage if one of the doctors leaves and refuses to buy tail malpractice insurance.

Also, nurse practitioners and registered nurses can often qualify for insurance with high limits of liability for very low cost. Many physicians will not treat certain types of high-risk patients unless they at all times have a nurse practitioner in the room with them to make sure that there is plenty of coverage, witnesses to what is said, and appropriate follow-up.

4. Failure of Multiple Physician-Owned Practices to Have Appropriate Buy-Sell and/or Shareholder Agreements in Place. Many successful medical practices are run on a handshake or a long-forgotten and now archaic agreement, but when problems or changes in circumstances arise the results can be catastrophic- and quite lucrative for the legal profession.

For the sake of example, assume that Doctor A and Doctor B are lifelong friends who have practiced together 25 years and share 50% each ownership of a medical practice without current legal agreements. Their spouses have also been best friends.

They have always worked approximately the same and have always been paid the same. A couple of years ago they were offered \$3,000,000 for the practice, which involved signing 5 year non-competes and 5-year employment agreements. They also own the practice real estate together in a separate company under which they have signed a \$2,000,000 mortgage on real estate now worth only \$1,500,000.

If Doctor A becomes disabled, they may not be able to agree on how much Doctor B should be paid to administer the practice. Disagreements may also arise regarding the hiring of a replacement doctor or doctors.

They may also not be able to agree on a price or terms for Doctor B to buy Doctor A out.



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Often disabled physicians believe they will be returning to work. Meanwhile, their partners see the writing on the wall and take a more skeptical view of their capacity for recovery. The practice can be significantly damaged during this period of time until the disabled physician's status on returning to work is absolutely confirmed.

What if Doctor A becomes a drug addict or begins having an affair with medical practice personnel that could cause obliteration of the practice? How can Doctor B force Doctor A to leave, or to even behave? How can Doctor B protect the practice and himself from responsibility for Doctor A's misconduct?

What if Doctor A dies? Doctor A's widow may believe that the practice is worth \$3,000,000 and will be voting Doctor A's stock unless or until she is bought out. How can Doctor B convince Doctor A and her lawyers and valuation experts that the practice has lost significant value because of Doctor A's death? How can Doctor B run the practice if Doctor A's widow will not agree to any significant changes in situations where such changes become necessary?

How can Doctor B attract a new doctor to the practice if he has to disclose that he is not getting along with the 50% widow owner of the practice?

The list of examples goes on and on. It does take time and money to put together an appropriate Buy-Sell/Employment/Shareholder document package. Almost no two are the same as circumstances change. However, it is a valuable investment that every practice should make.

In addition, applicable state law and/or Medicare law often requires that compensation be based upon methods determined in advance that do not take into account the referral of patient services. As mentioned under number 2 above, the referral of a patient within a group practice for certain testing or other "designated health services" under the Stark Law can be a felony unless there is a properly documented method of sharing that qualifies under the Stark Laws. Failure to have this in writing in advance of a particular calendar quarter can constitute a felony offense.

5. Failure to Procure and Maintain Proper Insurances. There are myriad insurances required to appropriately safeguard a medical practices from the normal risks of doing business, particularly in view of the American trial system.

Fortunately most of these risks can be reasonably handled on an affordable basis, assuming that proper coverage is in place.



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The most important coverage is clearly malpractice insurance, which is addressed below as a separate section, but other insurances which are essential to the well-being of physicians and their medical practices include:

- 1) disability insurance,
- 2) overhead insurance to handle practice expenses during a period of disability or in the event of a natural disaster such as a hurricane or acts of terrorism,
- 3) liability insurance to cover non-malpractice obligations, such as if patients or others hurt themselves in the parking lot or fall on slippery areas in the office,
- 4) workers' compensation insurance to protect the practice against state laws that can require lifetime support and/or significant monetary payments to be made to an employee injured in the course of employment, and
- 5) unowned automobile liability insurance to insure against the liability that occurs to a medical practice if any employee is in an automobile accident while running errands or otherwise working in the course of medical practice business.

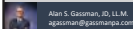
Individual automobile liability policies should also be reviewed to ensure that each physician has coverage for medical practice-related driving. Many personal policies will not cover business driving without additional policy riders. The author commonly recommends at least \$3,000,000 - \$5,000,000 worth of umbrella liability coverage to cover all business and personal driving, and driving by others who might use the doctor's car.

There are thousands of disabled physicians in the United States now living on disability insurance. The author has more than 15 clients who have been able to "retire" on their disability insurance. This explains why the rates are so high to procure such coverage, but also why having good coverage is a necessity rather than a luxury for physicians who do not have adequate retirement savings to support themselves and their families for their remaining lifetimes.

Sometimes individual health insurance policies will not cover on-the-job injuries under the presumption that a doctor will be covered under workers' compensation for on-the-job injuries. Doctors who do not have workers' compensation insurance, which is often waived to save money, should check their health insurance policies to make sure that they are covered for on-the-job injuries.

6. Failure to Make the Medical Malpractice and Doctor Judgment-Proof. There are many ways that a medical practice and a doctor can work to make themselves a less attractive target for a plaintiff's lawyer.

Often the practice incurs debt in its name, and the lender or lenders have liens on practice and personal assets that must be paid before a plaintiff is able to levy upon a doctor's practice. Also, valuable assets like real estate and furniture and equipment can be owned by a separate entity that would lease those assets to the medical practice to make them inaccessible, or at least less accessible, to a malpractice claimant.



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It is a very basic accounting system principle that the person or people who physically open the envelopes containing checks payable to the practice record the checks onto a log and ensure that the checks are properly deposited. These deposits are then reported to a separate employee who has the ability to record the payments in the practice's computer system.

It is a fatal error to allow one individual to have physical possession of checks and also the ability enter payments or write-offs onto the practice's billing computer system. Even spouses have been known to steal from medical practices, especially when there are multiple partners.

Many practices use a post office box for checks to eliminate the risk of someone being able to "snatch a few checks from the mail" before they can be posted. Many banks offer check-depositing services and addresses that can be used as well. These are often known as "lock box" arrangements.

Larger practices can have someone from their CPA firm visit the practice on an annual basis without advance notice to the practice personnel. This demonstrates to employees that there is some degree of monitoring going on and can discourage practice theft.

8. Using Greedy Investment Advisors. The number of different investments and life insurance and annuity arrangements that can be sold to doctors and their practices in the financial world. The quality of each particular investment vehicle can vary dramatically in terms of actual financial safety, conservative versus aggressive orientation, likelihood of being acceptable to the IRS in the event of an audit, and as to the amount of commissions paid to advisors who may suggest such arrangements.

Expecting a physician to read a prospectus or to understand a complicated tax maneuver is like expecting a lawyer or a CPA to read an EKG- it is easy to be fooled!

If the advisors are earning a significant portion of the amounts invested as compensation, a degree of manipulation, non-disclosure, exaggeration or outright lying can take place.

In the pension world, actuaries and many CPA firms who practice extensively in the retirement plan arena can yield the great results for clients. Pension and profit-sharing plans are well-protected under applicable creditor laws and well-accepted under the tax law in conventional form.



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More aggressive plans such as 419A Welfare Benefit plans and 412i plans should be examined carefully by independent advisors before investing.

The author urges clients to use independent accountants who are not compensated directly or indirectly for the sale of financial products. The author has seen entire fortunes lost to tax shelter deals in the 1970s, leveraged real estate deals in the 1980s, land development deals in the 1990s, and now Madoff and related Ponzi and margined-securities deals in the present decade. Crime often pays, and the victim is the doctor who gets involved in these types of arrangements.

There is rarely a good reason for a pension or profit-sharing plan to own a life insurance or annuity product, except to compensate anyone who may be licensed in life insurance and annuities who has involvement in the pension or profit-sharing.

9. Unbalanced Investment Portfolio. Statistical studies show that a diversified portfolio of investments will generally outperform a non-diversified portfolio, with significantly less risk. Many successful clients own investment real estate, mutual funds allocated among the various classes of stock investments, and bond funds or CDs. It almost never makes sense for anyone to put all of their eggs in one basket.

Go For Singles and Doubles, Not Home runs. Time and time again we have seen physicians place significant portions of their financial assets into high risk investments or ventures with the intention of hitting "a home run" under risky circumstances.

There is almost always a direct and opposite correlation between expected rate of return and risk being taken. Many high income professionals recognize this and are nevertheless willing to take risks. Quite often, however, physician investors are assured that an arrangement is "virtually risk free" even though it is expected (or touted) to yield a significant return. If it is too good to be true... it probably is.

10. Doing Business with the Wrong People. Unfortunately, crime, and also deceitful or misleading behavior can be lucrative for the "bad or careless actor," and these individuals are often found courting doctors to do business and investment transactions or to provide consulting services.

Since the overwhelming majority of doctors are very honest and do not have formal business training, it is not difficult to market "unique propositions" to doctors and to eventually find a handful of doctors who may succumb to participate in a recommended arrangement.



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Commonly these "bad actors" will present themselves through relatives, friends and possibly even misled advisors.

Typically the doctor will be asked to invest in a startup or growing company, to help start a new business, or to be involved in the purchasing or financing of real estate.

Bad actors are often well-dressed, exhibit success in the forms of nice house and cars, and sometimes even jet airplanes, stunning vacations, trophy wives, and impressive club memberships.

A team of advisors can usually sniff out this type of individual or organization by checking references, or the lack thereof, licensing, and with other professionals who have worked with the applicable individual. The author has seen this occur in billing companies, unique invention startups, real estate ventures, medical related companies, ice machines (that did not exist), Ponzi schemes, and other situations.

If it sounds too good to be true it usually is! And do not forget the adage about the experienced businessman and the doctor who become partners. The businessman puts in his experience and the doctor puts in his money. At the end of the day the businessman has the money and the doctor merely has an experience!

Doctors with gamble-holic tendencies are often drawn to elusive schemes where the doctor is told that he or she has earned millions of dollars and should have colleagues put money in so that they can earn millions too, while in reality the "con job" is that the money is being stolen or used to pay debts on assets that will never be worth anything. A junior Madoff may be your next door neighbor or brother-in-law!

Every year the IRS publishes the "Dirty Dozen," a list of tax frauds, including schemes involving the internet, domestic tax crimes, offshore frauds and false claims for refunds. This is done for the benefit of citizens and their awareness of financial predators. The IRS website at <http://www.irs.gov/newsroom/article?id=206370.00.html> says in part, "Taxpayers should be wary of scams to avoid paying taxes that seem too good to be true, especially during these challenging economic times," Commissioner Doug Shulman said, "There is no secret trick that can eliminate a person's tax obligations. People should be wary of anyone peddling any of these scams."



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11. Failure to Have Anyone in the Practice Pay Attention to Contracts with Third Parties. Quite often medical practices get into disputes or find themselves stuck in agreements as a result of a trusting nature or lack of attention to details associated with contracts they enter into with third parties. Say, for example, somebody delivers a copier to the medical practice that the office manager has requested on a trial basis. Upon delivery, that person gets the receptionist to sign a contract accepting copier and binding the practice to 48 months of payments.

Another example is when a medical practice has a lease that gives the doctors the right to extend after a certain date, but they forget to give notice of extension by the deadline. The practice gets held up by the landlord for a larger rent payment or has to vacate and find new property.

A third example is when a lease for a large piece of equipment also requires the practice to maintain the equipment with one company only. The company may provide poor service or may not permit the practice to pre-pay the lease or re-finance it from a high rate of interest without paying tens of thousands of dollars in penalties.

Another trap some practices fall into is using an office manager or non-CPA accountant to draft legal documents that employ physicians or to set up companies for the practice, not realizing that the contracts have inappropriate provisions or do not cover essential items that a lawyer or appropriately qualified advisor would have pointed out.

F. Lee Bailey said that "anyone who acts as his own lawyer has a fool for a client."

Most successful lawyers hire other lawyers to do work for them personally when it is outside of their area of specialty, or sometimes even when it is within their area of specialty because of this phenomenon.

If lawyers are smart enough not to do legal work for themselves, why aren't doctors and their other advisors?

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8 COMMON LLC PLANNING ERRORS

By: Alan S. Gassman, J.D., LL.M.

Some of the most common problems we encounter in reviewing LLC arrangements for clients are:

1. TENANCY BY THE ENTIRETIES' DESIGNATION THAT WILL NOT QUALIFY AS TENANCY BY THE ENTIRETIES.

Many married couples in states that protect tenancy by the entireties assets from the creditors of one spouse or the other have their LLC interests titled jointly as tenants by the entireties.

But they don't realize that there are provisions in the operative documents which are inconsistent and would thus annul tenancy by the entireties characterization and protection.

Common examples of this are:

(a) By the rules of tenancy by the entireties, the joint interest must pass outright solely by the surviving spouse in the event of the death of the surviving spouse. Oftentimes an operational document will provide that on the death of a member, the interest of that member must be sold. Agreements are commonly not drafted to explicitly provide that on the death of a spouse, the other spouse will be the owner of the joint interests, without any inconsistent member agreement provisions.

(b) Similarly, provisions under an operative document which restrict transfers may actually be read to prevent one spouse from owning the entire member interest on the death of another spouse.

(c) While the certificate of ownership may be issued to both spouses as tenants by the entireties, oftentimes the Operating Agreements or Articles of Organization will provide for only one spouse or the other to be an owner.

2. ENTITY DOCUMENTS CAN DISQUALIFY S ELECTION.

Limited liability companies may be treated as S Corporations under the federal income tax law if certain very strict requirements are met and an S election is made.

If the S election is made but the S Corporation requirements are not met, then the company will be taxed as a "C Corporation," therefore exposing properties and income to double tax.



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8 COMMON LLC PLANNING ERRORS

By: Alan S. Gassman, J.D., LL.M.

Common causes of this catastrophic treatment are as follows:

(a) An operating agreement does not provide for all income to be distributed pro rata to ownership. Commonly "partnership style" clauses assure members that they will recapture their original investment or have some sort of an income sharing that would reflect a "second class of stock," which is not permitted under the S Corporation Rules.

(b) Although state law permits a limited liability company to have non-citizens, corporations, and other entities own LLC interests, these and certain other entities are not permitted owners of S Corporation stock, and will thus cause disqualification.

(c) Too high of a debt equity ratio could cause disqualification from S Corporation status.

3. FAILURE TO PLAN FOR CASH OR OTHER DISTRIBUTIONS/FAILURE TO USE AN INTERMEDIARY ENTITY.

Oftentimes a client will invest in a multiple member LLC, expecting to have charging order creditor protection, but not thinking through that positive cash flow that the other members will want to assure is distributed will become accessible to a judgment creditor who has a charging order against the LLC. Many clients are well advised to establish a "Family Holding LLC" or a family limited partnership to hold the multiple member LLC interests so that positive cash flow would pass to the family LLC, to be held and reinvested in a protected manner.

Clients who take ownership in a multiple member LLC as tenants by the entireties may wish to do so under a limited liability company or limited partnership owned by the spouses and another family member in order to assure that upon the death of one spouse tenancy by the entireties status would continue, and positive cash flow from the multiple member LLC will thus be protected.

4. FORCED SALE PROVISIONS.

Often well-drafted Operating Agreements will have provisions that would allow any member to force a sale of their member interest at any time or under certain circumstances, such as where another member is selling their interest ("tag along rights"). One advantage of a limited liability company under the laws of most states is that the sole remedy of a judgment creditor is a charging order – meaning that the creditor cannot actually force the sale of the limited liability company interest, become a forced owner, or reach into the limited liability company. A bankruptcy or state court judge may override charging order protection where a debtor member would have the right to simply "cash out" at the time when the judgment creditor has a charging order against the debtor.



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By: Alan S. Gassman, J.D., LL.M.

5. WE "FORMED IT OURSELVES" – OR "MY ACCOUNTANT TOOK CARE OF THIS."

While it is possible for any third grader to file a charter to establish the existence of an LLC with state authorities, in the author's experience the vast majority of LLCs that have been established by non-lawyer personnel have been implemented incorrectly. In most states it's the unauthorized practice of law for a non-lawyer to establish and implement a limited liability company for another party. Therefore, the types of non-legal firms that are willing to establish and implement limited liability companies tend to be unconcerned and ignorant, willfully or inadvertently, of the formalities, paperwork, and coordination needed to properly establish, document, implement and operate a limited liability company. Clients who buy \$99 "Total Service Incorporation Kits" run the same risks. The slogan "Pay us now or pay us later" comes to mind, but along with that comes "Pay us later and watch your assets looted by creditors and/or the Internal Revenue Service."

6. ASSUMING THAT LIMITED LIABILITY COMPANIES ARE AS WELL PROTECTED AS LIMITED PARTNERSHIPS IN ALL STATES.

Some states provide charging order protection for limited partnerships but not limited liability companies. Clients who have or will have children or other members residing in a state or jurisdiction that may not protect them may want to consider using limited partnerships or other entities in lieu of limited liability companies.

7. FAILURE TO PROPERLY RESPECT FORMALITIES AND THE EXISTENCE OF THE LLC.

It is generally very difficult to "break the corporate veil," but a debtor relying upon a limited liability company arrangement needs to be able to show that the company was the actual owner and operator of the property and/or business, that a charter was properly filed and maintained consistent with operational documents, accounting and tax treatment, and that the arrangement was not in reality a general partnership, a joint venture, or a proprietorship.

8. PERSONAL ACTIVITIES MAY NOT BE INSULATED BY USE OF AN LLC.

Some clients believe that they can carry on consulting, management, or related activities under the name of their LLC and not have potential personal liability. Under general tort law the officer of a company, and the manager of an LLC, will be responsible to third parties for personal negligence. Many clients are well advised to keep a low profile with respect to LLC activities, and to hire third parties to handle management decision making and day-to-day activities.



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The Ten Biggest Mistakes That Medical Practices Make In Their Investment and Business Planning 114

SELF EVALUATION

Avoiding Costly Mistakes in Medical Practice Planning

True/False

1. Starting to save early in a corporate pension plan significantly improves long-term financial security and can encourage longevity with the organization.
2. Doctors and practices should rely primarily on their bank's advice for loan decisions.
3. A well-structured estate plan should be created by licensed independent advisors.
4. Corporate and personal loans to family members are often not repaid.
5. Physicians should always view their career as the most important part of their life's goals.
6. Bad relationships and divorce can derail both personal and financial success.
7. A physician's unique talents can help differentiate their practice and improve success.

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

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Understanding Alzheimer's Disease: Diagnosis, Biomarkers, and Emerging Therapies

Understanding Alzheimer's Disease: Diagnosis, Biomarkers, and Emerging Therapies

Louis Kuritzky, MD
Clinical Assistant Professor Emeritus
University of Florida, Gainesville
Clinical Faculty
UCF/HCA Family Medicine Residency, Gainesville
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Off-label Mentions/Disclosures

Louis Kuritzky has
No off-label mentions and **no disclosures**
of relationships with Industry pertinent to this
presentation

Agenda

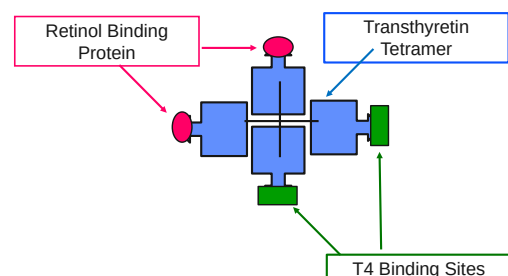
- Alzheimer's Disease: A Protein Misfolding disorders
- What the Heck Is A Protein Folding Disorder?
- Alzheimer's Disease: Pathobiology
- Evolving Terms & Definitions
- Alzheimer's Pharmacotherapy
 - Lecanemab
 - Donanemab

Alzheimer's Disease is
A Protein Misfolding Disorder

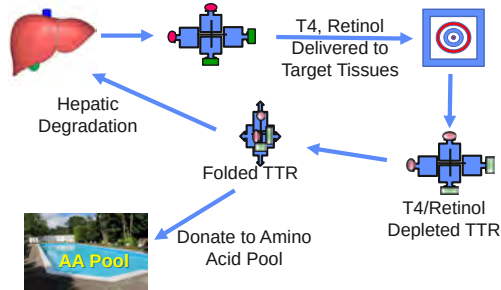
Protein Misfolding Disorders: Examples

Alzheimer's Disease	Cystic Fibrosis
Parkinson's Disease	Lewy Body Dementia
TTR Cardiomyopathy	ALS
AL Amyloidosis	Marfan's Syndrome
α -1-antitrypsin deficiency	Type 2 DM

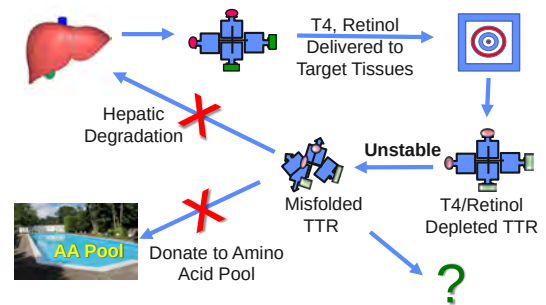
Transthyretin: Normal Configuration



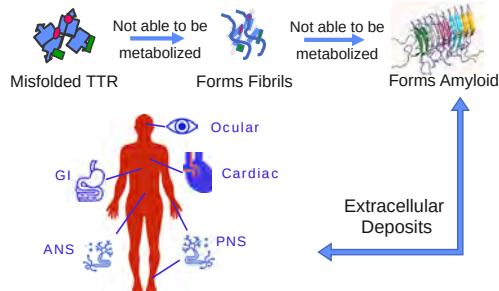
Transthyretin Metabolism: Normal Folding



Unstable Transthyretin Metabolism: Misfolding



The Fate of Misfolded TTR



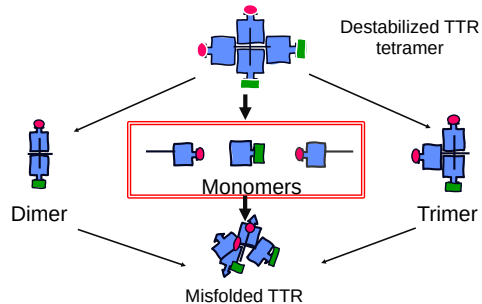
What Leads to Protein Instability?

Genetic Defects
(eg, Amino Acid
Substitutions)

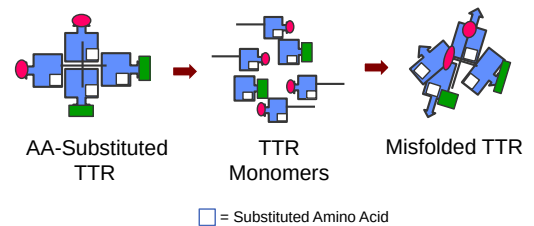
Protein
Senescence
(Age Concordant)

Over-Supply
(e.g., Multiple Myeloma, Light Chain Disease T2DM)

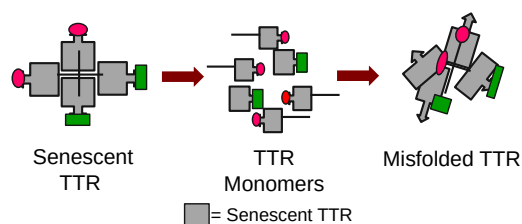
Unstable Transthyretin Can Misfold Destabilized TTR Fragments to Smaller Oligomers



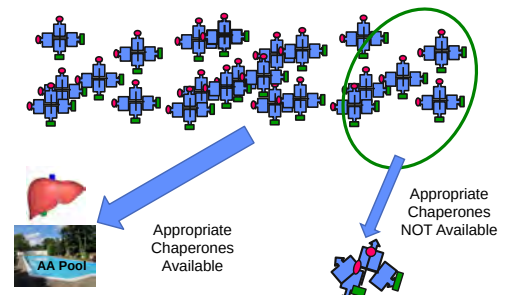
Unstable Transthyretin Can Misfold Genetic Defects: Amino Acid Substitution



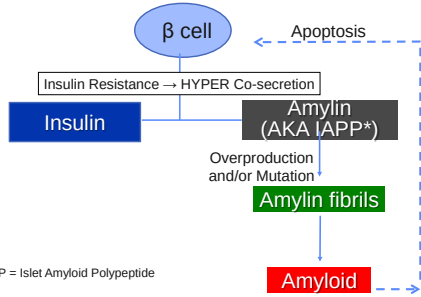
Unstable Transthyretin Can Misfold Senescent TTR



Excess Transthyretin Can Misfold Overproduction Outpaces Chaperone Process



β-Cell Failure in T2DM: The Amylin Amyloidosis Model

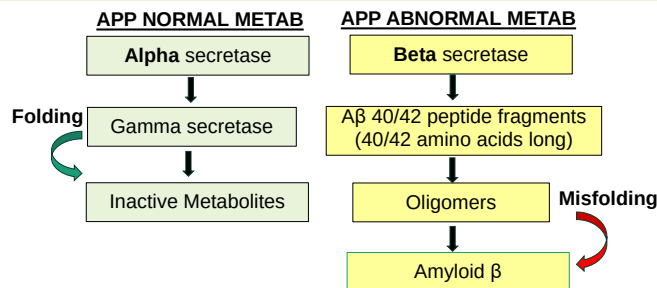


*IAPP = Islet Amyloid Polypeptide

Ponce-Lopez T, et al. *Intertech Open* 2019; DOI: <http://dx.doi.org/10.5772/intechopen.84473>

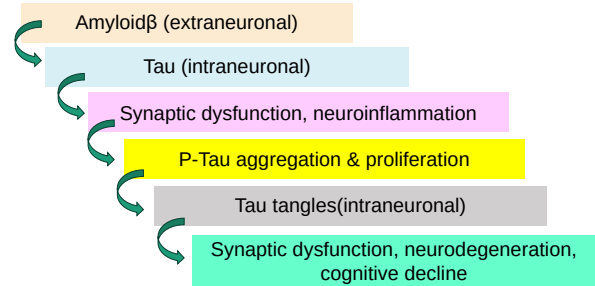
Alzheimer's Disease is
A Protein Misfolding Disorder

Alzheimer's: Amyloid Precursor Protein (APP) Misfolding



Ashraf GM *CNS Neural Disord Drug Targets*. 2014;13(7):1280–1293

Alzheimer's: The Amyloid Hypothesis Process



Adapted from Rabinovici GD, La Joie R *JAMA* 2023;333(6):507-508

DEFINITIONS

Alzheimer's Disease (AD): Definition 2024 Alzheimer's Association Workgroup

"We define AD to be a biological process that begins with the appearance of AD neuropathologic change (ADNPC) while people are aSx. Progression of the neuropathologic burden leads to the later appearance and progression of clinical Sx."

Jack CR, et al. *Alzheimer's & Dementia* 2024;1-27

Alzheimer's Disease (AD): Definition 2024 Alzheimer's Association Workgroup

"We define AD to be a biological process that begins with the appearance of AD neuropathologic change (ADNPC) while people are aSx. Progression of the neuropathologic burden leads to the later appearance and progression of clinical Sx."



Jack CR, et al. *Alzheimer's & Dementia* 2024;1-27

Alzheimer's Disease (AD): Definition 2024 Alzheimer's Association Workgroup

"Although many individuals die with ADNPC without experiencing Sx, this can be attributed to the exponential rise in all-cause mortality rates with older age."

= if you have ADNPC and live long enough, you will get the clinical syndrome

Jack CR, et al. *Alzheimer's & Dementia* 2024;1-27

The Down's Syndrome: Alzheimer's Linkage

"Alzheimer disease is...invariable... in individuals with Down syndrome...who have an extra copy of the APP gene as a result of the trisomy."

Knopman D Goldman-Cecil Medicine Elsevier (Philadelphia) 2024:2412-2425

Typical Clinical Presentation

Alzheimer's: Significant Other Process

Stage 1 Denial:
"We all forget things..."

Stage 2 Denial:
"Maybe she's just going thru a rough patch..."

Ambivalent Uncertainty:
"It seems like more than just 'some slip-ups'"

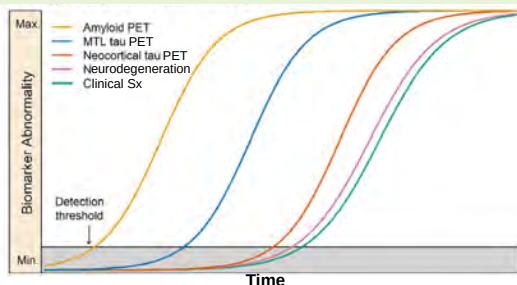
Reality-based Apprehension:
"I'm afraid something bad might happen if...."

Alzheimer's: The Patient as Innocent Co-Conspiritor **Anosognosia**

"...a pervasive and nearly invariant aspect of dementia is a loss of insight (**anosognosia**) into the extent of one's cognitive and functional losses."

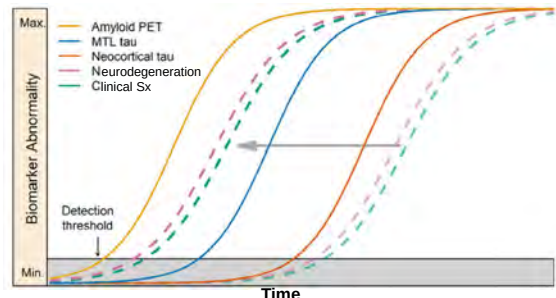
Kass JS Ferri's Clinical Advisor 2025 Elsevier (Philadelphia) 2025:71-78

AD Presentation As Per Pathologic Marker



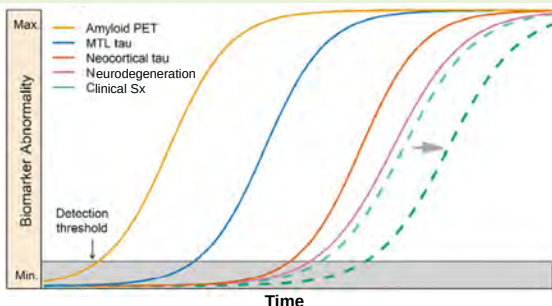
Jack CR, et al. *Alzheimer's & Dementia* 2024:1-27

AD: Effect of Coexisting Pathologies



Jack CR, et al. *Alzheimer's & Dementia* 2024:1-27

AD: Effect of Cognitive Reserve



Jack CR, et al. *Alzheimer's & Dementia* 2024:1-27

Down's Syndrome: Impacted by AD?

- Down's → ↑ amyloid precursor protein & Aβ
- Lifetime AD risk = 95%
- "Virtually all individuals with Down's have sufficient ADNPC to meet neuropathological criteria for a Dx of AD by their mid-40s."
- Sx onset:
 - Typically mid-50's
 - Low competing mortality causes

Jack CR, et al. *Alzheimer's & Dementia* 2024:1-27

Dx

AD: Evolution of Dx Testing

"...the most significant advance in AD diagnostics...has been...blood-based markers with some (not all) assays exhibiting accurate diagnostic performance. This now makes the biological Dx of AD (which previously required PET or CSF assays), more generally accessible and is projected to revolutionize clinical care...."

Jack CR, et al. *Alzheimer's & Dementia* 2024;1:27

AD: Fundamental Principles Alzheimer's Association Workgroup

"AD is defined by its unique neuropathologic findings; therefore, detection of AD neuropathologic change by biomarkers is equivalent to diagnosing the disease....Sx are a result of the disease process and are not necessary to Dx AD."

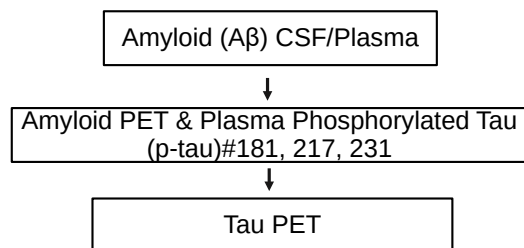
Jack CR, et al. *Alzheimer's & Dementia* 2024;1:27

What About Core 1 Markers in an aSx Person?

"Although Sx may not appear for years, the disease nonetheless exists at this initially detectable stage and will eventually produce Sx if the individual lives long enough."

Jack CR, et al. *Alzheimer's & Dementia* 2024;1:27

AD: Sequence of Core Biomarker Appearance



Jack CR, et al. *Alzheimer's & Dementia* 2024;1:27

AD: What is a 'Core 1 Biomarker'?

"Core 1 biomarkers define the initial stage of AD...and can identify the presence of AD in both symptomatic and asymptomatic individuals."

Jack CR, et al. *Alzheimer's & Dementia* 2024;1:27

AD: Core 1 Biomarkers

- Amyloid (Aβ)
 - Aβ42 (Plasma or CSF)
 - Amyloid (PET)
- Tau (Plasma or CSF)
 - Phosphorylated tau (**p-tau217**, p-tau 181, p-tau 231)

Jack CR, et al. *Alzheimer's & Dementia* 2024;1:27

Dx Alzheimer's By Core 1 Markers

- Alzheimer's Dx criteria (any 1 or more):
 - + Amyloid PET
 - Plasma Aβ42/40
 - + plasma p-tau217, % p-tau217 (p-tau217/non-p-tau 217)
 - [+CSF p-tau181/Aβ42, t-tau/ Aβ42, Aβ42/40]

Jack CR, et al. *Alzheimer's & Dementia* 2024;1:27

Alzheimer's Disease (AD): Dx Alzheimer's Association Workgroup

"An abnormal Core 1 biomarker result is sufficient to establish a Dx of AD and to inform clinical decision making throughout the disease continuum."

Jack CR, et al. *Alzheimer's & Dementia* 2024;1:27

AD: What is a 'Core 2 Biomarker'?

"Core 2 biomarkers become abnormal later in the evolution of AD and are more closely linked with the onset of Sx than are Core 1 biomarkers....when combined with Core 1, [they] may be used to stage biological disease severity."

Jack CR, et al. *Alzheimer's & Dementia* 2024;1:27

Alzheimer's Disease (AD): Dx Alzheimer's Association Workgroup

"Later-changing Core 2 biomarkers (biofluid and tau PET) can provide prognostic information and when abnormal, will ↑ confidence that AD is contributing to Sx."

Jack CR, et al. *Alzheimer's & Dementia* 2024;1:27

AD: Fundamental Principles Alzheimer's Association Workgroup

"Unimpaired individuals with abnormal biomarker test results are at risk for Sx due to AD. They are not at risk for a disease they already have."

Jack CR, et al. *Alzheimer's & Dementia* 2024;1:27

What About the 'Worried Well'?

"...the clinical use of AD biomarkers is presently intended for the evaluation of Sx individuals, not cognitively unimpaired individuals. AD **can** be diagnosed in aSx individuals, but we do not believe this **should** be done for clinical purposes at this time."

Jack CR, et al. *Alzheimer's & Dementia* 2024;1:27

Differential Dx

AD: Fundamental Principles Alzheimer's Association Workgroup

"Clinical syndromes commonly seen with AD may also be caused by disorders other than AD, and therefore clinical presentation alone is not diagnostic of AD."

Jack CR, et al. *Alzheimer's & Dementia* 2024;1:27

Alzheimer's: Red Flags

- Onset <65
- Fluctuating level of consciousness
- Behavioral/emotional/personality Δ >> Cognitive Δ
- Rapidly progressive (<1 year)
- Gait Impairment
- Lateralizing signs: hemiparesis, spasticity, CST signs
- Movement disorder
- Myoclonus
- Rigidity, bradykinesia

Kass JS Ferri's *Clinical Advisor* 2025 Elsevier (Philadelphia) 2025;71-78

Dementia: Could it be Hepatic Encephalopathy?

"Patients with dementia may instead have hepatic encephalopathy and should be screened with the FIB-4 index for cirrhosis...new research...of more than 68,000 individuals...with dementia ...found that almost 13% had FIB-4 scores indicative of cirrhosis and potential hepatic encephalopathy

Am J Med doi: 100.1016/j.amimed.2024.06.014

BASELINE WorkUp

Baseline Lab for Cognitive Impairment

- CBC, CMP, LFT's
- Thyroid Function
- B1, B12, Folate
- FIB-4
- RPR/VDRL or TPA
- HIV
- ESR
- A1c
- Urine: Heavy Metals
- Urine: Drug Screen
- CXR
- MRI (CT Alternative)

Kass JS Ferri's Clinical Advisor 2024 (Elsevier) Philadelphia

Initial Workup

- Meds:
 - Benzodiazepines
 - Anticholinergics (except darifenacin)
 - Opiates
 - Barbiturates (including Fioricet)
 - Neuroleptics (antipsychotics)
- Depression

Kass JS Ferri's Clinical Advisor 2025 Elsevier (Philadelphia) 2025;71-78

Alzheimer's-Specific Neuroimaging

- For AMYLOID PLAQUES: Amyloid β PET
 - florbetapir*
 - flutemetamol*
 - florbetaben*
- For NEUROFIBRILLARY TANGLES: Tau PET
 - flortaucipir*

* FDA approved for this diagnosis

Kass JS Ferri's Clinical Advisor 2024 (Elsevier) Philadelphia

Cognitive Assessment

Dementia: Do You Need Formal Neuropsychiatric Testing?

"Brief mental status testing can be done easily and quickly in the office. Formal neuropsychologic testing.....is **not required** for straightforward cases."

Kass JS Ferri's Clinical Advisor 2025 Elsevier (Philadelphia) 2025;71-78

Dementia: Office-Based Cognitive Tests

- Mini-Mental State Examination (MMSE)
- Mini-Cog
- Montreal Cognitive Assessment (MOCA)
- Self-Administered Gerocognitive Exam (SAGE)
- Saint Louis University Mental SLUMS

Pharmacology

Can You Prevent Clinical Decline in aSx AD?

“...disease-targeted therapies have not been approved for cognitively unimpaired individuals with AD. For this reason, we currently recommend against diagnostic testing in cognitively unimpaired individuals...”

Jack CR, et al. *Alzheimer's & Dementia* 2024;1-27

EDITORIAL

The Supplement Paradox Negligible Benefits, Robust Consumption

Pieter A. Cohen, MD

Dietary supplements encompass a wide variety of products from vitamins, minerals, and botanicals to probiotics, protein powders, and fish oils.¹ During the past 2 decades, a steady stream of high-quality studies evaluating dietary supplements have been published, revealing more than 10 000 calls related to ephedra poisonings per year.^{2,3} Long-term risks began to be recognized as well, for example, beta-carotene supplements were found to actually increase the risk of lung cancer among smokers.^{4,5} Not all supplements, of course, lack evidence of efficacy.

Cohen PA *JAMA* 2016;316(14):1453-1454

Alternative Pharmacotherapy: Ginkgo Biloba

“Ginkgo biloba is marketed widely as effective in delaying cognitive impairment; however, trials have shown that **it is not effective** in reducing the incidence of Alzheimer dementia or dementia overall.”

Kass JS *Ferri's Clinical Advisor* 2024 (Elsevier) Philadelphia

The Supplement ‘Story’: Part A

“... a steady stream of high-quality studies evaluating dietary **supplements** has yielded predominantly **disappointing results**...whereas **evidence of harm has continued to accumulate.**”

Cohen PA *JAMA* 2016;316(14):1453-1454

The Supplement ‘Story’: Part B

IF part A is true, why would the public continue to spend their \$\$ on supplements?

Cohen PA *JAMA* 2016;316(14):1453-1454

The Supplement ‘Story’: Part C “Truth” in Advertising??

“...even after high-quality studies that show no meaningful clinical differences between supplements and placebos are published, the law provides manufacturers latitude to continue advertising their products based on earlier, low quality data.”

Cohen PA *JAMA* 2016;316(14):1453-1454

The Supplement ‘Story’: Part C Example

“For example, Ginkgo biloba continues to be sold ‘to support mental sharpness’ despite a large, high-quality NIH-funded study that found evidence to the contrary.”

Cohen PA *JAMA* 2016;316(14):1453-1454

What's The Deal with APOE4? Apolipoprotein E

- Primary cholesterol transport protein in CNS
- 3 APOE variants:
 - ApoE2: Protective against AZD
 - ApoE3: No effect on AZD incidence
 - ApoE4: ↑AZD risk (heterozygote ↑3x, homozygote ↑15x AZD risk)
- Because of test imprecision, not recommended

Kass JS Ferri's Clinical Advisor 2024 (Elsevier) Philadelphia

What's The Deal with APOE4? APOE4 status Predicts Risk of ARIA Events

- Donanemab (TRAILBLAZER-ALZ* Trial) ARIA-E events
 - APOE4 homozygous: 40.6%
 - APOE4 heterozygous : 22.8%
 - Non-APOE4: 15.7%

*N = 1,736

Rabinovici GD, La Joie R JAMA 2023;330(6):507-508

Research

JAMA | Original Investigation

Donanemab in Early Symptomatic Alzheimer Disease The TRAILBLAZER-ALZ 2 Randomized Clinical Trial

John R. Sims, MD, Jennifer A. Zimmer, MD, Cynthia D. Evans, PhD, Ming Lu, MD, MS, MPH, Paul Ardayfio, PhD, JonDavid Sparks, PhD, Alette M. Wassels, PhD, Sergey Shcherbinin, PhD, Hong Wang, PhD, Emel Serap Monkul Nery, MD, Emily C. Collins, PhD, Paul Solomon, PhD, Stephen Salloway, MD, Liana G. Apostolova, MD, Oskar Hansson, MD, PhD, Craig Ritchie, MD, PhD, Dawn A. Brooks, PhD, Mark Mintun, MD, Daniel M. Slomirsky, MD, PhD, for the TRAILBLAZER-ALZ 2 Investigators

Sims JR, et al. JAMA 2023;330(6):512-527

Early AZD: Donanemab The TRAILBLAZER-ALZ Trial Outcome

“Among participants with early symptomatic AZD and amyloid and tau pathology, donanemab significantly slowed clinical progression at 76 weeks...”

Sims JR, et al. JAMA 2023;330(6):512-527

What is donanemab?

- Monoclonal IgG₁ antibody
- Specific target: insoluble N-terminal truncated β-amyloid (present only in β-amyloid brain plaque)
- Adhesion of IgG1 antibody to brain plaque → ↑microglial phagocytosis → ↑ β-amyloid clearance

Sims JR, et al. JAMA 2023;330(6):512-527

Early ALZ: Donanemab The TRAILBLAZER-ALZ Trial

- Study: RDBPCT Multinational (n=1,736)
- Inclusion
 - ALZ with MCI or mild dementia age 60-85
 - Amyloid PET +, Tau PET +
- Rx (IV Q4 weeks x 72 weeks):
 - donanemab 700 mg X 3 then 1400 mg
 - Placebo
- 1⁰ Outcome: Integrated ALZD Rating Scale Score

Sims JR, et al. JAMA 2023;330(6):512-527

What is the Integrated Alzheimer's Disease Rating Scale?

- IADRS Measures
 - Cognition
 - Daily function
 - Global disease severity
- Scale: 0-144 (lower is worse)
- Minimum meaningful increment of change*
 - ALZD with MCI: 5 points
 - ALZD with mild dementia: 9 points

* AKA MCID (minimal clinically important difference) “A threshold... above which a patient or physician would consider the change meaningful.”

Sims JR, et al. JAMA 2023;330(6):512-527

Donanemab: TRAILBLAZER-ALZ Trial Monitoring for Excessively LOW βAmyloid Levels

- Assessed by βAmyloid PET at 24 and 52 weeks
 - A: <11 Centiloids at either assessment
 - B: 11-25 Centiloids at both assessments
- If fell below A or B, donanemab withheld

Placebo

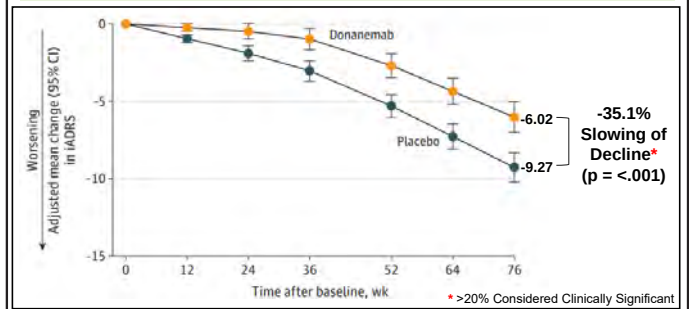
Sims JR, et al. JAMA 2023;330(6):512-527

TRAILBLAZER-ALZ Trial: ARIA Amyloid Related Imaging Abnormalities (ARIA)

- ARIA = any of edema, effusion (ARIA-E), microhemorrhages, macrohemorrhages, hemosiderin deposits (ARIA-H)
- MRI Week 4, 12, 24, 52, 76 and at investigator discretion
- Hold Rx until ARIA resolves then resume
- Stop Rx for macrohemorrhage

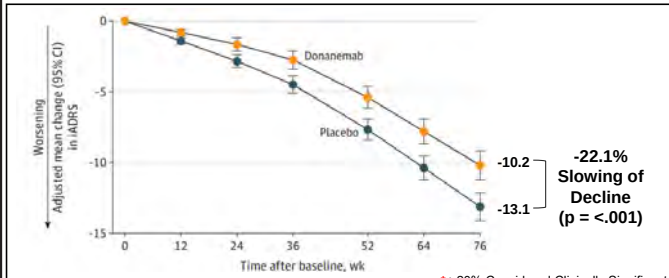
Sims JR, et al. JAMA 2023;330(6):512-527

Donanemab: iADRS (low/medium tau population)



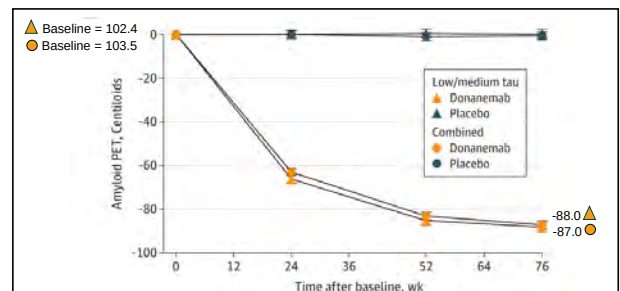
Sims JR, et al. JAMA 2023;330(6):512-527

Donanemab: Δ iADRS (Combined Population)



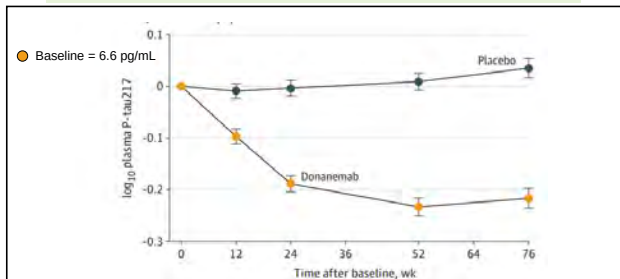
Sims JR, et al. JAMA 2023;330(6):512-527

Donanemab: Δ Brain Amyloid (PET) X 76 Weeks



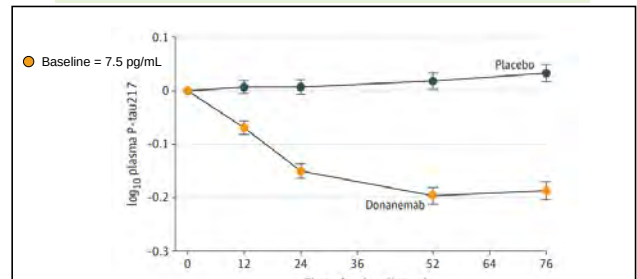
Sims JR, et al. JAMA 2023;330(6):512-527

Donanemab: Δ Plasma p-Tau (Low-medium Tau Population)



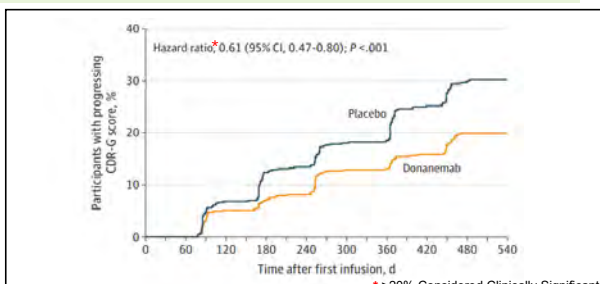
Sims JR, et al. JAMA 2023;330(6):512-527

Donanemab: Δ Plasma p-Tau (Combined Tau Population)



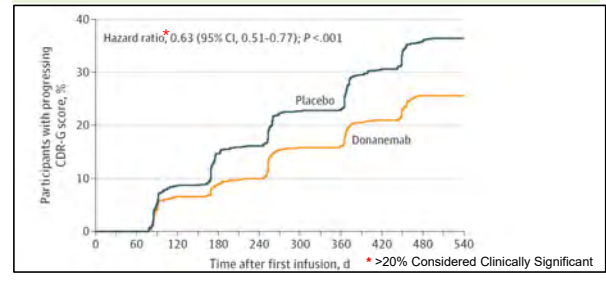
Sims JR, et al. JAMA 2023;330(6):512-527

Clinical Dementia Global Rating Score (Low-medium Tau)



Sims JR, et al. JAMA 2023;330(6):512-527

Clinical Dementia Global Rating Score (Combined Tau)



Sims JR, et al. JAMA 2023;330(6):512-527

Donanemab TRAILBLAZER-ALZ Adverse Effects

	Donanemab	Placebo
Death	16 (1.9%)	10 (1.1%)
Death Related to Rx	3 (0.4%)	1 (0.1%)
Infusion Reactions	74 (8.7%)	4 (0.5%)
≥1 Serious AE	148 (17.4%)	138 (15.8%)
AE → Rx D/C	112 (13.1%)	38 (4.3%)
ARIA-E	205 (24.0%)	17 (1.9%)
ARIA-H	168 (19.7%)	65 (7.4%)

Sims JR, et al. JAMA 2023;330(6):512-527

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Lecanemab in Early Alzheimer's Disease

C.H. van Dyck, C.J. Swanson, P. Aisen, R.J. Bateman, C. Chen, M. Gee, M. Kanekiyo, D. Li, L. Reyderman, S. Cohen, L. Frolich, S. Katayama, M. Sabbagh, B. Vellas, D. Watson, S. Dhadda, M. Irizarry, L.D. Kramer, and T. Iwatsubo

Van Dyck CH, et al. NEJM 2023;388(1):9-21

Lecanemab: Early Alzheimer's Disease

- Study: DBRPCT MCI-early Alzheimer's
- Inclusion(n = 1,795)
 - Age 50-90
 - +βAmyloid (by PET or CSF)
- Rx: lecanemab 10 mg/kg Q2weeks vs Placebo
- 1^o Endpoint (at 18 weeks): CDR-SB Score (Clinical Dementia Rating-Sum of Boxes score)

Van Dyck CH, et al. NEJM 2023;388(1):9-21

Lecanemab for Early Alzheimer's Disease Conclusions

"Lecanemab reduced markers of amyloid in early Alzheimer's disease and resulted in moderately less decline on measures of cognition and function than placebo at 18 months but was associated with adverse events."

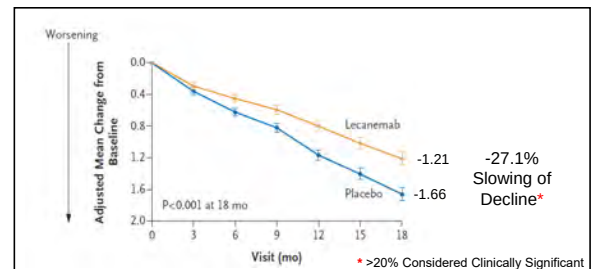
Van Dyck CH, et al. NEJM 2023;388(1):9-21

What is Lecanemab?

"Lecanemab is a humanized monoclonal antibody that binds with high affinity to soluble Aβ protofibrils...."

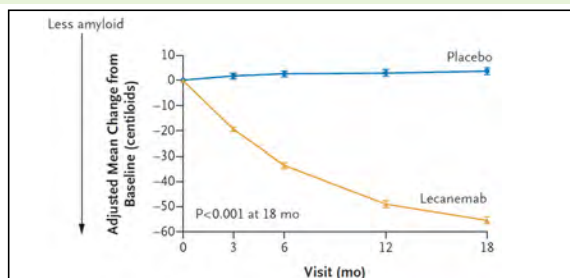
Van Dyck CH, et al. NEJM 2023;388(1):9-21

Lecanemab: ΔCDR-SB Score



Van Dyck CH, et al. NEJM 2023;388(1):9-21

Lecanemab: Amyloidβ on PET



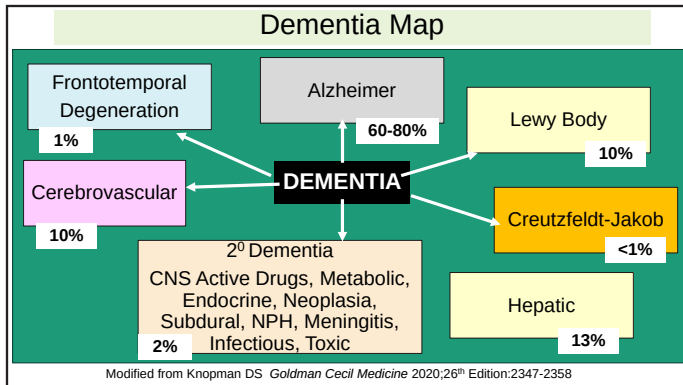
Van Dyck CH, et al. NEJM 2023;388(1):9-21

Lecanemab: Adverse Effects

	Lecanemab	Placebo
Death	6 (0.7%)	7(0.8%)
Infusion Reactions	237 (26.4%)	66 (7.4%)
>1 Serious AE	126 (14.0%)	101 (11.3%)
AE → Rx D/C	62 (6.9%)	26 (2.9%)
ARIA-E	113 (12.6%)	15 (1.7%)
ARIA-H	155 (17.3%)	81 (9.0%)

<Less than >greater than = about the same as donanemab in TRAILBLAZER-ALZ
NOT A HEAD TO HEAD COMPARISON

Sims JR, et al. JAMA 2023;330(6):512-527



SELF EVALUATION

Understanding Alzheimer's Disease: Diagnosis, Biomarkers, and Emerging Therapies

1. Alzheimer's disease is best characterized as which of the following types of disorder?
 - a. Autoimmune disorder
 - b. Protein misfolding disorder
 - c. Vascular disorder
 - d. Neurotransmitter deficiency disorder
2. T/F - Clinical symptoms are required to diagnose Alzheimer's disease under current definitions.
3. Which of the following is considered a Core 1 biomarker for Alzheimer's disease?
 - a. MRI showing hippocampal atrophy
 - b. Amyloid PET imaging
 - c. EEG abnormalities
 - d. CT scan findings
4. What is the primary mechanism of action of donanemab?
 - a. Inhibits tau phosphorylation
 - b. Enhances acetylcholine release
 - c. Promotes clearance of amyloid plaques via monoclonal antibody binding
 - d. Blocks NMDA receptors
5. T/F - Ginkgo biloba has been shown in high-quality studies to reduce the incidence of Alzheimer's disease.

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

FACULTY

Neil Gokal, MD, FAAFP

Neil Gokal, MD, FAAFP is a family medicine physician and physician-leader based in Southern Nevada, with a focus on population health, quality outcomes, and medical education. He has served as the inaugural Associate Program Director of the Valley Health System Family Medicine Residency, the largest in the state, and holds academic appointments at Roseman University, UNLV School of Medicine, and Touro University Nevada. With a background in biomedical engineering and global health, Dr. Gokal also serves as Executive Chair of One World Surgery, providing care to underserved communities in the Dominican Republic and Honduras. He is a Fellow of the American Academy of Family Physicians and a recognized leader in physician wellness and professional advocacy.

You may contact Dr. Gokal with any questions or comments at Nilesh.Gokal@optum.com

THE
2026-27

Medical-Dental-Legal
UPDATE

Obesity Management and Weight Loss Pharmacotherapy

Neil Gokal, MD, FAAFP



Disclosure

- Accountability ~~Blame~~
- Ability ~~Fault~~

Objectives

- Understand global and national impact of Obesity
- Reflect on fiscal impact vs quality outcomes
- Be aware of updated recommendations
- Learn strategies of assessing and evaluating for Obesity
- Review approach to treatment

Patient Case

A 33 yo F presents to establish care and vital signs show:

Height 5'8"
Weight 255
BMI 38.8

Based on this, you would classify this patient as having:

- A) Morbid obesity
- B) Obesity
- C) Class II obesity
- D) Class IV obesity



Around the World

Since 1990:	In 2022:	In 2024:
• adult obesity has more than doubled • adolescent obesity has quadrupled	• 1 in 8 people living with obesity • 2.5 billion adults with overweight • 890 million with obesity • 43% of adults with overweight • 16% with obesity • Over 390 million children and adolescents aged 5–19 years with overweight	• 35 million children under the age of 5 with overweight

WHO Good Practice Statement

“Obesity is a chronic **complex** disease that requires lifelong care beginning with clinical assessment and early diagnosis. Once diagnosed, individuals should have access to **comprehensive chronic care programs** offering sustained behavioral and lifestyle interventions. When appropriate, pharmacological, surgical or other therapeutic options may be used to support effective disease management. In parallel, care should address the prevention and treatment of obesity-related complications and comorbidities.”

Dec 2025

WHO Conditional Recommendation

“In adults living with obesity, GLP-1 receptor agonists or GIP/GLP-1 dual agonists may be used as long-term treatment for obesity.”

Dec 2025

USPSTF Recommendation

Adults	The USPSTF recommends that clinicians offer or refer adults with a body mass index (BMI) of 30 or higher (calculated as weight in kilograms divided by height in meters squared) to intensive, multicomponent behavioral interventions.	B
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USPSTF Recommendation

Children and adolescents 6 years or older	The USPSTF recommends that clinicians provide or refer children and adolescents 6 years or older with a high body mass index (BMI) (≥ 95 th percentile for age and sex) to comprehensive, intensive behavioral interventions. See the Practice Considerations section for more information about behavioral interventions.	B
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OMA

Every person with obesity should have access to evidence-based treatment.



USDA

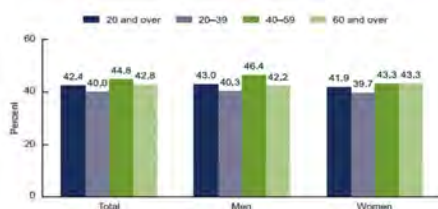


“Nearly 90% of health care expenditures are on chronic diseases [many of which] are the predictable result of the Standard American Diet—a diet reliant on highly processed foods and coupled with a sedentary lifestyle. This changes today.”



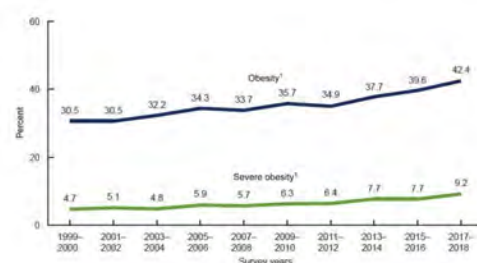
“
Obesity is the second most preventable cause of death in the United States.

Obesity Prevalence

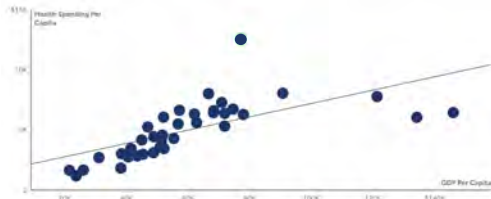


“
a significant public health epidemic which has progressively worsened over the past 50 years

Trend

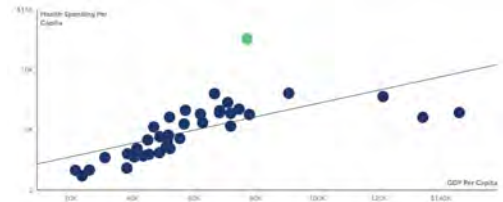


GDP & Health Consumption per Capita



GDP & Health Consumption per Capita

the U.S. spends a greater amount on health care than any other high-income nation

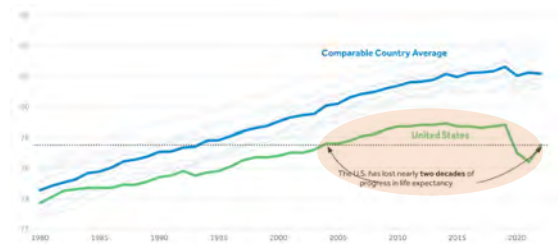


Health expenditures per capita

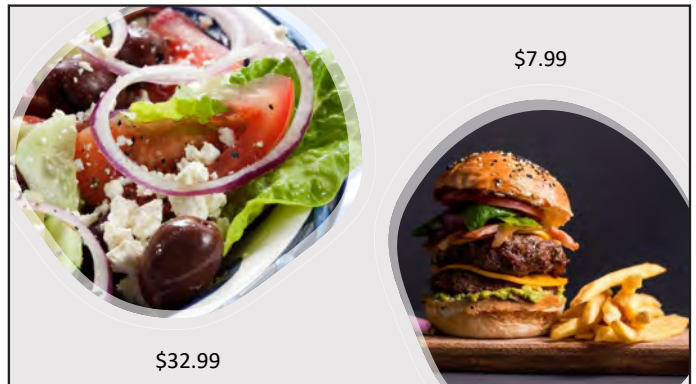
United States	\$10,900
Netherlands	\$8,000
Germany	\$6,000
France	\$4,700
Japan	\$4,700
Comparable Country Average	\$4,000
Thailand	\$3,800
Belgium	\$3,800
Sweden	\$3,400
Australia	\$3,300
Canada	\$3,300
United Kingdom	\$3,300
Spain	\$3,300

On average, other large, wealthy countries spend about half as much per person on health as the U.S.

Life Expectancy



- Diabetes Mellitus
- Heart Disease
- Hyperlipidemia
- Depression
- Arthritis
- Apnea
- Cancers



- Diabetes Mellitus
38.4 million
- Heart Disease
150 million
- Hyperlipidemia
3 million
- Depression
21 million

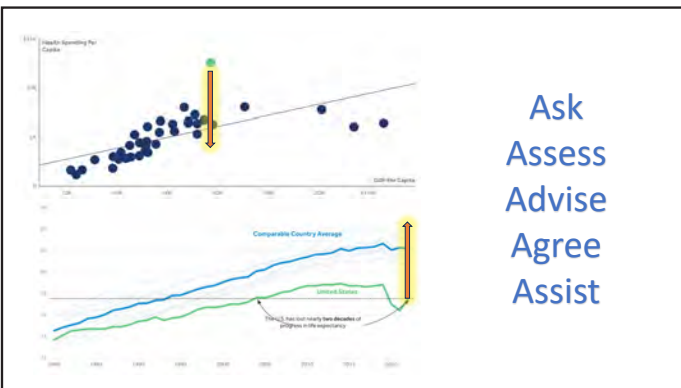
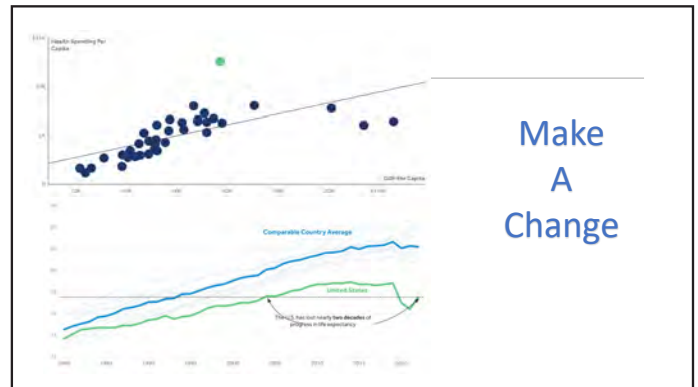
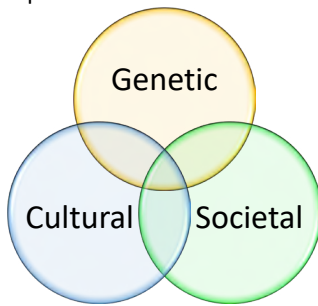


- Diabetes Mellitus
\$640,000,000,000
- Heart Disease
\$555,000,000,000
- Hyperlipidemia
\$23,011,000,000
- Depression





Influencers and Impact



First Glance, Lasting Impressions, Self Check

- Quick fix
- Chemical life
- Value vs Cost



BMI Classification

Classification	BMI (kg/m ²)	ICD -10
Underweight	< 18.5	R63.6
Normal weight	18.5 – 24.9	Z68.2
Overweight	25.0 – 29.9	E66.3
Obese	≥ 30.0	E66.9
Class I Obesity	30.0 – 34.9	E66.811
Class II Obesity	35.0 – 39.9	E66.812
Class III Obesity	≥ 40.0	E66.813

(33 yo F w BMI 38.0) = 33 yo F with Class II Obesity)

“
A 5% to 10% weight loss can significantly improve health, quality of life, and economic burden of an individual and a country as a whole.”

Patient First Terminology

SAY THIS	NOT THIS
Patient with obesity	Obese
Patient with unhealthy weight	Fat
Nutrition Pattern or Eating Habits	Diet
Physical Activity or Movement	Exercise

Behavioral Counseling

"If you are tired of starting over, stop giving up"

< 50% adults with overweight or obesity received weight-loss counseling

Recommended for patients with BMI ≥ 30

Accountability systems

History: weight changes, weight goals, social support, eating behaviors

Evaluate for stressors + emotional triggers

Celebrate successes

Weight Promoting Medications

Class	Types
Antidepressants	TCA, paroxetine
Antihistamines	Diphenhydramine, cetirizine, fexofenadine
Antipsychotics	Chlorpromazine, clozapine, olanzapine, quetiapine, risperidone, brexpiprazole, lithium, thioridazine
CVD	Atenolol, metoprolol, propranolol, CCB
Chemotherapy	Tamoxifen, cyclophosphamide, methotrexate, aromatase inhibitors, corticosteroids
Diabetes	Insulin, meglitinides, sulfonylureas, thiazolidinediones
Hormones	Estrogen, IM Progesterin
Insomnia	Zolpidem
Seizure Meds	Carbamazepine, gabapentin, pregabalin, valproate

Nutrition

"Contradictory as it seems, malnutrition is a key contributor to obesity."

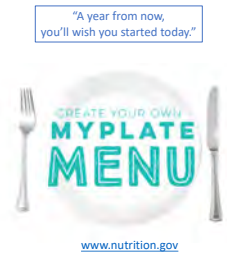
— Madeleine M. Kunin

- Meal timing
- Food content and access
- Portions
- Preparation methods
- Consider cultural and financial barriers
- Calorie Counting

Caloric intake goal:
Women = 1000-1500 kcal/day
Men = 1200-1800 kcal/day

Nutrition

- Dietary approaches
 - Atkins (low carb high protein)
 - DASH (low sodium heart healthy)
 - Fasting
 - Jenny Craig/ Weight Watchers
 - Ketogenic (low carb high fat)
 - Mediterranean (heart healthy)
 - Plant Based



USDA Dietary Guidelines 2025

- Protein: 1.2-1.6 g/protein per kg/body wt/d
- Dairy
 - full fat, no sugar
- Healthy Fats
 - <10% sat fat
- Vegetables: 3 servings/d + Fruits: 2 servings/d
 - colors
- Whole Grains: 2-4 servings/d
 - fiber
- Portion
 - calories, hydration
- Limit Processed Foods
 - sugar, syrup, -ose
- Limit Alcohol



Physical Activity

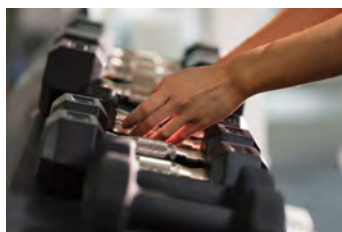
- Evaluate lifestyle
- Identify barriers
- Set SMART goals
 - Specific:** Clearly define what you want to achieve
 - Measurable:** Establish criteria to track progress and success
 - Achievable:** Ensure that the goal is realistic and attainable
 - Relevant:** Align the goal with broader objectives or values
 - Time-bound:** Set a deadline for achieving the goal

"What keeps you active?"

Physical Activity

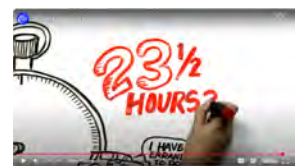
- 150 min/week moderate intensity or 75 min/week vigorous intensity
- Muscle strengthening 2 or more days/week
- Balance training for older adults

"Excuses don't burn calories."



AAFP Simplified Start

- Sit Less
- One thing Daily
- Make it Fun
- "If at first you don't succeed, move, move again."



23 and 1/2 hours: What is the single best thing we can do for our health?

Approach to Pharmacology

Efficacy based on percentage of total body weight loss



Most Effective

- Incretin Analogs (GLP1, GLP1/GIP)
- Combination Oral

Somewhat Effective

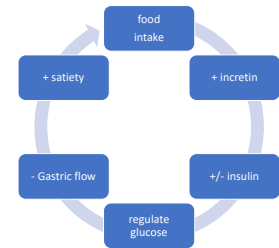
- Phentermine
- Diethylpropion

Least Effective

- Orlistat
- Hydrogel

Incretins Explained

- Primary Incretin Hormones
 - Gastric inhibitory polypeptide (GIP)
 - Glucagon-like peptide-1 (GLP-1)



Incretin Analog Medications

Not (yet) FDA approved for weight loss

Liraglutide (Saxenda)

Semaglutide (Wegovy)

• Ozempic

• Rybelsus

Tirzepatide (Zepbound)

• Mounjaro

Setmelanotide (Imcivree)

FDA Approved GLP/GLP+GIP

Rx	Age	Route	Dosing	Avg Wt Reduction	Contraindication
Liraglutide	12 yoa+	Daily Injection	.6mg/ 1.2mg/ 1.8mg/ 2.4mg/ 3mg q weekly	4.8%	• Phx or FHx Medullary Thyroid Cancer • Multiple Endocrine Neoplasia (MEN) 2 • GI disease • Pancreatitis
Semaglutide	12 yoa+	Weekly Injection	.25mg/.5mg/1mg/1.7mg/2.4mg q 4 weeks	11%	
		Daily Pill	1.5mg/4mg/ 9mg/25mg q 30 days		
Tirzepatide	Adult	Weekly Injection	2.5mg/ 5mg/ 10mg/ 15mg q 4 weeks	15%	

Duration: Liraglutide- D/c if wt loss <4% after 16 weeks, others... ?

Combination Orals

Rx	Age	Route	Dosing	Avg Wt Reduction	Contraindication
Phentermine-Topiramate (Qsymia)	12 yoa+	Oral	3.27mg/23mg x 2 weeks 7.5mg/46mg If wt loss <3% after 12 weeks: 11.25mg/69mg x 2 weeks 15mg/92mg	8.5%	Glaucoma Hyperthyroid MAOI use Cardiovascular Disease
Naltrexone-Bupropion (Contrave)	Adult	Oral	1 QAM x 1 week 1 BID x 1 week 2 QAM + 1 QPM x 1 week 2 BID	3%	Uncontrolled HTN Seizures Disordered Eating MAOI use Opioid use

Duration: D/C if wt loss <5% after 12 weeks

Amphetamine Derivatives

Rx	Age	Route	Dosing	Avg Wt Reduction	Contraindication
Phentermine	16 yoa+	Oral	15-37.5mg daily	3.6%	Uncontrolled HTN Cardiovascular Disease Hyperthyroidism Glaucoma
Diethylpropion			25mg TID OR 75mg ER QD	5.4%	

Duration:
Phentermine- at plateau (tolerance)
Diethylpropion- if no response after 4 weeks

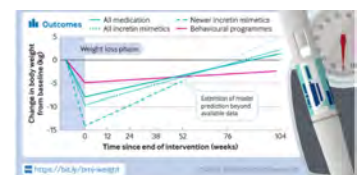
Least Effective

Rx	Age	Route	Dosing	Avg Wt Reduction	Contraindication
Orlistat (Xenical)	12 yoa+	Oral	120 mg TID	2.8%	Malabsorption Cholestasis
Alli OTC			60 mg TID		
Hydrogel (Plenity)	Adult	Oral	2.25 mg (3 caps) BID	<2%	GI motility GI structural anomalies

Treatment Duration: 2026 BMJ Review

With Rx Cessation:

- Baseline weight regained in 1.7 years
- Rapid weight regain + reversal of cardiometabolic benefits
- Regain faster with cessation of Rx than with comprehensive behavioral approach



Bariatric Surgery



↓ all-cause mortality



↓ risk of developing obesity-related conditions



More effective than pharmacotherapy in DME hyperglycemia



BMI Thresholds vary from 30-40

WHO Good Practice Statement

“Obesity is a chronic **complex** disease that requires lifelong care beginning with clinical assessment and early diagnosis. Once diagnosed, individuals should have access to **comprehensive chronic care programs** offering sustained behavioral and lifestyle interventions. When appropriate, pharmacological, surgical or other therapeutic options may be used to support effective disease management. In parallel, care should address the prevention and treatment of obesity-related complications and comorbidities.”

Dec 2025

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SELF EVALUATION

Obesity Management and Weight Loss Pharmacotherapy

1. A 33-year-old woman with a BMI of 38.8 would be classified as which of the following?
 - a. Morbid obesity
 - b. Obesity
 - c. Class II obesity
 - d. Class IV obesity
2. T/F - Obesity is defined as a chronic, complex disease requiring lifelong management.
3. According to recommendations discussed, what level of weight loss is associated with meaningful improvements in health and quality of life?
 - a. 1–2%
 - b. 3–4%
 - c. 5–10%
 - d. >20%
4. Which of the following hormones are classified as incretins?
 - a. Insulin and glucagon
 - b. Lipase and amylase
 - c. GIP and GLP-1
 - d. Cortisol and epinephrine
5. T/F - Weight loss medications can be continued indefinitely as long as the patient tolerates them.

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

FACULTY

Mark D. Olszyk, MD, MBA, FACEP

Mark D. Olszyk, MD, MBA, FACEP, is an emergency physician and physician executive who serves as Chief Medical Officer and Vice President of Medical Affairs at Carroll Hospital, part of LifeBridge Health in Maryland. He brings broad experience across military, academic, VA, rural, and community settings, with a focus on physician leadership, quality, and patient safety. A former Vice Chair of the Maryland Board of Physicians, Dr. Olszyk has led major initiatives in credentialing reform, quality improvement, and the integration of artificial intelligence into clinical operations. He is a Clinical Assistant Professor, a nationally recognized speaker on physician leadership and ethics, and the author of *The Chief Medical Officer's Essential Guidebook*.

You may contact Dr. Olszyk with any questions or comments at MOlszyk@lifebridgehealth.org.

THE
2026-27

Medical-Dental-Legal
UPDATE

Ethics, Artificial Intelligence, and the Future of Trust in Healthcare

Mark D. Olszyk, MD, MBA, FACEP

Ethics, Artificial Intelligence, and the Future of Trust in Healthcare

A practical ethics framework for AI-mediated care

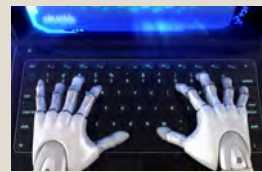
Mark Olszyk, MD

Ethics • AI • Trust in Healthcare

1

Why this matters now

- AI has moved from research labs to the bedside.
- It can read scans, flag sepsis, draft notes, and predict deterioration.
- Powerful capabilities create ethical complexity—especially around trust.
- Goal: keep core clinical ethics intact while adopting new tools.



Ethics • AI • Trust in Healthcare

2

Overview

- Ethical foundations: norms and the four principles
- Why AI challenges the model—and a proposed fifth principle (explicability)
- What “trustworthy medical AI” requires
- Consent & patient data stewardship
- Safety, justice, responsibility, and “safe failure”
- A practical deployment checklist



Ethics • AI • Trust in Healthcare

3

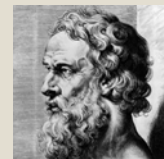
Ethical Norms

Virtue ethics: virtue

Axiomatic: values

Deontology: duty

Utilitarianism: consequence



https://maverick.fandom.com/wiki/The_Jiang_Infantry



Biomedical Ethics



Autonomy

Respecting an individual's freedom to make their own decisions



Beneficence

Acting in the best interest of the individual; providing benefit



Non-maleficence

Avoiding and doing no harm to the individual



Justice

Treating all individuals with fairness, equality, and impartiality

<https://neuroethicscanada.wordpress.com/tag/>

Biomedical Ethics: Autonomy

Autonomy —

- Moral decision-making assumes **rational agents** can make **informed** and **voluntary** choices
- Negative obligation**: do **not** interfere with a person's choices
- Positive obligation**: provide **appropriate information** so an informed decision is possible
- People are free to decide for themselves **if they do not harm others**
- Operational expression in healthcare: **Informed consent**



Biomedical Ethics: Autonomy & AI

Autonomy Requirements for AI in Healthcare

- Disclosure & transparency**
 - Tell patients when AI is used in **care decisions** or **documentation**
- Meaningful choice**
 - Offer **opt-out** when feasible without compromising access to care
- Understandability at the point of decision**
 - Avoid "black box" dependence for material decisions when alternatives exist
- Preserve shared decision-making**
 - Clinicians document **clinical reasoning**, not just AI output
- Data autonomy & privacy**
 - Explain what data is used, where it goes, who can see it, and retention
- Ambient AI safeguards**
 - Clear notice that ambient tools may listen; simple "pause/stop" process
 - Prevent unintended **naming of consultants**, misattribution, or inaccurate EMR text



Biomedical Ethics: Nonmaleficence

Nonmaleficence = "Do no harm"

- Harm includes **thwarting** or **defeating someone's interests** (not just physical injury)
- A primarily **negative duty/obligation**: avoid causing harm through action or omission
- Common applications:
 - **Research ethics** (minimize risk, protect participants)
 - **Pollution** and **environmental harms** (avoid preventable harm to communities)



Biomedical Ethics: Nonmaleficence & AI

Nonmaleficence Requirements for AI in Healthcare

- Safety before scale**
 - Validate AI tools for the intended population and setting before broad rollout
- Risk management & monitoring**
 - Continuous monitoring for performance drift, unexpected errors, and near misses
- Avoid automation harm**
 - Require human oversight for high-stakes decisions (diagnosis, disposition, treatment)
- Data privacy as harm prevention**
 - Prevent misuse of data (secondary use without appropriate approvals/consent)
- Documentation and workflow harms**
 - Ambient AI protections: avoid misquotes, wrong attribution, and unintended consultant naming in the EMR
 - Standards for editing, attestation, and clinician accountability for final notes
- Research ethics alignment**
 - If AI use is investigational: IRB oversight, risk disclosure, and participant protections

Biomedical Ethics: Beneficence

Beneficence: Core Ethical Ideas

- Beneficence = promote the patient's good**
- An affirmative duty to:
 - **Prevent harm**
 - **Remove/mitigate harm**
 - **Advance welfare** (healing, relief of suffering, functional improvement)
- Requires weighing **benefits vs burdens/risks** and choosing the most helpful course



Biomedical Ethics: Beneficence & AI

Beneficence Requirements for AI in Healthcare

- Prove clinical value**
 - Prefer tools with evidence of benefit in similar populations/settings
- Right tool, right task**
 - Define intended use, exclusions, and clinical scenarios where AI should not be used
- Human-centered workflow**
 - Design for clinician and patient needs; reduce cognitive load, not add noise
- Maintain quality of care**
 - Guard against "efficiency bias" where throughput goals override patient benefit
- Continuous improvement**
 - Monitor benefit over time (not just accuracy): outcomes, equity, unintended consequences
- Patient experience and trust**
 - Use AI to enhance communication, clarity, and follow-through (e.g., better visit summaries)

Biomedical Ethics: Justice

Justice: Core Ethical Ideas

- Justice = fairness** in distribution of benefits and burdens
- Treat similar cases similarly; ensure **equitable access** and **non-discrimination**
- Requires attention to structural inequities that can amplify harm or reduce opportunity



Biomedical Ethics: Justice & AI

Justice Requirements for AI in Healthcare

- Equity and bias controls**
 - Mitigate disparities; do not deploy models that systematically disadvantage groups (race/ethnicity, sex, age, language, disability)
- Access and resource allocation**
 - Monitor whether AI shifts resources away from high-need patients
- Guard against "proxy discrimination"**
 - Require review when AI outputs affect referrals, prioritization, or denials
- Accountability and appeal**
 - Clear processes to challenge AI-influenced decisions (patients and clinicians)
- Ongoing equity monitoring**
 - Regular audits of outcomes and workflow impacts; publish internal dashboards where appropriate

How AI challenges the principles

- Autonomy: black-box outputs can be hard to explain or question
- Beneficence: must improve real outcomes—not just throughput
- Nonmaleficence: errors, drift, or cyber issues can directly harm patients
- Justice: access and performance can vary across groups; bias can be embedded
- Bottom line: ethics shifts from “is it accurate?” to “is it safe, fair, transparent, and governed?”



Ethics • AI • Trust in Healthcare

5

What do we mean by “trustworthy medical AI”?

- Not just technically accurate—AI embedded in a trustworthy system.
- Five recurring themes to assess before and after deployment:

Data quality

Algorithmic bias

Opacity

Safety & security

Responsibility

These map directly back to autonomy, beneficence, nonmaleficence, justice, and explicability.



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7

Biomedical Ethics: 5th Principle 1/3

Explicability: Core Ethical Ideas (the “5th principle”)

• **Explicability** = intelligibility + accountability

• **Intelligibility**: Can we describe how it works—and its limits—in plain language?

• **Accountability**: If something goes wrong, can we identify who is responsible?

• Explicability **bridges technical complexity** and **meaningful consent/transparency**



Biomedical Ethics: 5th Principle 2/3

Explicability Requirements for AI in Healthcare (Practical Guardrails)

• Patient- and clinician-facing explanations

- Communicate **confidence/uncertainty**, key limitations, and common failure modes

• Documentation of AI involvement

- Record when AI influenced a recommendation (where appropriate) and what inputs were used

• Clear accountability map

- Define responsibility across the lifecycle:
 - **Requester/owner** (clinical sponsor)
 - **Builder/vendor** (model development and updates)
 - **Validator** (quality/safety review)
 - **Operator** (day-to-day use)
 - **Approver/governance** (go/no-go decisions)
- Specify who responds to incidents and who has authority to pause/disable the tool

Biomedical Ethics: 5th Principle 3/3

• Model governance and change control

- Update notices, and re-validation when models change
- Audit trails for inputs/outputs, user actions, and downstream impact

• Transparency that supports consent

- Patient disclosure language aligned to use case (decision support vs ambient documentation)
- Make opt-out/alternatives understandable and practical when feasible

• Explainability “right-sized” to risk

- Higher-stakes use cases require stronger explainability, testing, and oversight
- Low-stakes workflow tools still need clarity on limits and error handling

Theme 1 — Data quality

- “Garbage in, garbage out” becomes bedside risk.
- Incomplete, mislabeled, or unrepresentative data → flawed recommendations.
- Implications:
 - Technical: standards for curation + continuous monitoring
 - Clinical: wrong suggestions at the point of care
 - Legal: poor data can translate into negligent design



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Theme 2 — Algorithmic bias

- Under-represented groups in training data → systematic under-diagnosis or misclassification.
- Justice demands more than overall accuracy:
 - Bias audits and transparent reporting by subgroup
 - Diverse, representative datasets
 - Ongoing monitoring for drift that worsens equity
- Make “equity performance” a go/no-go criterion.



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Theme 3 — Opacity

- Opaque outputs undermine autonomy and explicability.
- Clinicians can’t easily justify decisions if the rationale is “the model says so.”
- Mitigations:
 - Prefer interpretable models when feasible
 - Provide plain-language explanations + limitations
 - Treat AI as decision support—not a decision maker



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10

Theme 4 — Safety & security

- Nonmaleficence requires:
 - Robust testing before deployment
 - Post-deployment surveillance and incident review
 - Cybersecurity and resilience planning
- Risks include adversarial attacks, data drift, and software failures.
- Design for “graceful degradation” rather than catastrophic failure.



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Theme 5 — Responsibility (AI has no personhood)

Humans remain the duty-bearers. Responsibility is layered:

Developers	Design • training data • validation • documentation • updates
Institutions	Procurement • local validation • governance • training • monitoring
Clinicians	Appropriate use • clinical judgment • override when needed

Governance clarifies roles, audits, escalation, and incident pathways.

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Informed consent: why history still matters

- Modern consent grew out of painful lessons from unethical research.
- Tuskegee and Henrietta Lacks illustrate how hidden use of bodies/data destroys trust for generations.
- AI risks repeating this pattern if data are harvested, repurposed, or shared without clear disclosure.
- Explicability is tightly linked to meaningful consent.

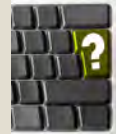


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AI and informed consent: the new questions

- Do patients know when AI is involved in diagnosis or treatment?
- Do they understand what data were used to train the tool?
- Can consent be meaningful if the model's reasoning is largely opaque?
- Practical translation:
 - Explain what the tool does, what it doesn't do, and key uncertainties
 - Make “AI disclosure” standard language in consent and patient portals



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1

How much control should patients have over their data?

- Autonomy and respect suggest patients should have:
 - Clear notice of data use for AI training/improvement
 - Meaningful choices (opt-in/opt-out where feasible)
 - Access and correction rights (and deletion where legally possible)
- Nonmaleficence & justice add:
 - Minimize re-identification risk
 - Strict governance over who can access training data
 - Include patient representatives in AI oversight



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1

Where AI can help (beneficence)

- Earlier detection of deterioration via predictive monitoring
- Decision support for sepsis, imaging, and medication safety
- Improved reliability for drug–drug interaction checking
- Patient-facing tools: symptom checkers, virtual follow-up, remote monitoring
- Potential impact: fewer delays, less travel/waiting, safer care



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1

Where AI can hurt (nonmaleficence)

- Automation bias: clinicians accept AI outputs uncritically
- Hidden performance drop-off when used outside its training context
- Alert fatigue and workflow mis-fit
- Mitigations:
 - Rigorous local validation before go-live
 - Training clinicians to question (not worship) the model
 - Clear override guidance + monitoring for drift



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1

Justice: bias, access, and the rich–poor divide

- Who is in the data? Models trained on wealthier/majority populations may underperform for others.
- Who gets the technology? High-resource centers adopt first; others lag.
- Who bears the burden of failure? Disadvantaged communities often suffer first and longest.
- Justice requires:
 - Intentional inclusion + subgroup performance reporting
 - Design for low-infrastructure settings when relevant
 - Global partnerships where low- and middle-income countries are co-creators



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1

Safe failure at the bedside

- Assume AI will fail sometimes—the question is **how** it fails.
- Safe failure means the system degrades gracefully to a known safe baseline.
- Practical elements:
 - Downtime procedures (like EHR downtime) and drills
 - Uncertainty detection: flag “out-of-distribution” cases for human review
 - Logs and audit trails to reconstruct decisions when things go wrong



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1

A practical checklist for ethical AI deployment

Autonomy & Explicability

- Disclose AI use
- Plain-language limits/uncertainty
- Consent processes address AI

Beneficence

- Strong evidence of benefit
- Define success metrics
- Retire tools that don't deliver value

Nonmaleficence

- Safe-failure guardrails
- Downtime procedures
- Monitor harms & drift

Justice

- Bias audits
- Report by subgroup
- Plan equitable access

Governance & Accountability

- Multidisciplinary oversight
- Patient voices included
- Audit trails & incident pathways

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2

SELF EVALUATION

Ethics, Artificial Intelligence, and the Future of Trust in Healthcare

1. Autonomy — what's the best "AI disclosure" practice?
 - a. Only disclose AI use if the patient asks
 - b. Disclose AI use routinely when it influences care decisions or documentation
 - c. Disclose AI use only for research studies
 - d. Disclose AI use only if the vendor requires it
2. Nonmaleficence — which risk is explicitly called out?
 - a. Clinicians become less empathetic
 - b. Automation bias (accepting AI outputs uncritically)
 - c. Patients demand more imaging
 - d. Hospitals stop using protocols
3. Beneficence — what's the "right" standard for adopting an AI tool?
 - a. It should reduce documentation time
 - b. It should be popular at peer hospitals
 - c. It should demonstrate clinical value with evidence of benefit in similar settings
 - d. It should be highly accurate in the vendor demo
4. Justice — what is the key "go/no-go" equity criterion?
 - a. Overall accuracy above 90%
 - b. Equity performance verified by subgroup reporting and bias audits
 - c. A single champion clinician endorses it
 - d. The tool is FDA-cleared
5. Explicability — what is it (per the "5th principle" slide)?
 - a. Faster model inference time
 - b. Intelligibility + accountability
 - c. Open-source code for every tool
 - d. A legal disclaimer in the consent form
6. Safe failure — what does "safe failure at the bedside" mean?
 - a. The AI never makes errors after go-live
 - b. The AI is turned off permanently if it misses one case
 - c. The system degrades gracefully to a known safe baseline with downtime procedures and audit trails
 - d. Clinicians must always follow the AI recommendation
7. Responsibility — who are the duty-bearers in medical AI?
 - a. The AI system itself
 - b. Only the vendor/developer
 - c. Humans across developers, institutions, and clinicians, with governance clarifying roles and escalation
 - d. Only the bedside clinician

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

FACULTY

Barry Franklin, MD

Barry Franklin, MD, of Royal Oak Michigan, is Director of Preventive Cardiology and Cardiac Rehabilitation at Beaumont Health, Royal Oak, Michigan. He holds faculty appointments as Professor of Physiology at Wayne State University School of Medicine and Professor of Internal Medicine, Oakland University William Beaumont School of Medicine. Pursuing his interest in combining exercise physiology with cardiology, Barry and his associates have studied the physiologic and clinical responses to numerous occupational and leisure-time activities in people with and without heart disease. Other research interests include the prevention of heart disease; cardiovascular risk reduction; obesity and metabolism; exercise testing and prescription; and lifestyle medicine.

You may contact Dr. Franklin with your questions or comments at barry.franklin@corewellhealth.org.

THE
2026-27

Medical-Dental-Legal
UPDATE

Beaumont

Beaumont Health
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4949 Coolidge Highway
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Barry A. Franklin, PhD
Director of Preventive Cardiology and Cardiac Rehabilitation

The Impact of Physical Activity and Fitness on Long-Term Health

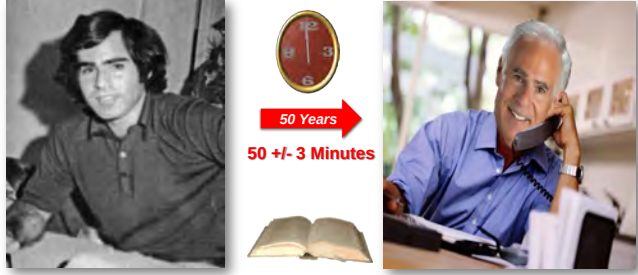
The Impact of Physical Activity and Fitness on Long-Term Health

Barry A. Franklin, PhD
Corewell Health, William Beaumont University Hospital
Preventive Cardiology/Cardiac Rehabilitation
Oakland University Wm. Beaumont School of Medicine
email: Barry.Franklin@CorewellHealth.org
No Disclosures



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Share Lessons Learned about the Role of Regular Physical Activity and Cardiorespiratory Fitness on Modulating Health Outcomes....

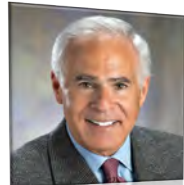


~ 1975 2025

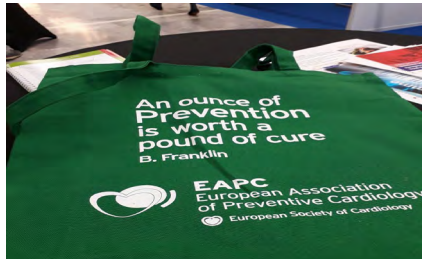
PREVIEWS

- Favorite Professional Story
- My Research/Academic Journey Started with the Pennsylvania State University

My Favorite Professional Story



Barry A. Franklin, Ph.D.



"Dr. Franklin, I was so pleased to see your famous quote on our European Preventive Cardiology conference bag. Congratulations!"
Dr. Aashish Contractor
Mumbai, India



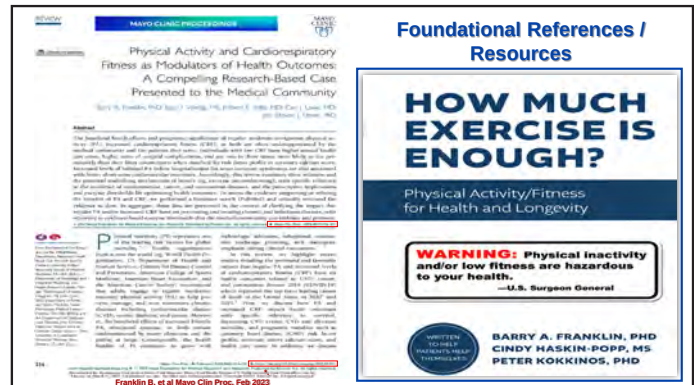
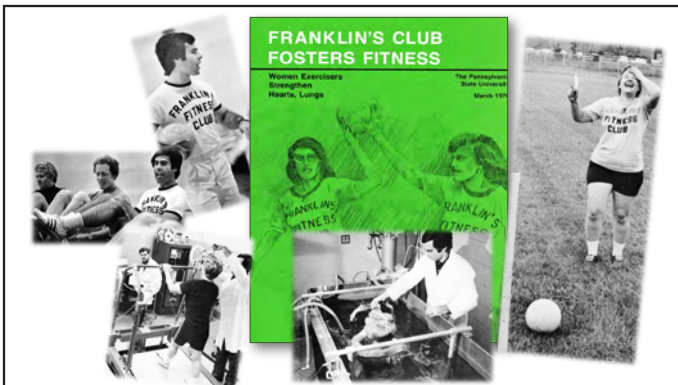
Benjamin Franklin
American Statesman
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The Pennsylvania State University: The Laboratory for Human Performance Research



Effects of physical conditioning on cardiorespiratory function, body composition, and serum lipids in normal weight and obese middle-aged women.



Outline (Topic # 1 of 7)

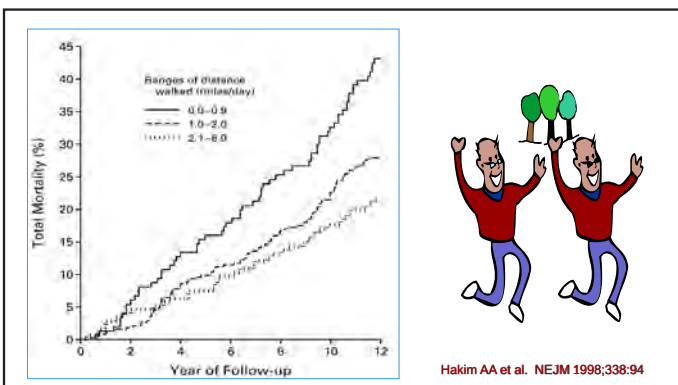
- Physical Activity (PA) and Cardiorespiratory Fitness (CRF) as Modulators of Mortality
- Impact of PA and CRF on Heart Failure Survival/Incidence, Cancer, COVID-19, Dementia and Stroke
- Impact of Chronic PA on Hospitalization for Acute Coronary Syndrome: Role of Exercise Preconditioning
- Impact of PA/CRF on Surgical Outcomes

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

METHODS	707 nonsmoking retired men 61 to 81 years of age; distance walked/day
RESULTS	12-year follow-up, 208 deaths; mortality rate among the men who walked < 1 mile/day was nearly twice that among those who walked > 2 miles/day
CONCLUSIONS	Regular walking is associated with a lower overall mortality rate in older, physically capable men

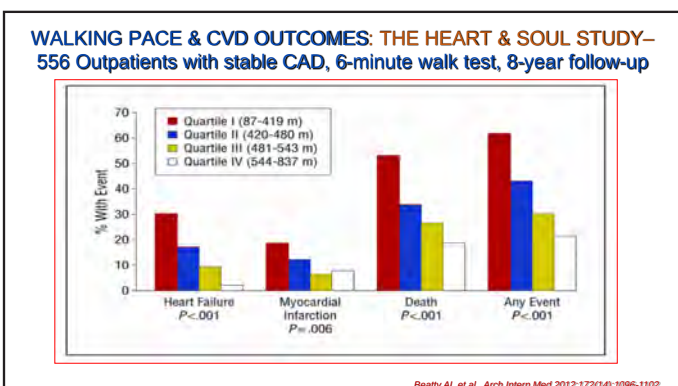
*Hakim AA et al. NEJM 1998;338:94



Reduced Walking Speed: An Underappreciated Vital Sign ?

At a minimum, routinely assess physical activity and simply observe your patient's gait speed the next time he/she leaves your office. A tortoise-like pace (**slower than 2 miles per hour**) may provide the most telling "vital sign" of your physical exam that day. **Why was >3 mph protective ?**

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

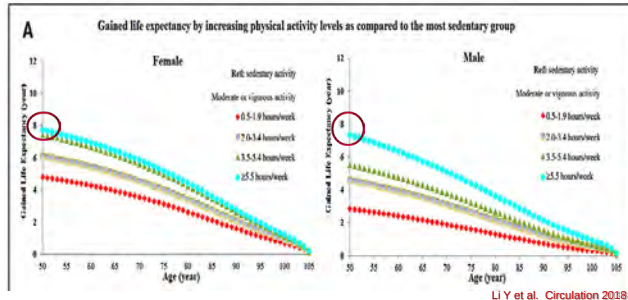


Impact of Healthy Lifestyle Factors on Life Expectancies in the US Population

Background: Americans have a shorter life expectancy compared with residents of almost all other high-income countries. We aim to estimate the impact of 5 low-risk lifestyle factors on premature mortality and life expectancy in the US population.

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

Results: During up to 34 years of follow-up, the most physically active cohorts of men and women (>5.5 hrs/wk) demonstrated 7-to-8 year gains in life expectancy.



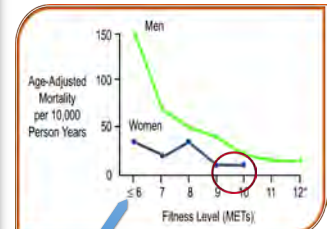
Original Contributions

Physical Fitness and All-Cause Mortality

A Prospective Study of Healthy Men and Women

Abstract
The purpose of this study was to examine the association between physical fitness and all-cause mortality in a prospective study of healthy men and women. The study included 10,000 men and women who were free of cardiovascular disease, cancer, and other major chronic diseases at baseline. Physical fitness was assessed by a maximal treadmill test, and all-cause mortality was determined by linkage to the National Death Index. The results showed that higher levels of physical fitness were associated with lower rates of all-cause mortality, independent of age, sex, and other risk factors. The association was particularly strong for men and for those with higher baseline risk factors.

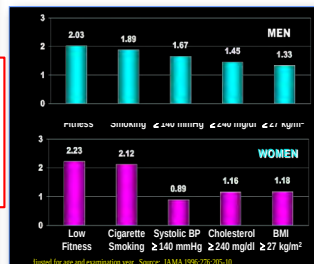
Moving on to Cardiorespiratory Fitness.....



JAMA 1989;262:2395-2401

Influences of Cardiorespiratory Fitness and Other Precursors on Cardiovascular Disease and All-Cause Mortality in Men and Women

Fit persons with any combination of smoking, elevated blood pressure, or elevated cholesterol level had lower adjusted death rates than low-fit persons with none of these characteristics.



Changes in Physical Fitness and All-Cause Mortality*

Subjects 9,777 men

Design E₁ → 5 years → E₂ → 5 years → Follow-up (mortality)



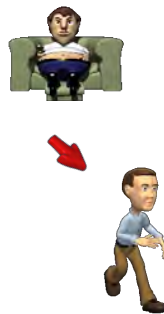
*Blair SN et al. JAMA 1995;273:1093

Results

E ₁		E ₂	Death Rate* (man-years)
Unfit	→	Unfit	122.0/10,000
Fit	→	Fit	39.6/10,000
Unfit	→	Fit	67.7/10,000

* For each minute increase in treadmill time between examinations there was a 7.9% decrease in risk of mortality (p<0.001).

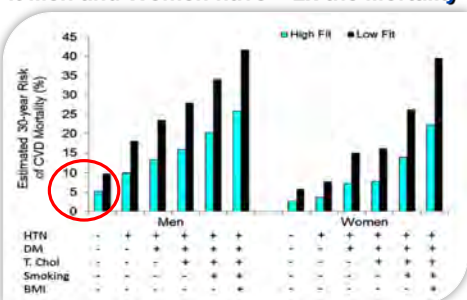
TAKE HOME MESSAGE: As CRF increases, mortality decreases; as CRF decreases, mortality increases.



If there was a pill that you could take to cut your risk in **HALF** of dying from cardiovascular disease (CVD) over the next 30 years, would you take it? There is such a pill---and its called EXERCISE.



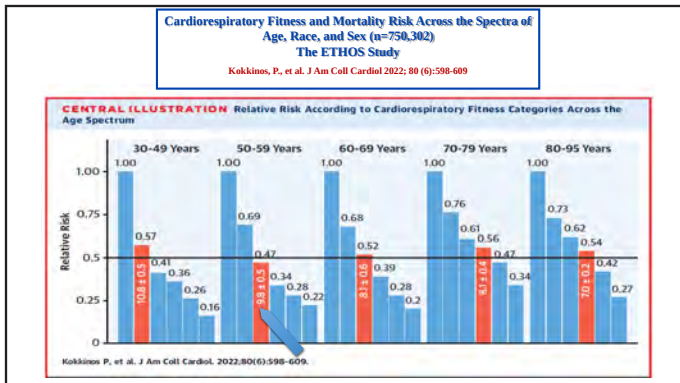
Regardless of the Risk Factor Profile, Low Fit Men and Women have ~ 2x the Mortality



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

Although physical activity or exercise training may not make all people lean, it appears that an active/fit way of life has important health benefits for men and women with varied coronary risk factor profiles.





Mechanisms: Cardioprotective Effects of Moderate-to-Vigorous Physical Activity and Exercise Training*

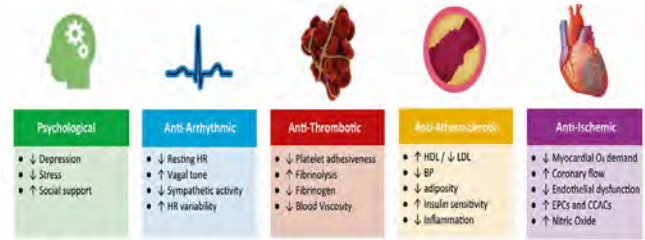
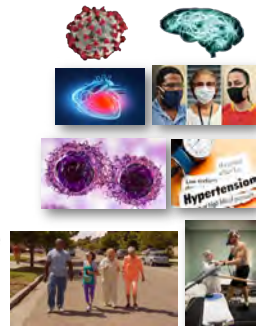


Fig. 5. Different domains of cardioprotective effects of habitual physical activity and exercise training. HR, heart rate; HDL, high-density lipoprotein; LDL, low-density lipoprotein; BP, blood pressure; O₂, oxygen; EPCs, endothelial progenitor cells; CACs, calcified/circulating angiogenic cells.

Outline (Topic # 2)

- Physical Activity (PA) and Cardiorespiratory Fitness (CRF) as Modulators of Mortality
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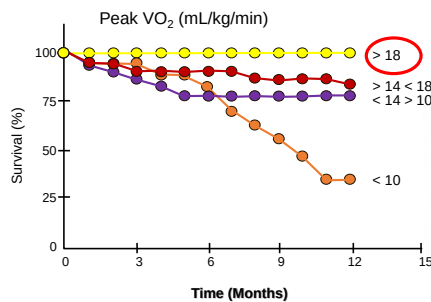
Value of Peak Exercise Oxygen Consumption for Optimal Timing of Cardiac Transplantation in Ambulatory Patients With Heart Failure

Fitness as a Prognostic Indicator For Heart Failure*

Conclusions. Cardiac transplantation can be safely deferred in ambulatory patients with severe LV dysfunction and peak exercise VO₂ of > 14 mL/kg/min or ~ 4 METs. Patients with an aerobic capacity > 18 mL/kg/min (5.1 METs) demonstrated 100% survival.

*Mancini DM et al. Circulation 1991;83:778-786

THE MAGIC OF > 5 METs !



Mancini DM et al. Circulation 1991;83:778-786

Risk Factors For Heart Failure*



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

Low Fitness as a Risk Factor For Heart Failure*

CRF and BMI were assessed in 20,254 US male veterans (mean age 58.0 years), who completed a maximal ETT between 1987 and 2017. All had no evidence of ischemia or HF prior to testing. They were classified based on age-stratified quartiles of peak METs achieved as: least-fit, low-fit, moderate-fit, and high-fit; and according to BMI as: normal weight, overweight, and obese. During a median follow-up of 13.4 years, there were 2979 HF events.



Kokkinos P et al. Eur J of Heart Fail (2019) doi:10.1002/ehf2.3433

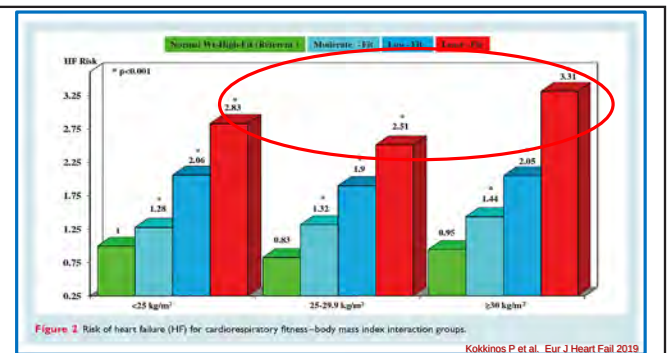


Fig. 2. Risk of heart failure (HF) for cardiorespiratory fitness-body mass index interaction groups.

Kokkinos P et al. Eur J Heart Fail 2019

TAKE HOME MESSAGE: Regardless of BMI, individuals with low CRF are more likely to develop HF in their later years. When it comes to HF, it's better to be overweight/obese and fit, than normal weight and unfit.

PA and CRF as Modulators of Cancer Incidence and Outcomes

In an analysis of 1.44 million individuals, higher levels of leisure-time PA were associated with a lower risk of 13 of 26 cancers evaluated.

The U.S. Dept. of HHS and the ACSM came to similar conclusions in that there is strong evidence to support the benefits of regular PA for the prevention of:

Breast, colon, endometrial, kidney, bladder, esophageal, and stomach cancer



Moore SC et al. JAMA Intern Med 2016;176:816-825
Physical Activity Guidelines Advisory Committee Report 2018
Patel AV et al. Med Sci Sports Exerc 2019;51:2391-2402

Diagnosed Cancer, CRF and Survival*

Finally, in a systematic review that included 71,654 individuals and 2002 cancer-related deaths, individuals diagnosed with cancer that had the highest CRF had a 45% reduced risk of cancer mortality compared with the lowest CRF.

TAKE HOME MESSAGE: Regular MVPA and increased CRF are associated with reduced cancer risk and better survival outcomes among individuals diagnosed with cancer.



*Schmid D et al. Ann Oncol 2015;26:272-278

Physical Inactivity as a Risk Factor for Severe COVID-19 Outcomes*

> 48,000 adult patients in the Kaiser Permanente healthcare system were identified with a COVID-19 diagnosis (Jan-Oct 2020). All had ≥ 3 self-reported PA assessments in the previous 2 yrs, classified into 3 PA categories: consistently inactive; some activity; consistently meeting/exceeding PA guidelines.

PA Guidelines		
Consistently Inactive	Some Activity	Meeting/Exceeding Guidelines
Risk of Hospitalization OR, 2.26	lower odds for adverse events	
Admit to ICU OR, 1.73		
Death OR, 2.49		

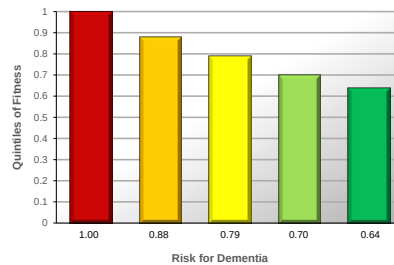


Conclusion: Habitual PA to lower COVID illness severity should be promoted by the medical community.



* Sallis R et al. Br J Sports Med 2021;55:1099-1105

Middle Age Fitness (Quintiles) and Dementia Risk



Most fit ~36% less likely have dementia

- 19,458 men & women;
- Mean age 49.9 yrs
- Treadmill Fitness test
- Followed avg. 25 yrs;
- 1659 dementia cases.

Defina LD et al. Annals of Int Med; 2013; 158(3)

Hypertension

ORIGINAL ARTICLE

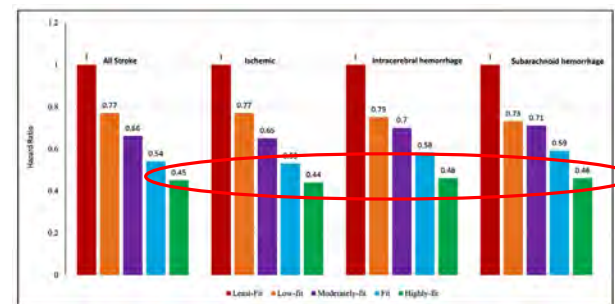
Stroke Incidence in Patients With Hypertension According to Cardiorespiratory Fitness

Stroke Incidence in Patients With Hypertension According to Cardiorespiratory Fitness

RESULTS: During a median follow-up of 10.6 years, 15,925 patients developed a stroke. Stroke risk declined progressively with higher CRF and was 55% lower for the High-fit individuals (hazard ratio, 0.45) compared with the Least-fit. Poor CRF was the strongest predictor of stroke risk of all comorbidities studied (hazard ratio, 2.24). Finally, changes in CRF reflected inverse and proportional changes in stroke risk.

Stroke incidence in patients with hypertension according to cardiorespiratory fitness. The study included 15,925 patients who developed a stroke during a median follow-up of 10.6 years. The hazard ratio for stroke was 0.45 for high-fit individuals compared with least-fit individuals. Poor CRF was the strongest predictor of stroke risk of all comorbidities studied (hazard ratio, 2.24). Finally, changes in CRF reflected inverse and proportional changes in stroke risk.

Hypertension 2024;81:1747-1757 DOI: 10.1161/HYPERTENSIONAHA.124.23066



Hypertension 2024;81:1747-1757 DOI: 10.1161/HYPERTENSIONAHA.124.23066

Variable	HR (95% CI)	P-value
High-Fit (Reference)		
Least-fit	2.34 (2.10-2.60)	<0.001
Low-fit	1.72 (1.54-1.94)	<0.001
Moderate-fit	1.49 (1.39-1.59)	<0.001
Fit	1.21 (1.13-1.29)	<0.001
Other Comorbidities		
Chronic Kidney Disease	1.71 (1.65-1.78)	<0.001
Atrial Fibrillation	1.54 (1.44-1.66)	<0.001
Dyslipidemia	1.40 (1.34-1.46)	<0.001
Age (per 10 years)	1.36 (1.33-1.38)	<0.001
Sleep Apnea	1.33 (1.29-1.38)	<0.001
Diabetes Mellitus	1.33 (1.28-1.37)	<0.001
Alcohol Abuse	1.21 (1.15-1.27)	<0.001
Cardiovascular disease	1.15 (1.11-1.19)	<0.001
Systolic BP (per 10 mm Hg)	1.09 (1.07-1.10)	<0.001

Hypertension 2024;81:1747-1757 DOI: 10.1161/HYPERTENSIONAHA.124.23066

Outline (Topic # 3)

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- Impact of PA/CRF on Surgical Outcomes



Corewell Health East

Merits of exercise therapy before and after major surgery

Thomas J. Hoogeboom¹, Jeroen J. Driessens², Erik H.J. Habets³, and Theo J.G. van't Hof-Grootenboer⁴

TAKE HOME MESSAGE: People who go into emergent or elective surgery with average to high levels of CRF have far fewer complications and experience earlier hospital discharge than their low-fit counterparts. Impact of *prehabilitation*...

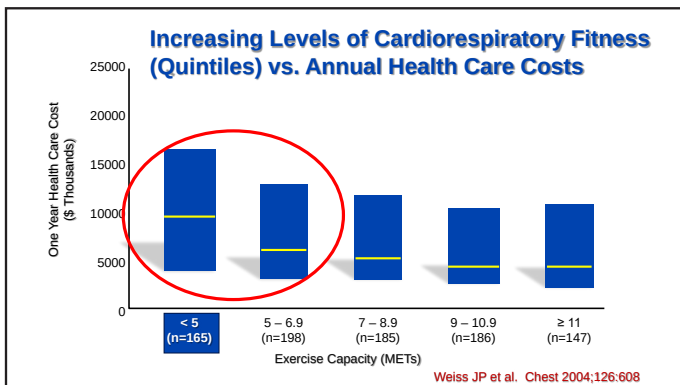
Hoogeboom TJ et al. Curr Opin Anaesthesiol 2014;27:355-360

Outline (Topic # 5)

- CRF and HealthCare Costs
- Independent and Additive Benefits of CRF on Prescribed Cardioprotective Medications
- Prescriptive Implications and Exercise Thresholds for Maximizing Health Outcomes: Initial/Optimal Training Intensities

HCC inversely related to exercise capacity (METs)

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CRF and Health Care Costs*

Using the Veterans Exercise Testing database, researchers reported that each 1-MET higher level of CRF was associated with \$1,592 annual reduction in health care costs/person.

↑ CRF → ↓ Health care costs

*Myers J et al. Mayo Clin Proc 2018;93:48-55

Daily Energy Expenditure and Its Relation to Health Care Costs in Patients Undergoing Ambulatory Electrocardiographic Monitoring

Jason Kitzinger, MD¹, Ryan Warner, MD², Michael J. Ryan, MD³, Michael J. Ryan, MD⁴, Michael J. Ryan, MD⁵, Michael J. Ryan, MD⁶, Michael J. Ryan, MD⁷, Michael J. Ryan, MD⁸, Michael J. Ryan, MD⁹, Michael J. Ryan, MD¹⁰

Applying the HR Index to Estimate Activity METs

FORMULA:
METs = 6 HR Index - 5

HR Index = $\frac{\text{Activity HR}}{\text{Rest HR}}$

Using the HR index formula in 843 patients (mean age 62.3) who underwent 24-hour ambulatory electrocardiographic (ECG) monitoring, we estimated average and peak daily METs and related these data to subsequent hospital encounters and health care costs.

RESULTS: Patients who achieved daily bouts of peak energy expenditure >5 METs had fewer hospital encounters (p=0.006) and median health care costs that were nearly 50% lower (p<0.001) than their counterparts who attained <5 METs.

Am J Cardiol 2017;119:658-663

Outline (Topic # 6)

- CRF and HealthCare Costs
- Independent and Additive Benefits of CRF on Prescribed Cardioprotective Medications
- Prescriptive Implications and Exercise Thresholds for Maximizing Health Outcomes: Initial/Optimal Training Intensities

Cardiac Meds
Fitness
Meds + Fitness

Mortality

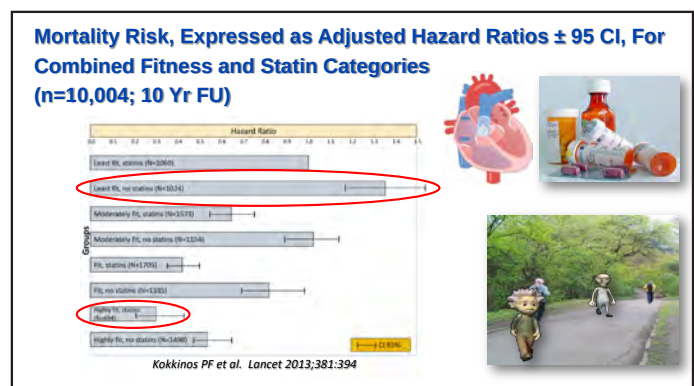
4.5x↓

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What happens when you combine cardioprotective drugs plus fitness?

Take Home Message: Statin treatment and increased fitness are independently associated with low mortality among dyslipidaemic individuals. The combination of statin treatment and increased fitness resulted in substantially lower mortality risk (4.5x) than either alone, reinforcing the importance of physical activity/cardiorespiratory fitness for individuals with dyslipidaemia.

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



Outline (Topic # 7)

- CRF and Health Care Costs
- Independent and Additive Benefits of CRF on Prescribed Cardioprotective Medications
- Prescriptive Implications and Exercise Thresholds for Maximizing Health Outcomes: Initial/Optimal Training Intensities



Initial and Optimal Exercise Training Intensity Goals

Steps/Day > 7,000 > 3 METs

Stair Climbing (> 6 flights/day) ↓

Mortality Reductions: "Good" Age – and – sex adjusted CRF Levels

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Why Prescribe Exercise ? To Combat the Health Consequences of Our Increasingly Hypokinetic Lifestyle



Self driving chairs. Instead of standing in line you sit and the chair moves. Right now only in Japan. Coming soon to Europe & the U.S. ?

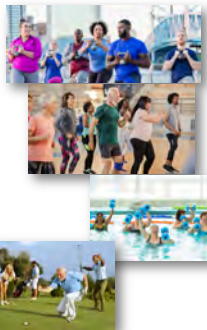


Contemporary PA Guidelines: Health vs Survival Benefits

The 2020 World Health Organization Guidelines on PA advise adults to engage in at least 150-300 min. of moderate intensity PA or 75-150 min. of vigorous intensity PA, or combinations thereof throughout the week.

Nevertheless, others have reported health benefits at PA volumes far below these thresholds

Bull FC et al. Br J Sports Med 2020;54:1451-1462
Wen CP et al. Lancet 2011;378:1244-1253
Lee DC et al. J Am Coll Cardiol 2014;64:472-481



Just 15 min/day of Walking is Associated with an ~ 10% Reduction in All-Cause Mortality; Running is Superior to Walking and Requires Less Time to Achieve the Reduction in Mortality (3:1 to 4:1 ratio)



Wen CP et al. JACC 2014;64:482-484

Accelerometer – assessed physical activity: What have we learned?

"Because of the precision of measurement, we now realize that the **magnitude** of association between physical activity (PA) and good health is larger than previously known from the self-report studies.

And, because we can measure small – whether by amount, intensity or duration – 'doses' far better than previously, we are beginning to discover that no dose of PA is too small to be healthful."

I-Min Lee, MD, ScD
Professor of Medicine,
Harvard Medical School



Climbing Stairs to Live Longer: Disguise Your Exercise*

• Systematic Review/Meta-Analysis

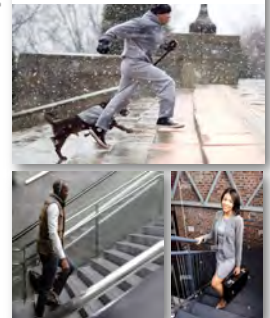
- 5 studies; n=455,578 participants.
- 35 to 84 years (53% women).

• Results

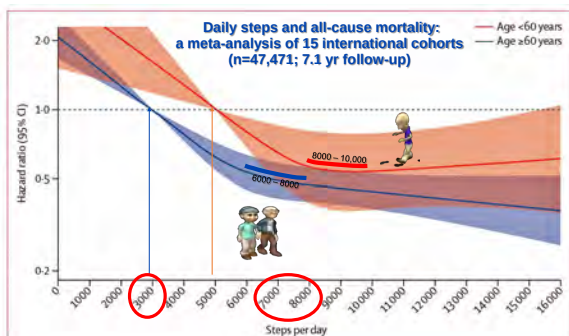
- Compared with not climbing stairs, stair climbing was associated with a 30% and 35% reduced risk of all-cause and CVD mortality, respectively.

Take Home Message: "Even brief bursts of physical activity have beneficial health effects, and short bouts of stair climbing should be an achievable target to integrate into daily routines." **Dr. Sophie Paddock**

* Rocky Balboa racing up the steps of the Philadelphia Museum of Art.

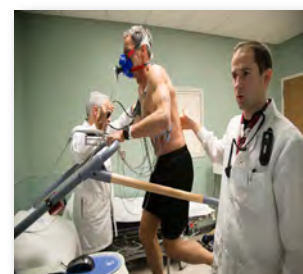


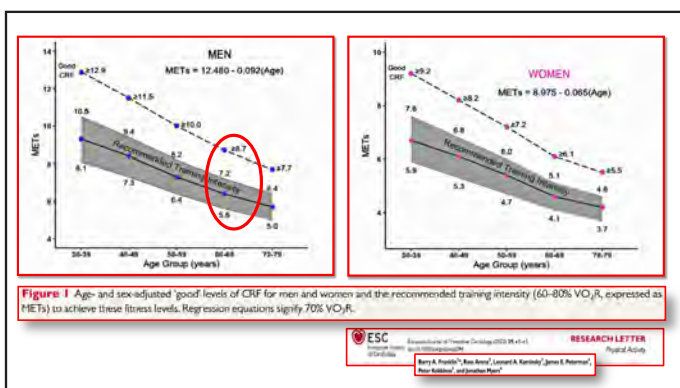
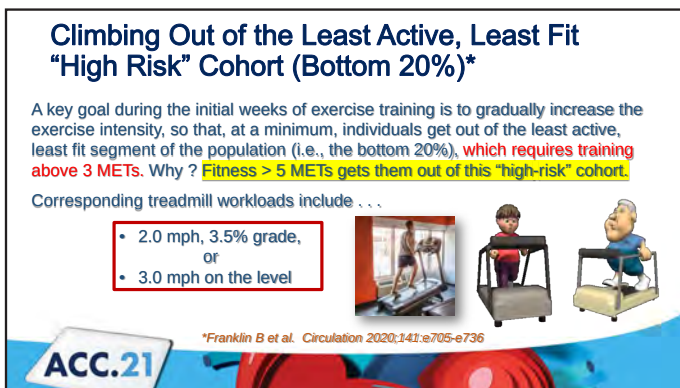
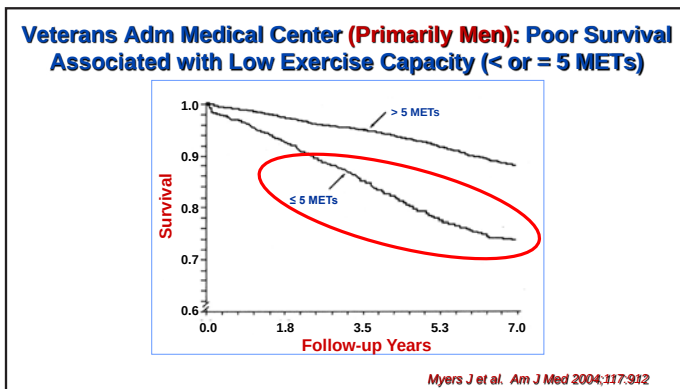
* ≥ 5 flights/day → lower risk of ASCVD and mortality.
HAS = 10-19 floors per week



Paluch AE et al. Lancet Public Health 2022; 7: e219-28

Training Intensities to Maximize the Survival Benefits of Exercise? Age, Sex-Adjusted Targets





Credits and Conclusions

"Franklin, you got 2 min. 30 sec. to wrap up this presentation for the AEI on time."

CREDIT LINE

"If I can see further it is by standing on the shoulders of giants." *Sir Isaac Newton*

This presentation was made possible, in large part, by the extraordinary research contributions of many past and present esteemed colleagues and friends, as well as their pioneering work in the clinical exercise physiology, epidemiology, and preventive cardiology fields

"A candle that lights another candle does not diminish it's own brightness." *Earl Nightingale*

TAKE HOME MESSAGES

Collectively, these data substantiate the profound and favorable impact that regular PA and/or increased CRF have on:

- Improving survival
- Surgical, and hospitalization-related outcomes
- Reducing healthcare costs
- Combatting CVD, HF, cancer, COVID, dementia, stroke and the *inexorable* aging process

The 'Magic' of an Exercise Capacity > 5 METs & Brief Bouts of Intermittent MV Lifestyle PA

The Phenomenon of "Blue Zones"

An elderly Sardinian man

5 Key Longevity Habits

HOW THEY LIVE LONGER

Super seniors in three widely separated regions share a number of key habits, despite many differences in background and beliefs.

CONCLUSIONS

In closing, "the increasing integration of regular physical activity and improved cardiorespiratory fitness as *medically prescribed interventions* should produce unparalleled *synchrony* and *synergies* in favorably modifying health outcomes worldwide."

"What you think, or what you know, or what you believe is, in the end, of little consequence. The only thing of consequence is what you do."

John Ruskin

Thank You

TIMER: 50.0 minutes

SELF EVALUATION

The Impact of Physical Activity and Fitness on Long-Term Health

1. T/F - Walking speeds (usual pace) of your patient can have strong prognostic significance. A tortoise-like pace (<2mph) suggests a higher mortality, whereas a walking pace >3mph is highly protective.
2. Researchers at the Cooper Clinic in Dallas, Texas reported that at any given risk factor profile, low-fit men and women have ~_____ times the mortality, as compared with their high-fit counterparts.
 - a. 1.5
 - b. 2.0
 - c. 3.0
 - d. 4.0
3. According to an early study of patients with systolic heart failure, a directly measured aerobic capacity >_____ mL/kg/min, was associated with 100% survival over a 12 month follow-up period.
 - a. 10
 - b. 12
 - c. 14
 - d. 16
 - e. 18
4. Two major studies showed that patients undergoing either bariatric surgery or coronary artery bypass surgery with a pre-operative exercise capacity <_____ METs were more likely to have a higher surgical morbidity / mortality.
 - a. 3
 - b. 4
 - c. 5
 - d. 6
 - e. None of the above
5. Although 10,000+ steps per day have been traditionally recommended to improve health outcomes, recent studies in men and women suggest, regardless of age, that _____ steps per day provide near optimal survival benefits.
 - a. 2,500 – 3,500
 - b. 5,000
 - c. 7,000 – 8,000
 - d. 12,000 – 13,000
 - e. None of the above
6. Which of the following is / are not associated with inhabitants of “Blue Zones”, who typically live to the ages of 95 to 110 years.
 - a. Don't smoke
 - b. Modest alcohol consumption
 - c. Eat fruits, veggies, and whole grains
 - d. Be active every day
 - e. Keep socially engaged and put family first

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

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Managing Depression: Evidence-Based Approaches for Primary Care

Managing Depression: Evidence-Based Approaches for Primary Care

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Disclosure

Louis Kuritzky has

NO RELEVANT INDUSTRY
RELATIONSHIPS

to disclose in relation to this presentation

Off-Label Content

- Thyroid hormone supplementation for augmentation therapy of MDD
- Initial dual antidepressant therapy of MDD

The 4 Main Things I've Done Wrong in Managing Depression

My (and maybe your?) 4 Main Errors in MDD Management

- Acceptance of "Better" instead of "Well"
- Insufficient Monitoring
- Failure to employ augmentation
- Failure to stratify Rx intensity to severity

Error #1

Acceptance of BETTER rather than WELL

- Better vs Well = Responder vs Remission
 - Responder = 50% ↓ Sx Score
 - Remission = Sx score < MDD threshold
- When Better may *not* be acceptable
 - INR close to therapeutic
 - Incontinence
 - Myopia
 - ED

Error #2 Insufficient Concrete Monitoring

- Global subjective vs validated Sx score

Error #3 Failure to Employ Augmentation: Missteps

- Hung on too long hoping for effect
- Switched thru too many multiple classes
- Despite credible evidence of efficacy, infrequently employed augmentation
 - Thyroid hormone
 - Atypical antipsychotics (esp aripiprazole)

Error #4 Failure to Stratify Rx Intensity to Severity

- HTN:
 - Polypharmacy routine
 - Stage 2 HTN initiate 2 drugs
- DM
 - Polypharmacy routine
 - A1c > 7.6 initiate 2 drugs (AACE Guideline)
- Exceptional to *initiate* 2 agents for MDD Sx

So I'm Going to Try to Convince You To...

- Revise your Rx goal to REMISSION
- Perform routine Sx score MONITORING (like BP for HTN, A1c for DM)
- Consider AUGMENTATION more often
- Consider INITIAL POLYPHARMACY more often

Why Bother?

Consequences
Epidemiology

Depression: Consequences



Consequences of Depression

- Clinicians commonly focus upon affective consequences of depression, like mood and sleep alterations. Over the last 30 years, where has suicide ranked as a cause of death in the USA?

- #1
- Consistently in the top 10
- Consistently in the bottom 1/3

Top 10 Causes of Death, USA 2013

Heart Disease	611,105	Alzheimer's	84,757
CA	584,861	Diabetes	75,578
COPD	149,205	Flu/pneumonia	56,979
Accidents	130,557	Renal	47,112
CVA	129,978	Suicide	41,149

<http://www.cdc.gov/nchs/fastats/leading-causes-of-death>
accessed 2/1/2016

Top 10 Causes of Death, USA 2016

Heart Disease	633,842	Alzheimer's	110,561
CA	595,930	Diabetes	79,535
COPD	155,041	Flu/pneumonia	57,062
Accidents	146,071	Renal	49,959
CVA	140,323	Suicide	44,193

Heron M *National Vital Statistics Reports* 2018;67(6):1-77

Top 10 Causes of Death, USA 2020

Heart Disease	690,882	COPD	151,637
CA	598,932	Alzheimer	133,382
COVID	345,323	Diabetes	101,106
Accidents	192,176	Influenza/Pneu	53,495
Stroke	150,050	CKD	52,260
#11	Suicide	44,834	

Ahmad RB, Anderson RB *JAMA* 2021;325(18):1829-1830

Do You Think We
Over-estimate
or
Under-estimate
Suicide Frequency?

MI: Impact of Depression on Mortality

- OBJECTIVE: Determine impact of depression upon acute MI
- METHOD: Interview day 5-15 post admit (n=222)
- FOLLOWUP: 6 months
- OUTCOME: mortality H.R. = 5.76 (p=0.0006)

Frasure-Smith et al, *JAMA* 1993;270:1819-1825

Depression in Elderly HTN May ↑ CVD

- SHEP Trial (n=4,736) adults >60 yrs
- Method: Rx ISH X 5 years (tenormin, HCTZ)
- Measured: Center for Epidemiology Studies Depression Scale (CES-D), depressive Sx, clinical psych eval
- Outcomes: Depression → 60% ↑ stroke, MI
80% ↑ mortality
- Any depressive Sx score > WNL → 2X ↑ RR death

Smoller S. Medical Tribune 1994(April 7):p 7

Scope of the Problem

Depression: Scope of the Problem

- Patients frequently seek help from primary care clinicians in reference to anxiety and/or depression. Which is more common?
- a) MDD > anxiety disorder
 - b) Anxiety disorder > MDD
 - c) Anxiety disorder = MDD
 - d) MDD > anxiety disorder, but only in men

Maryland BRFSS State of the State Report

2009 Survey Results on Maryland
Healthy Behaviors and Lifestyles
November 2010



Maryland Department of Health & Mental Hygiene
Family Health Administration
Office of Health Policy and Planning

www.marylandbrfss.org

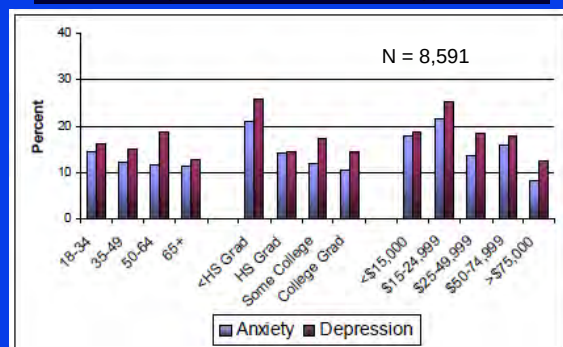
Maryland BRFSS 2010 Report What Was the Telephone Interviewers Question?

“Has a doctor or other healthcare provider ever told you that you had an anxiety disorder or depressive disorder?”

N = 8,591

Maryland BRFSS State of the State Report November 2010
www.marylandbrfss.org

Maryland BRFSS 2010 Report



Maryland BRFSS State of the State Report November 2010
www.marylandbrfss.org

Maryland 2010 BRFSS Report Bottom Lines

- Anxiety: 12%
- Depression: 16%
- Men < Women
 - Anxiety: 10.5% vs 14.3%
 - Depression: 14.2% vs 17.3%
- ↑income (>\$75K) → less anxiety or depression
- Less education → more anxiety or depression
- No impact of age

Maryland BRFSS State of the State Report November 2010
www.marylandbrfss.org

Why Don't We Make the Dx of MDD More Often?

- 'Oblique' presentation
 - Fatigue
 - Insomnia
 - Weight
- Concern to 'R/O Important Organic First'
 - Anemia
 - Hypothyroidism
 - Systemic Disease
- Stigma

Dx

DSM-5 Dx Criteria: Major Depression

- ≥5 Sx including depressed mood &/or anhedonia for ≥ 2 weeks representing a change from prior function
- Others symptoms may include:
 - Significant unintentional weight change (↑or↓)
 - Insomnia or hypersomnia nearly every day
 - Psychomotor agitation/retardation
 - Pervasive loss of energy/fatigue
 - Feelings of worthlessness/XS or inappropriate guilt
 - Difficulty concentrating
 - Recurrent thoughts of death/suicide

Am Psych Assoc DSM-5 2013

But Let's Not Miss....



Screening for Bipolar Prior to Depression Rx

- Traditional medical dogma advocates screening for bipolar disorder prior to initiating antidepressants, lest a mania episode be induced. Which statement below is correct?
 - a) Increased risk of mania induced by MDD Rx has never been confirmed in a RCT
 - b) Numerous trials show substantial ↑ risk
 - c) Observational data does shows ↑ risk
 - d) Observational data shows ↓risk

The FDA-mandated Language for BPD Screening

"Screening patients for BPD"— A major depressive episode may be the initial presentation of BPD. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for BPD. Whether any of the Sx described above represent such a conversion is unknown. However, prior to initiating Rx with an antidepressant, patients with depressive Sx should be adequately screened to determine if they are at risk for BPD; such screening should include a detailed psychiatric history, including a FHx of suicide, BPD, and depression. It should be noted that _____ is not approved for use in treating BPD.

Duloxetine and Mirtazapine Prescribing Information

Risk of Transition from MDD to Bipolar NESARC

- NESARC: National Epidemiologic Survey on Alcohol and Related Conditions
- Study: nationally representative household survey conducted by National Institute on Alcohol Abuse and Alcoholism
- Wave 1 (2000-2001): n=43,093
- Wave 2 (2004-2005): n=34,653

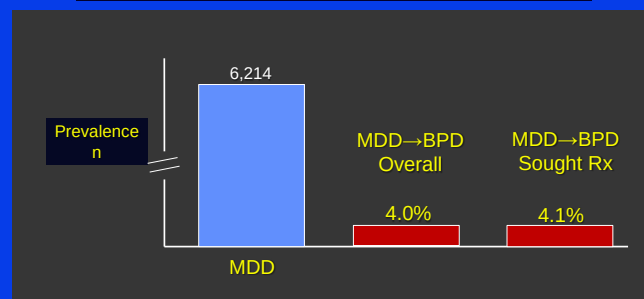
Gilman SE, et al RH J Clin Psychiatry 2012;73(6):829-836

NESARC: Transition MDD → Bipolar

- Wave 1: AUDADIS structured interview for MDD and BPD as per DSM-IV criteria
- Clinical characteristics survey
 - Age at onset
 - Anxiety
 - Atypical features
 - Panic
 - Family History
 - Substance Use
 - # Episodes
 - Childhood abuse
- Wave 2: Interview of MDD pts (N=6,214) for mania Sx over prior 3 years

Gilman SE, et al RH J Clin Psychiatry 2012;73(6):829-836

NESARC: Results at 4 years



Gilman SE, et al RH J Clin Psychiatry 2012;73(6):829-836

NESARC: Results

"These transition rates [$\pm 4\%$] are comparable to rates observed previously in follow-up studies...which have ranged from 4%-9% across varying time periods, and the 1% annual conversion rate reported by Angst et al."

Gilman SE, et al RH J Clin Psychiatry 2012;73(6):829-836

Preventing BPD Dx Delay

Positive Screen
Q1: 7+
Q2: +
Q3 ≥ Moderate

Hirschfeld RM et al Am J Psychiatry 2000;157:1873-1875

The Mood Disorder Questionnaire bipolar screening tool

Please answer each question to the best of your ability.

1. Has there ever been a period of time when you were not your usual self and...

	YES	NO
you felt so good or so happy that other people thought you were not your usual self or you were so hyper that you got into trouble?		
you were so irritable that you shouted at people or started fights or arguments?		
you felt much more self-confident than usual?		
you got much less sleep than usual and found you didn't really miss it?		
you were much more talkative or spoke much faster than usual?		
thoughts raced through your head or you couldn't slow your mind down?		
you were so easily distracted by things around you that you had trouble concentrating or staying on track?		
you had much more energy than usual?		
you were much more active or did many more things than usual?		
you were much more social or outgoing than usual; for example, you teased friends in the middle of the night?		
you were much more interested in sex than usual?		
you did things that were unusual for you or that other people might have thought were excessive, foolish, or risky?		
spending money got you or your family into trouble?		

2. If you checked YES to more than one of the above, have you ever been unable to work, having family, money, or legal troubles, getting into arguments or fights?

3. How much of a problem did any of these cause you—like being unable to work, having family, money, or legal troubles, getting into arguments or fights?

Please circle one response only

	No Problem	Minor problem	Moderate problem	Serious problem
Have any of your blood relatives (ie, children, siblings, parents, grandparents, aunts, uncles) had manic-depressive illness or bipolar disorder?				

Pharmacologic Rx

Depression: Rx Goals

- The preferred treatment goal of MDD should be
 - a) $\geq 10\%$ Sx Score reduction
 - b) $\geq 30\%$ Sx Score reduction
 - c) $\geq 50\%$ Sx Score reduction
 - d) Remission

Rx Goal: REMISSION Why?

“Remission is the aim of Rx because patients whose depression has remitted have **better functioning** and a **better prognosis** than those without remission.”

Rush AJ, et al *Am J Psych* 2011;168(7):689-701

Goal Attainment: How are we Doing?

“Antidepressant meds, when used as monotherapy in placebo-controlled registration trials, typically results in 30-35% remission rates.”

Rush AJ, et al *Am J Psych* 2011;168(7):689-701

Goal Attainment: How are we Doing?

“Lower remission rates (25%-30%) are reported for patients with more chronic depressions.”

Rush AJ, et al *Am J Psych* 2011;168(7):689-701

Is There a BEST Antidepressant?

Depression: Rx Goals

- As far as therapeutic efficacy, is there a 'best' antidepressant?
- a) SSRIs are most efficacious
- b) SNRIs are most efficacious
- c) Heterocyclics are most efficacious
- d) All antidepressants are similarly effective

Rx: Example Primary Care Choices

- Heterocyclics
 - Tricyclics: amitriptyline, imipramine
 - Tetracyclics: mirtazapine, maprotiline
- SSRIs: paroxetine, fluoxetine, citalopram
- SNRIs: venlafaxine, duloxetine
- Aminoketone: bupropion

EFFICACY: A BEST Antidepressant?

"According to the APA Guidelines for MDD in adults...the data indicate

**SIMILAR RATES OF RESPONSE TO ALL
ANTIDEPRESSANT DRUGS;**

therefore, the choice must be predicated on other factors."

American Psychiatric Association. Am J Psychiatry 1993;150

Best Antidepressant?

"A series of pivotal effectiveness studies in psychiatry....showed that virtually all antidepressant strategies had ...similar efficacy in major depression."

Parikh SV "Antidepressants are not all created equal" Lancet 2009;373:700-701

BEST Antidepressant?

- Study: metaanalysis 117 RCT (H:H)
 - n=26,000
 - 12 antidepressants studied
- No industry involvement
- Analyses:
 - Efficacy = $\geq 50\%$ $\downarrow$ Sx at week 8
 - Acceptability = D-C by week 8 (any reason)

Cipriani A, Furukawa TA, Salanti G, et al "Comparative efficacy and acceptability of 12 new-generation antidepressants" Lancet 2009;373:746-758

Best Antidepressant: Winners

Superior Efficacy	Superior Tolerability
escitalopram (Lexapro)	bupropion (Wellbutrin)
mirtazapine (Remeron)	citalopram (Celexa)
sertraline (Zoloft)	escitalopram (Lexapro)
venlafaxine (Effexor)	sertraline (Zoloft)

Cipriani A, Furukawa TA, Salanti G, et al "Comparative efficacy and acceptability of 12 new-generation antidepressants" Lancet 2009;373:746-758

And the BIG WINNER Is.....

"Balancing efficacy and acceptability and lower drug costs, the researches concluded that SERTRALINE might be particularly appropriate as a first-choice Rx."

Cipriani A, Furukawa TA, Salanti G, et al "Comparative efficacy and acceptability of 12 new-generation antidepressants" Lancet 2009;373:746-758

TCAs : Side Effect Profile

- Dry mouth
- Weight Gain
- Urinary Retention
- Hypotension
- Constipation
- Sedation

TCAs & Seniors: ? NOT?

"...TCAs are included in the Beers Criteria list of potentially inappropriate medications associated with high rates of adverse drug events among older adults."

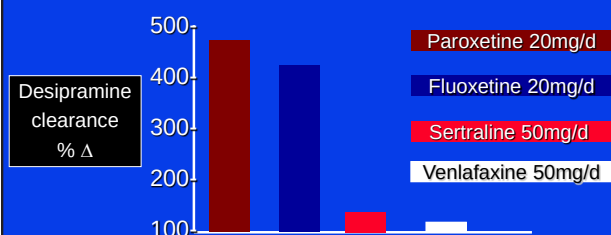
Taylor WD "Depression in the Elderly"
NEJM 2014;371:13:1228-36

TCAs & Seniors: HOWEVER

"If SSRIs or SNRIs are ineffective, TCAs may be considered (either as monotherapy or as augmentation)."

Taylor WD "Depression in the Elderly"
NEJM 2014;371:13:1228-36

Antidepressants: P450 IID6 System



Results are NOT from head-to-head comparison

Preskorn S. Am J Med 1993;94(Suppl 5A)

Some Commonly Used Drugs Metabolized by P450 IID6

- Chlorpromazine
- Clomipramine
- Codeine
- Desipramine
- Dextromethorphan
- Imipramine
- Metoprolol
- Nortriptyline
- Perphenazine
- Propranolol
- Thioridazine
- Timolol

Mendoza R. Psychopharmacology Bulletin #27; 1991:453

Augmentation

When Should You Consider Augmentation?

"Current guidelines ...recommend using augmentation strategies after the failure of 2 antidepressants or if there is a partial response with a primary antidepressant."

Ercis M, et al *J Clin Psych* 2023;84:2:72-75

Augmentation Rx for MDD

- Adding liothyronine (T₃) to sertraline (vs sertraline alone) for MDD might be anticipated to result in
 - No efficacy benefit over sertraline alone
 - A substantial increase in anxiety
 - Significantly more HTN
 - >50% RR ↑ of attaining remission

Another Safe Path For Maximizing Rx?

- Study: DBRPCT Adults with MDD (n=124)
- Rx: Sertraline + Liothyronine (T₃) or Sertraline + Placebo X 8 wks.
 - Week 1: Sertraline 50 mg/d, T₃ 20-25 mcg/d
 - Weeks 2-8: Sertraline 100 mg/d, T₃ 40-50 mcg/d
- Outcomes:
 - Primary: HAMD responder rate (= ↓50%)
 - Secondary: Remission rate (HAMD score ≤6)

Cooper-Kazaz R, Apter JT, et al *Arch Gen Psych* 2007;64:679-688

Another Safe Path For Maximizing Rx?

	S + T3	S + Pl	p
Responder Rate	70%	50%	0.02
Remission Rate	58%	38%	0.02
Pre-Rx TSH	1.7 mIU/L	1.61 mIU/L	NS
Post-Rx TSH	0.41 mIU/L	1.59 mIU/L	<0.001
AEs	No Between-Group Adverse Event Signal		

Cooper-Kazaz R, Apter JT, et al *Arch Gen Psych* 2007;64:679-688

JAMA | Original Investigation

JAMA 2017;318(2):132-145

Effect of Antidepressant Switching vs Augmentation on Remission Among Patients With Major Depressive Disorder Unresponsive to Antidepressant Treatment The VAST-D Randomized Clinical Trial

Somaia Mohamed, MD, PhD; Gary R. Johnson, MS; Peijun Chen, MD, PhD, MPH; Paul B. Hicks, MD, PhD; Lori L. Davis, MD; Jean Yoon, PhD; Theresa C. Gleason, PhD; Julia E. Vertrees, PharmD, BCPP; Kimberly Weingart, PhD; Ilanit Tal, PhD; Alexandra Scrymgeour, PharmD; David D. Lawrence, MS; Beata Planeta, MS; Michael E. Thase, MD; Grant D. Huang, MPH, PhD; Sidney Zisook, MD; and the VAST-D Investigators

VAST-D

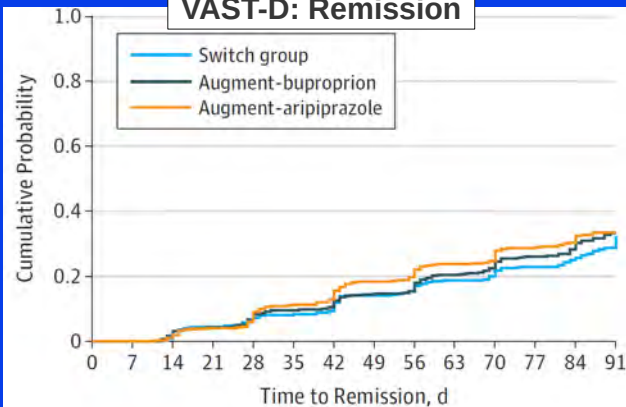
VA **A**ugmentation and **S**witching **T**reatment
for Improving **D**epression Outcomes

MDD: Switch vs Augment VAST-D

- Study: RSBT MDD adults (n=1,522)
- Inclusion:
 - failed SSRI, SNRI, or mirtazapine
 - QUIDS-C₁₆ score ≥ 11 (= moderate MDD)
- Rx:
 - Switch: current Rx to bupropion (≤ 300 mg/d)
 - Augment A: add aripiprazole (≤ 15 mg/d)
 - Augment B: add bupropion (≤ 300 mg/d)
- 1^o Outcome: Remission

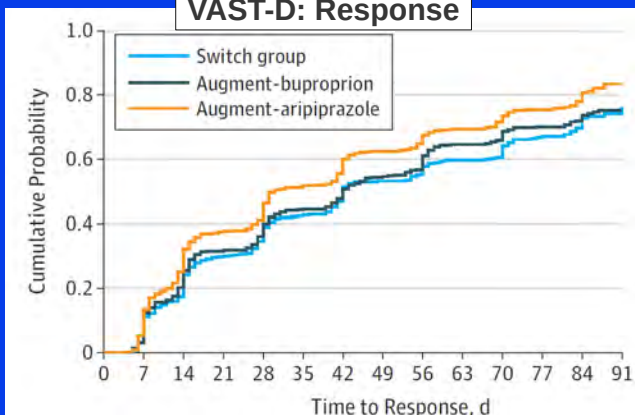
Mohammed S et al JAMA 2017;318(2):132-145

VAST-D: Remission



Mohammed S et al JAMA 2017;318(2):132-145

VAST-D: Response



Mohammed S et al JAMA 2017;318(2):132-145

VAST-D: Outcomes

Group	Remission	Response
Switch to bupropion	22.3%	62.4%
Augment with Aripiprazole	28.9%*	74.3%*
Augment with Bupropion	26.9%	65.6%

*p < 0.05 vs Switch

*p < 0.05 vs Switch or Bupropion Augmentation

Mohammed S et al JAMA 2017;318(2):132-145

VAST-D: Tolerability

- Lowest D-C rate: aripiprazole augmentation
- HOWEVER

Weight Gain $\geq 7\%$

Group	Week #12	Week #36
Switch to bupropion	2.3%	5.2%
Augment with Aripiprazole	9.5%	25.2%
Augment with Bupropion	1.9%	5.2%

Mohammed S et al JAMA 2017;318(2):132-145

Could
INITIAL DUAL ANTIDEPRESSANT Rx
($\neq$ Augmentation)
Out-perform Monotherapy?

Initial Dual Antidepressant Treatment

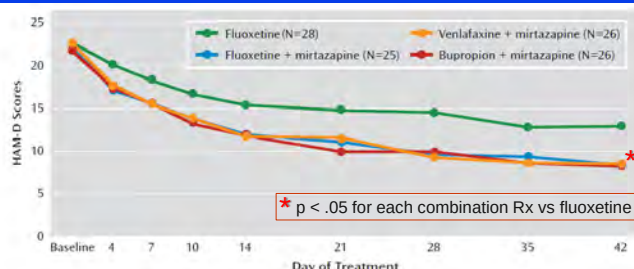
- Remission is attained in only 25%-35% of MDD patients treated with monotherapy. How does dual antidepressant Rx (adding mirtazapine) compare to fluoxetine monotherapy?
- a) Adding mirtazapine doubles remission rates
- b) Adding mirtazapine has no effect
- c) Adding mirtazapine reduces remission rates
- d) Minimally improved remission rates are counterbalanced by adverse effects

Initial DUAL Antidepressant Rx

- Study: DBRCT Adults MDD (n= 105)
- Inclusion: Baseline HAM-D ≥ 18
- Rx (6weeks):
 - fluoxetine 20 mg/d
 - mirtazapine 30 mg/d + fluoxetine 20 mg/d
 - mirtazapine 30 mg/d + venlafaxine 225 mg/d
 - mirtazapine 30 mg/d + bupropion 150 mg/d
- 1^o Outcome: HAM-D Score

Blier P et al *Am J Psych* 2010;167(3):281-288

Initial DUAL Antidepressant Rx vs Monotherapy



Blier P et al *Am J Psych* 2010;167(3):281-288

DUAL Antidepressant Rx vs Monotherapy: Remission (= HAM-D ≤ 7)

Rx	Remission Rate	*p
Fluoxetine	25%	
Fluoxetine + mirtazapine	52%	<0.05
Mirtazapine + venlafaxine	58%	<0.05
Mirtazapine + bupropion	46%	NS

*p versus fluoxetine monotherapy

Blier P et al *Am J Psych* 2010;167(3):281-288

DUAL Antidepressant Rx vs Monotherapy: Conclusions

- Combo Rx
 - 'as well tolerated' as mono
 - greater ↓ HAM-D scores
 - substantially improved remission rates

Blier P et al *Am J Psych* 2010;167(3):281-288

DUAL Antidepressant Rx vs Monotherapy: Conclusions

"The results of this study, taken together with those of 3 prior DB studies, provide mounting evidence that combination therapy from Rx initiation provides superior clinical effectiveness in the Rx of major depression."

Blier P et al *Am J Psych* 2010;167(3):281-288

Evolving Rx

Evolving Rx

JAMA Psychiatry | Original Investigation

Efficacy and Safety of Intranasal Esketamine Adjunctive to Oral Antidepressant Therapy in Treatment-Resistant Depression A Randomized Clinical Trial

JAMA Psychiatry 2018;75(2):139-148

Ella J. Daly, MD; Jaskaran B. Singh, MD; Maggie Fedgchin, PharmD; Kimberly Cooper, MS; Pilar Lim, PhD; Richard C. Shelton, MD; Michael E. Thase, MD; Andrew Winokur, MD, PhD; Luc Van Nueten, MD; Hussein Margi, MD, FRCPC; Wayne C. Drevets, MD

MDD Esketamine Nasal Spray

- Premise: "Approximately 1/3 of patients with MDD do not respond to available antidepressants."
- Objective: Assess esketamine efficacy, safety and dose-response in Tx-resistant depression

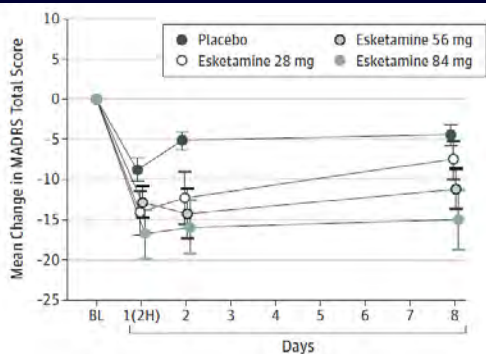
Daly EJ et al JAMA Psychiatry 2018;75(2):139-148

Esketamine for Treatment-Resistant Depression (TRD)

- Study: DBRPCT Adults with TRD (n=67)
- Inclusion: non-response to ≥ 2 meds (as per MGH Antidepressant Rx Response Questionnaire)
- Rx (*added* to current Rx regimen):
 - Phase 1: esketamine Nasal 28, 56, 84 mg twice weekly X two one-week intervals
 - Phase 2: open-label dose frequency taper 8 wks (2x/wk x 2 weeks, 1x/wk x 3 weeks, 1x/2wks x 2)

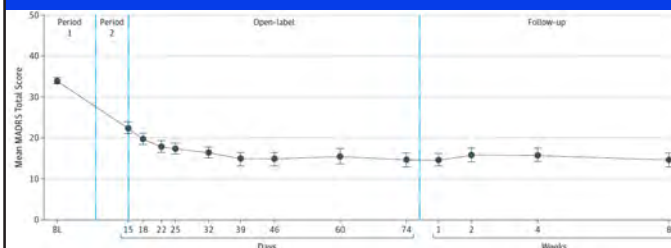
Daly EJ et al JAMA Psychiatry 2018;75(2):139-148

Montgomery-Asberg Depression Rating Scale Score



Daly EJ et al JAMA Psychiatry 2018;75(2):139-148

Montgomery-Asberg Depression Rating Scale Score



Daly EJ et al JAMA Psychiatry 2018;75(2):139-148

Non-Traditional Pharmacologic Rx

St. John's Wort vs. Imipramine

- STUDY: DB Dx MDD, n=135
- Rx: hypericum 300 mg tid vs imipramine 25mg tid
- Measured: CGI, HAMD, side effects
- Results
 - clinical efficacy : hypericum = imipramine
 - side effect profile : hypericum < imipramine

Vorbach EU, Hubner WD, Arnoldt KH J Geriatr Psychiatry Neurol 1994;7(suppl 1):S19-S23

St. John's Wort Efficacy : Metaanalysis

- Randomized Trials X 23 (n=1757), mod-severe MDD
- Results: "Hypericum extracts were significantly superior to placebo and similarly effective as standard antidepressants"
- Side effects: hypericum = 19.8%, drugs = 52.8%
- Dropouts: hypericum = 0.8%, meds = 3.0%

Linde K, Ramirez G, Mulrow CD et al BMJ 1996; 313 : 253-8

CAM: My Story Line

- Sample Size?
- Published?
- Site?
- Product Consistency?
- Surveillance

Our Role as Clinician-Counselor

Essential Tools: Carl Rogers

- Genuinity
- Empathy
- Unconditional positive regard

Kaplan HI, Sadock BJ (1985), Comprehensive Textbook of Psychiatry. Baltimore: Lippincott Williams & Wilkins

Counseling: The Meaning of Struggle

"Her dream began with winter darkness. Out of this darkness came a great hand, fisted. It was a man's hand, powerful and hollowed....The fist opened and in the long plain of the palm lay three small pieces of coal. Slowly the hand closed, causing within the fist a tremendous pressure.

The pressure began to generate a white heat and still it increased. There was a sense of weighing, crushing time. She seemed to feel the suffering of the coal with her own body, almost beyond the point of being borne. At last she cried out to the hand, 'Stop it! Will you never end it! Even a stone cannot bear to this limit...even a stone...' "

Goldberg J *I Never Promised You a Rose Garden* 1964 New York: New American Library

Counseling: The Meaning of Struggle

"After what seemed too long a time for anything molecular to endure, the torments in the fist relaxed.

The fist turned slowly and very slowly opened. Diamonds, three of them. Three clear and brilliant diamonds, shot with light, lay in the good palm. A deep voice called to her, 'Deborah' and then, gently, 'Deborah, this will be you.'"

Goldberg J *I Never Promised You a Rose Garden* 1964 New York: New American Library

Counseling: The Meaning of Struggle



The Story of the Butterfly



After Our Hour Together, I Hope You Will More Often.....

- Revise your MDD Rx goal to REMISSION
- Perform routine Sx score MONITORING (like BP for HTN, A1c for DM)
- Consider AUGMENTATION more often
- Consider INITIAL POLYPHARMACY more often

SELF EVALUATION

Managing Depression: Evidence-Based Approaches for Primary Care

1. What is the preferred treatment goal in managing major depressive disorder (MDD)?
 - a. $\geq 10\%$ symptom reduction
 - b. $\geq 30\%$ symptom reduction
 - c. $\geq 50\%$ symptom reduction
 - d. Remission
2. T/F - A “responder” in depression treatment is defined as a patient achieving full remission of symptoms.
3. Which of the following is one of the major errors in managing depression identified in the lecture?
 - a. Overuse of augmentation
 - b. Excessive monitoring
 - c. Acceptance of “better” instead of “well”
 - d. Overuse of psychotherapy
4. After failure of two antidepressants or a partial response, what strategy is recommended?
 - a. Stop all medications
 - b. Switch to psychotherapy only
 - c. Consider augmentation
 - d. Avoid further pharmacologic treatment
5. T/F - All antidepressants have significantly different efficacy, with one class clearly superior.

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

Protecting Assets and Minimizing Legal Risk for Medical Professionals

Alan S. Gassman, Esq

A PREFACE BY DR. PARIKSITH SINGH

From the book *Creditor Protection for Florida Physicians*



I was very pleased when Alan asked me to write a preface to his book. We have worked together on my personal planning for over 10 years, and have exchanged ideas and written together on many topics. I have learned much from him, and each time I review the plan that he established for us I am impressed that it has withstood the test of time and needs very little changes notwithstanding our business and family growth and maturation over the years. I am pleased that he indicates that he has learned a lot from me as well.

Before Alan worked on my planning I attended a 3 hour lecture that he was commissioned to give for lawyers and accountants on business, estate planning and asset protection law for physicians. There were over 400 pages of materials, and he had to move fast to even introduce all of the topics that needed to be covered. Everyone was taking notes as quickly as they could. Hats off to him for all of the work that it must have taken to bring these subjects to the level of understanding for physicians and advisors who are not specialized tax, business and estate planning lawyers. This is a very impressive book.

As with any good book, it is easy to get lost in the trees while trying to understand the forest. While Alan does a very good job helping to distinguish between forest and tree, I thought that it would be good for the reader to have access to my shorthand guide that is based on my personal experience, and not necessarily everything that can and will happen to each of my colleagues.

Over the course of almost two decades as a physician, I have attended a University that most of us attend, sometimes without realizing, and have taken its courses as diligently as possible. This is the greatest University in the world, also known as the Harvard School of Hard-Knocks, the John Hopkins of Real-Life or the Ivy League of HHS and Misses.

It is a very painful and rewarding journey. There are hundreds of self-confessed teachers or guides, and many of them will easily mislead you. I too have been misled, taken advantage of, led to, and defrauded of my hard-earned money. I too have made a lot of mistakes. Fortunately, the good things I did outpaced my errors and kept me afloat. Good advisors that I could trust were very important and helpful, when I listened to them! If only I had called them in more often.

I realize I have been very fortunate. My business could have easily gone down the drain like many others. I could have been bankrupt just like other physicians that I have been closely involved with. There were times when I did not know where the money for payroll was going to come from which was due the next day. There was a time when all of our profits made were lost to problems caused by easily preventable errors.

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Essential Creditor Protection and Retirement Considerations

2

A PREFACE BY DR. PARIKSITH SINGH

From the book *Creditor Protection for Florida Physicians*

I realize now that understanding is a blessing that must be earned and then developed and appreciated. You can avoid much of the rigmarole of attending the more painful courses in the University of Life by learning in advance from others in order to more readily accomplish life goals, whatever they may be. It is in this vein that I share my understanding with fellow physicians about what a good business plan for a physician should or should not entail, and why the reality is that you have to understand some basic concepts and put things in order without exception, in order to have a financial and personal base to work from.

I prefer the term Business Planning to Asset Protection since I favor a comprehensive approach to one's business. While the safety and security of assets is vitally important, physicians must plan for long-term returns, have growth and personal satisfaction in the medical practice, take care of family and children and create appropriate trusts, retirement planning, corporations and other tax and health law compliant structures while fulfilling charitable goals and other primary objectives. Don't let the hurry to check e-mails, read the newspaper, and attend cocktail parties distract you from having a firm base to work from. Castles built in the sand don't last long!

The creation of a plan and system to protect acquired assets and to enhance and grow a business and profession helps in the development of short term goals and in the avoidance of impulsive or imprudent investments that can cause your hard earned money to fly out the window. Please focus on your long term disciplined plan to maximize what you achieve for yourself, family and others. This book can help you do this.

There are some common business errors to avoid right from the beginning, to my mind. These are:

1) Business planning

a) The structure of your business has to be right, and it is clearly best to make it right from the beginning. I have seen many instances in which the physician did not place his or her business under a legal entity. A properly created and managed corporate entity which holds and controls the business is the first fire-wall against litigation.

b) Do not mix entities. Do not mix personal with business. Your practice is not you, even though emotionally it may feel that way. If you happen to own separate businesses, keep them separate. The business should be owned separately perhaps from any other holdings, like real estate and vehicles.

c) Run the corporate entities in a clean arm's-length manner as if it were separate from you, which legally it is. Keep proper books, accounts, operating agreements and corporate records in a safe place, preferably after scanning them in a safe server.

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Essential Creditor Protection and Retirement Considerations

3

A PREFACE BY DR. PARIKSITH SINGH

From the book *Creditor Protection for Florida Physicians*

d) Make sure your spouse or significant other knows where all your documents are, how or where to access them in case you are disabled or deceased, and who the consultants are that need to be contacted in case of your demise.

e) The approach to business has to be right; practicing medicine is a service, a vocation and a profession but it is also a business. Hire competent and professional help. Avoid using family and friends for office or business work. Create proper policies and procedures for the business and, once created, adhere to them.

f) A systems approach is needed, which would entail looking at the overall picture, the environment, the community, processes, and personnel. Every practice is different. Know your niche and turn your challenges into advantages by working hard on them. Learn from your seniors and experts by being humble and accepting that you do not know everything. Expertise in medicine does not mean expertise in business, law, accounting or finances. Study and research this subject as if you and your family's life depends on it, which it does.

g) Hiring the best personnel is key to a successful business and the most difficult endeavor. A lot of people need to be screened to find loyal and capable and efficient help. One must take one's time to hire competence and lose no time to fire incompetence.

h) How will you deal with patients and train your staff to deal with them? This is very important. Constant training is a must. Employee morale and education are vital areas. Create the efficiency of a McDonald's or a Starbucks with the service of a Ritz Carlton or Walt Disney. Excellence and quality should be your mantra and should be the motto of every employee in your practice.

i) Hire the best consultants and professionals in all aspects. Not those who will agree with whatever you ask them to do. Not those that cost the least, nor those who get a commission out of your investments. Try to only use reputable and certified professionals who have much experience with physicians, a reputation to protect, and who will be honest on what they know and what they don't know, and what they think you need and don't need. Pay these professionals by the hour so that their motivation is to provide you with services instead of "professional products." Then listen to them even if they disagree with you, and especially if they disagree with you. Do not expect or force your consultants to always agree with you; a good consultant will always give you the best advice whether you like it or not. Let your professionals interact and work together as a team so that major issues don't fall between the cracks. For example CPAs and lawyers need to be in sync so that tax, business and estate planning are properly aligned. One good professional can catch another's error or failure to address an issue if they work together as a team.

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Essential Creditor Protection and Retirement Considerations

4

A PREFACE BY DR. PARIKSITH SINGH

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j) Get the best coverage. It is a fallacy that going bare or with minimum coverage will mean less liability or less lawsuits. Look to get good umbrella coverage. Remember, you are looking at an overall business plan, not creating a fly-by-night operation. Do not forget tail coverage or prior-acts coverage when you change practices. It is not as difficult to get, nor expensive, as many people think. Never change patient chart documents once a malpractice lawsuit is filed; that is a sure way to lose a lawsuit and the ability to have malpractice insurance in the future. Good record-keeping is mandatory for a good practice. If you see a mistake, never try to cover it up; fix it the right way.

k) Stay ahead of the future. The new medicine is less forgiving but also very rewarding to those who understand what is happening. Bring your practice to focus on an intensive compliance program which would include appropriate coding, documentation, licensure and disclosure. Data and its analysis will drive future health care. Do not be afraid of pay for performance; rather, create parameters and practice indicators for yourself before the government asks for them. Utilization review, disease and population management, and well-being/preventative health are the new trends in medicine. These are here to stay. If you are adaptable, you will become a better business and practice. Evaluate yourself constantly.

l) Do not retire too soon; stay on top of things until you are ready. Do not sell your practice out of fear. Make sure you do appropriate reference checking on potential buyers and involve CPAs and lawyers with experience in this area before you consider selling.

m) Protect your license, as it is your biggest asset. Do not indulge in risky activities, such as driving under influence, seeing female patients without appropriate chaperones, billing fraudulently, sexual harassment, unprofessional behavior, etc. They are just not worth it.

n) Each person is a potential patient or a potential lawsuit; be nice and professional all the time, whether you are in public or private. Treat everyone with due respect, as they should be.

o) Divorce is a very bad business plan. Think ten times before you jump into divorce. It is not only traumatic emotionally and mentally but also professionally. Communicate with your spouse and honor/respect/love them and get independent counseling even if you are sure that you don't need or could not survive it.

p) Learn to be bold once you have mastered the business. You do not stay at home until all the lights turn green, do you?

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Essential Creditor Protection and Retirement Considerations

5

A PREFACE BY DR. PARIKSITH SINGH

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q) Be careful with picking partners. A business partner is equivalent to your spouse. Bad business partners grow like cancer on the practice. As a rule, do not bring partners into your practice until you involve the specialist consultants and have a clear Operating Agreement and mechanisms to resolve disputes. Treat your partner with fairness and respect. Don't confuse friendship and family with business compatibility. Have zero tolerance for dishonesty or bad intentions with anyone you deal with.

2) Estate Planning

a) The time to start is now. Do not wait. A good business plan includes good estate planning.

b) Don't be cheap; Hire the best advisors that you can afford. In the long run they cost much less than doing this the wrong way or having to redo it later, or when it might be too late.

c) Be clear about what you want with your trusts and bequeathing; remember Warren Buffett who was very clear about what he wanted to do with his billions. You do not want to take the incentive to work hard from your children, and you do not want them to become stupid because they have rich parents. As Buffett said, "I want my children to have enough so that they can do anything, but I do not want them to have so much that they do nothing."

d) First do no harm; do not sign up with life insurance policies or retirement plans or investment brokers without proper research and checking with your honest hourly professionals. Life insurance can be great tools for asset protection, investment, retirement planning and life-transforming events for the family but one must carefully review the agents' commissions, cash value, guaranteed return, and penalties on early cancellation before signing up. Avoid 439 plans for tax savings.

e) Do not be cash poor. Liquidity is important for any good business plan. Keep enough cash or liquidity to cover your expenses for at least 6 months. Learn to create a nest egg which should only be invested in conservative portfolios. You can be aggressive with play money. Again, discipline is essential.

f) Focus on the core business; do not think that since you are a good doctor, you are a good businessman in every possible field, e.g., running restaurants, gyms, health food stores, gas stations, etc.

g) Take advantage of the yearly gift tax and the \$10,500,000 per couple 2013 exemption for estate taxes; do not forget the exemptions for generation skipping estate taxes and review these items with a competent tax and estate planning attorney. Your personal lawyer can bring in an expert to help him or her—let them know that you expect and appreciate this. Lawyers are not always keen on bringing in help. Make sure your lawyer can and will.

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Essential Creditor Protection and Retirement Considerations

6

A PREFACE BY DR. PARIKSITH SINGH

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h) Do not give your children a job in your practice at the highest level right at the beginning. Let them work at a friends office who will show them "tough love" and will treat your children as you would treat theirs. Let the children learn the value of a hard day's work and enjoy the fruits of their labor. Preferably, let your children have their first job somewhere other than your own practice or business.

3) Growth Strategies: These are part of your overall business plan. Remember, 9 out of 10 businesses fail. Many do so after enjoying a brief period of success at the very beginning and fail only when the growth is not managed properly. "Unplanned growth is the philosophy of a cancer cell," as has been aptly noted by Mirza Yawar Baig, a friend and consultant. Growth without profit has no meaning. The principles mentioned above should be applied constantly at periodic intervals to assess the state of one's company and one should always be ready to kick the tires, so to speak.

4) Ownership: It is key to understand that ownership of certain assets can be risky and should be managed well, e.g., cars, home, boats, etc. These are best addressed with a tax and estate planning attorney. Briefly, unprofitable or risky entities like cars or boats or planes should not be owned by an entity that also owns profitable or valuable lines of business, e.g., one's business or real estate. Also, one should instill the value of avoiding risky behavior among one's children. If they get involved in accidents under DUI or the influence of drugs, that is extremely dangerous to one's financial viability. A recent example of this scenario is Hulk Hogan, aka Terry Bollea, a case that involved damages in excess of 10 million, a tragic trauma to a young Marine, enormous stress and bad publicity. Have plenty of insurance as well.

This is but a brief review of the do's and don't's of a good business plan. All of these recommendations are culled from practical experience or direct or indirect observation and it is my hope that you will avoid learning these lessons in the University of Hard Knocks. Rather, you will study the subject or involve the experts so that this most valuable aspect of your life is made as fool-proof as possible.

Good luck and best wishes to a happy and prosperous productive life. I hope that this preface and the book are a good beginning.

Pariksinh Singh, M.D.
Physician and CEO
Access Health Care, LLC

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Essential Creditor Protection and Retirement Considerations

7

Key Practice Creditor Protection Strategies

1. Keep valuable assets outside of the practice entity.
2. Let creditors of the practice entity have a first lien on lienable assets.
3. Let the practice entity guarantee debt owed by other entities and pledge its assets as collateral for the debt.
4. Let the practice entity enter into long term leases that allow landlords to accelerate rent owed in the event of insolvency, and give landlords a lien on practice assets.
5. Give shareholders a lien on practice assets to secure their right to deferred compensation.
6. Consider New Parent F Reorganization.
7. Consider an ELOPE system to protect letters of protection or large accounts receivable.
8. You cannot have too much insurance.
9. Consider keeping separate entities, having separate functions and assets, while also complying with medical billing and associated laws.

Follow Up Checklist for presentation entitled: Essential Creditor Protection and Retirement Planning Considerations Presented by: Alan S. Gassman, Esq. - agassman@gassmanpa.com

ITEM	DONE	NEEDS TO BE DONE	NOT SURE	DELEGATE TO
1. Malpractice insurance in place with calendaring for renewal.				
2. Corporate malpractice insurance policy in place or considered.				
3. Nurse practitioners and nurses having separate policies?				
4. Insurance for automobile liability?				
5. Employment agreements in place to document that wages paid to the doctor should be exempt from creditor claims of the doctor.				
6. Does the PA lease real estate from a related entity? Is there a long-term lease agreement in place to insulate the owner entity from accidents on the property?				
7. Does the long-term lease give the landlord entity a UCC-1 field lien against the assets of the medical practice?				
8. Does the medical practice owe money to "friendly creditors" like a bank?				
9. Are the medical practice assets properly pledged as collateral for the loan by filing of UCC-1 financing statements?				
10. Will the practice acquire expensive equipment or other assets that can be held by an entity for the family to not be owned by the practice, or that can be leased in the same manner?				

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ITEM	DONE	NEEDS TO BE DONE	NOT SURE	DELEGATE TO
11. Are there any loans on buildings, to family members or otherwise, that can be collateralized by medical practice assets, by proper documentation that will normally include a guaranty by the practice entity and a UCC-1 financing statement/security agreement being executed?				
12. Are there employment agreements in place which clearly delineate wages, and are wages being paid and appropriately thereafter saved in creditor protected ways? Are dividends being spent first and wages being saved?				
13. Are there separate medical practice endeavors that should be separated into separate corporations, such as a specialty practice, a weight loss center, and/or a sleep center?				
14. Assume proper ownership configuration to also comply with Florida anti-referral laws.				
15. Do the doctors have non-competition covenants and/or have they given the medical practice patient file rights that might conceivably be enforceable by a creditor?				
16. If a shareholder/physician may have personal creditor problems, is the transferability of entity ownership properly limited, and perhaps pledged as collateral to a "friendly lender"?				
17. Are there Letters of Protection or other significant receivables that should perhaps be factored or otherwise handled in order to be less exposed to potential creditors?				
18. Review materials with advisors for further possible items of follow up?				

ASSET PROTECTION CHECKLIST – Page 1

PROTECTED OWNERSHIP CATEGORIES	NOTES	LIABILITY INSULATION	NOTES
1 Assets exempt by Florida Constitution, Statute, Common Law or Federal Law. (Note: The above exceptions do not apply to the IRS, FTC, SEC, or other "Super Creditors", such as the Department of Justice when pursuing RICO perpetrators.)		1 Make sure housekeeper, in-laws, and all others are covered if they drive your cars or reside in your residence.	
1(a) Homestead.		2 Car ownership, and which parent signed to be responsible for the driving of a minor.	
1(b) Tenancy by the entirety.		3 Car driving by children, spouses, employees and others.	
1(c) Pension and IRA.		4 Firewall protection provided by LLC's, companies and various partnerships (LLPs, LPLs and LLPs).	
1(d) Life insurance policies.		5 Triple Net Lease language to protect landlord – must give tenant total control of property.	
1(e) Annuities.		6 Managers may get sued.	
1(f) 529 Plans.		7 Delegate to management company.	
1(g) Disability and Social Security Benefits.		8 Guests may sign releases.	
1(h) Others.		9 Independent contractor arrangements.	
2 Changing Order Protection.		10 Bartenders for personal parties.	
3 Property owned by others.		11 No guests on wave runners.	
4 Property sold for Note or annuity payment rights.		12 No alcohol served to anyone under the age of 21.	
5 Third Party Settled Trusts.		13 Appropriate underlying and umbrella liability insurance – for each property, car, 4-wheeler, etc. But beware of exceptions and illegal situations that will not be covered.	
6 Self Settled Trusts in Asset Protection Trust jurisdiction.			
7 Foreign assets, entities and accounts in jurisdictions that do not recognize U.S. judgments.			
BUSINESS AND INVESTMENT CONSIDERATIONS		OTHER CONSIDERATIONS	
1 Liability and casualty insurance review, with personal use interaction and business umbrella to be considered.		1 Income and estate tax avoidance – buy a felony to avoid paying IRS taxes or to conspire to help someone avoid such payment – same applies as to debt owed directly to the FDIC and certain other governmental creditors.	
2 Friendly lenders.		2 Marriage and divorce – ex-spouse cannot invade TBE assets held with new spouse or invade new spouse's interest in a homestead or TBE homestead.	

ASSET PROTECTION CHECKLIST – Page 2

BUSINESS AND INVESTMENT CONSIDERATIONS	NOTES	OTHER CONSIDERATIONS	NOTES
3 Separate activities and exposures.		3 Impact on an estate plan.	
4 Leasing arrangements with landlord rent right secured by UCC-1 on tenant's property.		4 Federal and state criminal law.	
5 Car title.		5 Exposure of the advisor.	
6 Car ownership.		6 Exemptions that apply on death – do not make life insurance or annuities payable to an estate or to a trust that provides that estate obligations must be paid.	
7 Delegate to offshore employees.		7 Client guarantee.	
8 Employee causes of action – make sure they have Workers' Compensation.		8 Confidentiality – use an anonymously owned LLC from Wyoming, Delaware or Colorado to serve as manager of operational LLC's and Trustee of Homestead Land Trust, and file Certificates of Authority in each country where real estate is located.	
9 Separate intellectual property rights.		9 Equity stripping – debt secured by a mortgage or lien on valuable assets at risk may be payable to arm's-length lenders or related party lenders under a number of various arrangements.	
10 Alcohol at events.		10 Make your children self-supporting.	
11 Using independent contractors.		11 Get divorced soon, or not at all.	
12 Client/Patient/Supplier Arbitration Agreements.			
13 Consider New Parent F Reorganization to separate assets within a company without triggering capital gains.			
14 Consider factoring accounts receivable to a related company that may be held for descendants.			
15 Trusted or Partnership/LLC based Buy/Sell Life Insurance Arrangement.			
16 Consider leasing use of equipment on a triple net basis – be sure all activities are insured.			
17 Pension contributions.			

"It wasn't raining when Noah built the ark."



Amputee Awarded \$30M

Jurors say a mom who lost her fingers and feet deserves that much.

By Justin George and Colleen Jenkins
Published May 26, 2007

TAMPA – Sally Lucia, a mother of three who lost her fingers and feet after complications of tummy tuck surgery, deserves \$30-million, a jury in a malpractice suit said Friday. But it will be up to Hillsborough Circuit Judge Gregory P. Holder to sort out how much of that is owed by a former Tampa doctor and a hospital.

Defense attorneys predicted that Lucia, 47, would get somewhere between \$12-million and \$16-million, while her own attorneys declined to name figures.

Holder must now make sense of the jury's parceling out of blame and the impact of Florida's "Good Samaritan" law. That is expected to begin Wednesday.

Four women on the jury wouldn't leave the courtroom without seeing Lucia privately and telling her they did everything they could to ensure justice was served. Afterward, teary-eyed, they declined to comment.

Lucia said the verdict left her "overwhelmed, but in a good way." She said she was glad the trial was finally over.

Jurors assigned Memorial Hospital 40 percent blame. Dr. George Haeckle 20 percent blame and Dr. Charles McLaughlin 40 percent blame. McLaughlin reached a settlement for an undisclosed amount and was not on trial.

While Lucia viewed the verdict as a win, so did the attorney representing Haeckle. While finding fault, jurors said Haeckle did not act with reckless disregard, which could give him immunity under the state's "Good Samaritan" law.

The law protects emergency room doctors seeing patients in emergencies from malpractice judgments as long as a jury finds they didn't act recklessly.

An hour before jurors reached their verdict, they told Holder they were undecided. The trial had taken three weeks. They had deliberated 17 hours. He ordered them to keep talking.

Lucia's troubles culminated on Super Bowl Sunday 2001 when an ambulance carried her to Memorial Hospital in Tampa. She had undergone a tummy tuck 20 days earlier to repair abdominal muscle damage from three caesarean sections. Blood and fluid had collected in her wound. Her fingers were blue.

Her surgeon was out of town. Hospital staff called Haeckle, the on-call surgeon who was playing at a park with his children.

During closing arguments Wednesday, attorneys quibbled about what happened once doctor and patient met.



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Essential Creditor Protection and
Retirement Considerations 14

\$116M Is Awarded In Stroke Suit

•By TIMES STAFF WRITER
Published September 30, 2006

TAMPA – A jury on Friday awarded a \$116-million medical malpractice verdict to the family of a Tampa man who attorneys argued became a paraplegic after an unlicensed hospital worker misdiagnosed a stroke as sinusitis.

On Aug. 9, 2000, Allan Navarro, now 50, of Tampa went to University Community Hospital Carrollwood campus with nausea, double vision, headaches and an unsteady gait. He was sent home with the diagnosis of sinusitis, attorney Steve Yerrid said, and went on to suffer severe brain swelling. Twenty hours after his initial diagnosis, Navarro was back in the emergency room, getting treated for a stroke.

Yerrid said the decision was the largest jury award in a malpractice suit in Florida history. Punitive damages are expected to be considered on Tuesday.

Navarro, a former pro basketball player from the Philippines, came to the United States in the 1990s. His wife Marilyn, 52, and son, Scottie, 10, are named as claimants in the jury verdict, Yerrid said.

UCH officials could not be reached for comment late Friday.



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Essential Creditor Protection and
Retirement Considerations 15

Doctors in lawsuit now suing attorneys

By Carrie Weimer

Published March 7, 2007

TAMPA – They got hammered with a record-breaking \$217-million verdict for misdiagnosing a patient who suffered a stroke.

Now the doctors who were the target of that high-profile lawsuit are hoping to turn the tables. They're suing their attorneys.

Among the doctors' chief complaints: The attorneys turned down settlement offers of \$1-million and \$3-million, a fraction of the final judgment.

"This case should have never gone to trial," said Dr. Frank Winkles, who is representing Franklin, Favata & Huls physicians group and Carrollwood Emergency Physicians. "It should have settled. Those doctors were just hung out to dry," Winkles said.

The other doctor involved in the case, Michael Austin, is represented by Tampa attorney Barry Cohen, who said the lawsuit spoke for itself.

"The allegations are pretty clear," Cohen said.

The lawyers named in the suit, filed March 2 in Hillsborough Circuit Court, did not return telephone calls seeking comment. The lawyers are Louis J. LaCava and Victor Guzman, who work for a West Palm Beach firm that also has a Tampa branch. Also named is Brian Stokes, who is with the Unger Law Group, which is based in Orlando.

The disagreement stems from a medical malpractice case decided by a Tampa jury in October.

Allan Navarro, a former pro basketball player in the Philippines, went to the University Community Hospital Carrollwood emergency room August 9, 2000, complaining of nausea, headache, dizziness and double vision.

He was sent home five hours later with a painkiller prescription and a diagnosis of sinusitis.

No one realized Navarro was having a stroke. He returned to the hospital with more severe symptoms the next morning and underwent surgery hours later to relieve brain swelling. He ended up in a coma for three months and emerged from it permanently disabled.

Before his illness, Navarro was a machine operator earning just above minimum wage. Now he is confined to bed or must use a wheelchair.

Navarro's attorney sued. Testimony revealed that an unlicensed physician's assistant initially examined Navarro, and Austin based his diagnosis on that exam.



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Doctor Kills Self After Malpractice Verdict

Lawrence Grey, who specialized in vasectomy reversals, had been ordered to pay a former patient \$1-million.

By Bill Coats
Published May 4, 2006

TAMPA – On Friday afternoon, Dr. Lawrence Grey listened in a Hillsborough County courtroom as a jury announced its verdict: He should pay a former patient \$1-million.

Late Friday night, Grey's wife found him dead in the \$2-million Bayshore Boulevard home, hanging in a bedroom closet from a yellow nylon rope.

Grey's apparent suicide left lawyers in the malpractice case reeling.

Jeffrey Hunter, the Tampa lawyer who represented Grey, heard about the death Saturday night after a family outing.

"I was shocked," Hunter said Wednesday "I still am."

Timothy Moran, the Jacksonville lawyer who represented the former patient, learned of Grey's death Wednesday from a Times reporter.

"I never intended for something like this to happen," Moran said. "I blame his insurance company for not doing the right thing."

Moran said he offered to settle the case for \$250,000, the limit of Grey's insurance coverage, and later for \$175,000 but was turned down.

If the jury's verdict of \$1,005,000 stands, Grey's business will be liable for \$755,000.

Hunter wouldn't comment on the settlement decisions. He said he intends to ask for a new trial. If denied, he plans to appeal.

Grey, a 51-year-old urologist, specialized in microsurgery that reversed vasectomies, restoring his patients' abilities to father children.

Grey marketed himself online as the Vas Doctor. That's a reference to the vas deferens, the narrow tube through which sperm travels from the testicles, and which a surgeon snips in a vasectomy.

Grey used laser tools and techniques that he developed, he told the Tampa Bay Business Journal in a profile three years ago.

"The microbeam is strictly my own creation," Grey said in the profile. "The laser beam gives you a cleaner, more precise cut with less damage to tissue.

Hunter said Grey recently was performing 400 to 450 vasectomy reversals a year.



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Slip-and-Fall Verdict of \$12.2 million

November 2, 2017 by Bettina Altizer

A most unusual case.

Roughly ten years ago a most unusual slip-and-fall case resulted in a jury verdict of \$12.2 million. A 47-year-old woman stopped at a convenience store to buy a newspaper. While she was walking toward her car she slipped on a wet spot on the sidewalk that surrounded the store. The sidewalk was approximately 8 inches higher than the pavement. When she fell, she landed on her chest and chin. An eyewitness to the fall said that her head snapped backwards almost as if she had been hit by a boxer.

Plaintiff did not recall losing consciousness. Therefore, when she visited the emergency room, her chin was stitched, and she was released. The hospital's medical record, therefore, included nothing about either the intensity of her head "snapping" backward or that she had lost consciousness.



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Jury Verdict Against Pizza Hut in Case of Delivery Driver Collision

San Diego, CA. – A San Diego Superior Court jury today returned a verdict against Pizza Hut, Inc. for a total of \$16.8 million. The case arose out of a November 9, 2008 collision between a Pizza Hut delivery driver and a mother and daughter on Clairemont Drive in San Diego, California. During the event, the delivery driver, 18 year old Nicole Fisk, drifted across lanes, and collided head on with the vehicle containing Olina Marie Novak and her daughter Shan Marie Novak. Olina, 47 years old at the time of the accident suffered a severe cervical fracture. Her daughter, Shan, suffered a catastrophic and permanent brain injury. She today requires 24 hour care.

After the crash, Pizza Hut claimed its delivery driver had suffered a seizure caused by previously undiagnosed epilepsy, causing the collision. "Sudden medical emergency" is a defense to negligence under California law.

Attorneys representing the Novak family countered that Pizza Hut's driver knew she had a previous medical condition, and that Pizza Hut should have done more to ensure she could safely work as a professional driver. The driver, Nicole Fisk, was only 18 years old at the time, had held a drivers license for only 3 months, and had a history of "staring spells" and "blackout" episodes prior to the incident.

The jury agreed, finding both that there was no "sudden medical emergency" excusing the driver's conduct. The jury awarded Olina Novak a total of \$2.2 million and Shan Novak \$8.6 million.

John Ouzens of the Gomez Law Firm, attorney for the Novak family, stated, "This case was about corporate responsibility. Pizza Hut refused to accept its responsibility and the jury properly imposed it." Co-counsel Joseph Lavelle, of Werts McDade Wallace Moot & Brower added, "Today this jury made the roads safer for all of us. Hopefully from now on, corporate employers will do what they need to do to make sure they hire only safe drivers to get beyond the wheel daily as part of their job." Both firms represented the family at trial.

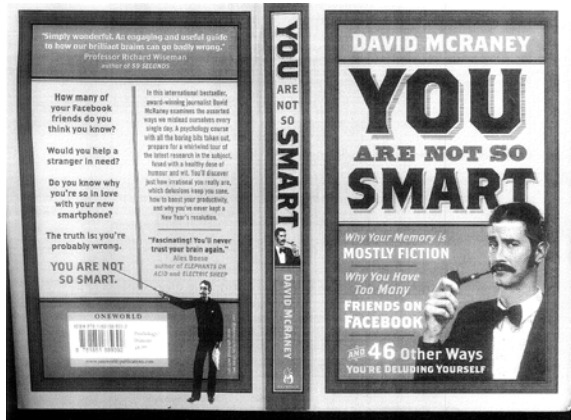


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•“You Are Not So Smart” by David McRaney is available on Amazon.com



You Are Not So Smart

(Excerpts from the book You Are Not So Smart by David McRaney)

Chapter Title	Your Misconception	The Truth
Introduction	You are a rational logical being who sees the world as it really is.	You are as deluded as the rest of us, but that's okay - it keeps you sane.
Chapter 3 - Confirmation Bias	Your opinions are the result of years of rational, objective analysis.	Your opinions are the result of years of paying attention to information that confirmed what you believed, while ignoring information that challenged your preconceived notions.
Chapter 5 - The Texas Sharpshooter Fallacy	You take randomness into account when determining cause and effect.	You tend to ignore random chance when the results seem meaningful or when you want a random event to have a meaningful cause.
Chapter 25 - The Affect Heuristic	You calculate what is risky or rewarding and always choose to maximize gains while minimizing losses.	You depend on emotions to tell you if something is good or bad, greatly overestimate rewards, and tend to stick to your first impressions.
Chapter 28 - Self-Serving Bias	You evaluate yourself based on past successes and defeats.	You excuse your failures and see yourself as more successful, more intelligent, and more skilled than you are.
Chapter 32 - The Misinformation Effect	Memories are played back like recordings.	Memories are constructed anew each time from whatever information is currently available, which makes them highly permeable to influences from the present.
Chapter 37 - Learned Helplessness	If you are in a bad situation, you will do whatever you can do to escape it.	If you feel like you aren't in control of your destiny, you will give up and accept whatever situation you are in.
Chapter 38 - Embodied Cognition	Your opinions of people and events are based on objective evaluation.	You translate your physical world into words, and then believe those words.
Chapter 41 - Self-Handicapping	In all you do, you strive for success.	You often create conditions for failure ahead of time to protect your ego.
Chapter 42 - Self-Fulfilling Prophecies	Predictions about your future are subject to forces beyond your control.	Just believing a future event will happen can cause it to happen if the event depends on human behavior.
Chapter 47 - The Illusion of Control	You know how much control you have over your surroundings.	You often believe you have control over outcomes that are either random or are too complex to predict.

PRIMARY CAUSES OF LIABILITY

Catastrophes in the Making

- Debt: General creditors, medical creditors, guarantees, provider agreements, etc.
- Tort Liability (civil breaches of contract, rather than criminal):
 - Auto owners and drivers (boats and other vehicles)
 - Errors and omissions - professional malpractice.
 - Aiding and abetting others who commit wrongdoings.
 - Premises liability- building owners. Think of that child on the tricycle going up the wheelchair ramp and flipping down the stairs. Also consider the following:
 - Hazardous waste.
 - Asbestos and other harmful building materials.
 - People hurt by construction defects.
 - People tripping and hurting themselves in the parking lot.
 - Tenants with rowdy customers who shoot people.
 - Inappropriate acts by lease management.
 - Children eating lead paint.

PRIMARY CAUSES OF LIABILITY

- Relationship Liability:
 - Joint and several liability.
 - Partnerships.
 - Co-signors or co-guarantors on notes.
 - Joint tort feasons (those who commit civil faults) can be jointly and severally liable for economic damages.
 - Co-conspirators.

Vicarious liability: An employer is generally liable for the activities of employees in the scope of the business. What if the receptionist runs over a child while running an errand?

 - Spoiled romances and accusations by a forlorn ex-girlfriend or boyfriend, especially if you employed him or her.
- Tax Liabilities:
 - Income taxes.
 - Trust fund - employee withholding – money stolen that should have gone to the government - paying employees as independent contractors.
 - Penalties, interest, and criminal implications.

PRIMARY CAUSES OF LIABILITY

- Others:
 - Divorce: Alimony and property settlement.
 - Child support.
 - Hazardous waste liability and related issues.
 - Student loans.
 - Business participation: Sexual discrimination, etc.
 - Involvement as trustee with relationship to pension plans.
 - Medicare and other payors.
 - Real estate liability:
 - Hazardous waste.
 - Lead paint.
 - Asbestos.
 - Tort liability.
 - Vicarious liability for building activities.
 - Civil rights or other violations.

PRIMARY CAUSES OF LIABILITY

- Medicare, Medicaid, and private pay refund liabilities: Carriers have been suing doctors not following referral laws for significant refunds.

Liabilities generally not cancelable in bankruptcy include the following:	Liabilities generally not covered by insurance include the following:
(i) Government student loans	(i) Civil rights violations committed by employees or others
(ii) Trust fund tax liability	(ii) Environmental liabilities, including sick building syndrome and lead paint issues
(iii) Hazardous waste liability	(iii) Criminal acts
(iv) Breach of fiduciary duty liabilities	(iv) Charitable and religious board activities
(v) Child support and alimony	(v) Jet skis normally cannot be insured for over \$250,000 per occurrence
	(vi) Acts of terrorism: Most casualty insurance clauses exempt acts of terrorism. The industry has been paying claims on goodwill up until now

Understanding Your Liability Insurance Coverage

The vast majority of carriers will only issue a \$250,000 policy on your home, a \$250,000 policy on your driving, and a \$250,000 policy on your vacation home. A separate "umbrella carrier" or "carriers" will then issue separate policies for above \$250,000, as shown in the example below. Sometimes one carrier will write two or more of the below described policies, but often there will be 3 or more carriers involved and coordination can be a challenge:

\$5,000,000 ↑ \$251,000	Umbrella Policy #1 Covers claims for home at \$300,000 and for cars at \$250,000. Must be "drop-down" umbrella if home policy is issued by Citizens or a comparable state agency that does not cover liabilities from pools, pets, or other notable exceptions.	\$5,000,000 ↑ \$301,000	Umbrella Policy #2 May need a separate umbrella for out-of-state vacation home, large boats or other items.
\$250,000 ↑ \$0	Policy #1 – Homeowners	Policy #2 – Vacation Home	Policy #3 – Car Driver and Owner Policy
			Policy #4 – Big Boat at Vacation Home



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UMBRELLA INSURANCE COVERAGE

Re: UMBRELLA LIABILITY INSURANCE COVERAGE

Dear _____:

As part of our planning I wanted to reiterate the importance of having an appropriately coordinated and "gap free" liability and casualty insurance program.

I am enclosing a sample letter that some clients use to help assure that they have coverage for common gaps or mistakes made in structuring liability insurance. If you would like assistance in completing this type of letter, please let me know.

The rest of this letter is about umbrella liability insurance coverage. We believe that it is very important to have appropriate limits of liability on automobile and homeowner insurance policies. Typically, the automobile and homeowner policies will be at \$500,000 coverage, and then there will be excess coverage under what is called a "personal umbrella policy."

The personal umbrella policy is used in combination with homeowners and auto policies to cover most clients' needs. If it is a true "umbrella" it will provide excess limits above and beyond your primary insurance coverage (such as homeowners, automobile or boat policy), and will also provide coverage for situations excluded or not addressed by underlying coverages. Each individual insurance company will have its own requirement for limits that you must have on your primary policies. You will want to be careful to assure that these policies are coordinated with your umbrella coverage.

Umbrella limits start at \$1,000,000 and can go over \$10,000,000. Pricing for these policies are based primarily on the number of houses and vehicles to be insured, with each additional \$1,000,000 of coverage being less expensive than the preceding. In your situation I would probably have \$_____ of umbrella liability insurance. Also, I would consider placing much of your brokerage account and other assets under a family limited partnership to further insulate you for creditor protection purposes.

Another coverage that is often underutilized by clients is called "uninsured motorist coverage." If you are in an automobile accident caused by someone who does not have enough coverage to pay for your damages, you can pursue your own insurance company to the extent of your "uninsured motorist" coverage. We encourage clients to see what it costs to have \$500,000 or more in uninsured motorist coverage to help compensate for catastrophic accidents that can happen.

Some carriers, including citizens and carriers who have assumed policies from citizens do not provide liability coverage for pool and pet or animal related liabilities. In this event the umbrella liability coverage may or may not apply. This is something that should be discussed with the insurance agency or carrier that provides liability coverage.

If we can provide you with any further information or with assistance concerning your insurances, please let us know.

Very truly yours,
Alan S. Gasman

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Dear Liability Insurance Agency and/or Carrier:

I recently met with my estate planning lawyer and wanted to make sure of the following:

- Please confirm that we have Personal Liability Umbrella Insurance covering our automobiles, boats, recreational vehicles, and all properties owned. I would like quotes on the following coverage limits, \$1,000,000, \$3,000,000 and \$5,000,000, with and without Uninsured Motorist coverage.
- Please confirm that we are covered for animal liability under our primary homeowners insurance and confirm that the Liability Umbrella would also extend to animal liability. We have been told that the primary homeowners may exclude animal liability and that some Liability Umbrella policies will not provide coverage when the primary homeowners insurance excludes same.
- Please confirm that we are covered for pool related accidents occurring on our property and also confirm that the Personal Liability Umbrella policy will also extend coverage to pool related accidents.
- Can you please confirm that we are covered for cars being driven by _____.
- Can you please confirm that we are covered for the investment property that we own at _____. It is titled under the name of _____.
- Can you please confirm that we are covered for our _____ boat, which is _____ foot long and is normally stored at _____. The horsepower is _____. Are we also covered for trailer the boat with our trailer?
- Also, can you please confirm that we are covered for our waterrunner/jet ski which is a _____ with horsepower of _____. It is stored at _____.
- You do not handle the coverage for our vacation _____ in _____ or our vacation _____ in _____. Is our potential liability relating to the use of these properties covered under our umbrella, or do we have to obtain a separate umbrella for these properties?
- Our _____ and _____ are stored and used up in our _____.
- _____ drives the car owned by _____ both for personal purposes and with respect to the _____ business. We assume our coverage includes business driving both by _____ and by _____ who occasionally drive the car for the business.
- Can you please confirm that we are covered for our motorcycle being driven by _____.
- Is there anything not mentioned above that comes to mind that we should be aware of?

Please send our lawyer, Alan S. Gasman, a copy of your response to this letter, which has been generated as a part of our estate planning. Alan's email address is AGasman@gasmanpa.com and his street address is 1245 Court Street, Suite 102, Clearwater, Florida 34746. His fax number is (727) 443-5829. Please send us a copy of your response as well.

If you have any further suggestions with respect to our coverages please let us know. Thank you very much for your assistance herewith.

Best personal regards,
CLIENT

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THE A B Cs OF MALPRACTICE INSURANCE

Claims made policy – only covers liabilities for where a claim against the doctor has been made while the policy is active.

Tail coverage – a separate policy purchased or awarded after practicing or when switching from one carrier to the other so that all future "claims made" will be covered.

Tail term – permanent, four years, or two years.

Retroactive coverage – provided by a new carrier that will cover claims made in the future for past practice time – only available when replacing prior coverage.

Occurrence policy – unlike "claims made" – covers all claims made, even after policy is terminated, without having to buy a tail policy.

Respondent Superior – an employer is responsible for the medical malpractice of its employee.

Rights of indemnity – an employee may have to repay an employer for liability incurred if the employer pays to settle the case and the employee was at fault.

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THE A B Cs OF MALPRACTICE INSURANCE

First year and stepped rates – it is far less likely that a lawsuit will be filed during the first year of a policy, and then somewhat more likely each consecutive year thereafter, so the rates rise annually until "mature" in the fourth or fifth year.

Corporate coverage – most policies are written for the individual doctor, but the corporation / employer can have a separate corporate policy that covers all doctors, practice extenders, etc. – usually relatively inexpensive and will increase overall coverage.

Defense only contracts – Gulf Atlantic in Jacksonville offers a \$100,000 defense cost policy – the carrier will not pay anything for liability, but will provide legal representation and expert witnesses so that a plaintiff lawyer has little to hope for if the doctor and practice being sued are "judgment proof" (have no or little exposed assets).

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2014 Competitive Malpractice Insurance Rates With Normal Discounts

	\$250,000/\$750,000 Competitive Mature Rates 2014			\$1M/\$3M Competitive Mature Rates 2014		
	Remainder of Florida	Dade County	Broward County	Remainder of Florida	Dade County	Broward County
Internal Medicine N/S	\$8,477	\$17,400	\$16,419	\$13,576	\$24,288	\$24,288
Family Practice	\$7,460	\$15,312	\$14,448	\$11,977	\$24,288	\$24,288
Dermatology N/S	\$3,763	\$9,048	\$8,538	\$5,447	\$15,834	\$14,941
Cardiology Invasive	\$11,868	\$24,360	\$22,986	\$20,769	\$42,630	\$40,226
Cardiology Interventional	\$13,563	\$27,840	\$26,270	\$23,736	\$48,720	\$45,972
Gynecology Surgery	\$11,868	\$23,360	\$22,986	\$20,769	\$42,630	\$40,226

Compliments of:
Charles L. Wasson, III, CPCU
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Essential Creditor Protection and Retirement Considerations 31

Advantages and Disadvantages of Lowering Malpractice Insurance Limits

I. ADVANTAGES:

1. Reduction of premiums.
2. In a horrendous situation, a carrier is going to be more likely to simply give up policy limits than to defend a complicated case.
3. In a small number of instances where the liability may be great, but negligence is hard to prove, some plaintiff firms may not pursue a suit if there are fewer dollars available at the end of the rainbow. The better firms may reject such claims, and the "second or third tier plaintiff firms" will more likely settle for less or lose the suit.
4. As a matter of principle, this will leave less money for plaintiffs' lawyers and people who sue doctors to help stop feeding the industry.
5. From a public records and future evaluation standpoint, the prospect of being able to settle any claim at \$250,000 instead of at a higher limit means that catastrophic claims will be characterized as having been \$250,000 matters as opposed to \$1,000,000 matters.

II. DISADVANTAGES:

1. If there is a serious claim, personal and practice assets will be exposed so that damages can exceed policy limits. IF A CLAIM VALUE EXCEEDS LIMITS OF LIABILITY, PERSONAL AND PRACTICE ASSETS MAY BE LOST, although this is generally unlikely if proper planning has been effectuated.

Advantages and Disadvantages of Lowering Malpractice Insurance Limits

2. Having to go through defending a claim with the risk of losing personal or practice assets results in significantly higher emotional distress for the physician, their partners, and loved ones.
3. Maintaining high limits going forward means that the carrier would have to defend claims for future acts at the same high limits. Reducing limits now means that claims made in the past will only be subject to the now lower limits.
4. Potential employed physicians, banks, and managed care plans may be reluctant to work with a practice having lower limits.
5. In case of an actual error & an injured patient, having more coverage might be the right thing.

III. THE MIDDLE GROUND:

1. Many physicians have chosen small out-of-state or offshore carriers or "self-insurance" programs in lieu of traditional malpractice insurance.
2. These programs usually cost much less than traditional malpractice insurance, and offer the doctors "more control" over the claims process.
3. These carriers are not registered with Florida, and upon becoming insolvent the doctor has no protection at all.
4. These carriers are much more likely to become insolvent than Florida carriers.
5. In some cases, these carriers do not satisfy the definitional requirements of "malpractice insurance", so the doctor is actually "bare", but may not know to follow the going bare rules. A patient with a judgment against such a doctor may have the ability to cause the doctor to lose his or her discharge in bankruptcy and medical license!

Advantages and Disadvantages of Lowering Malpractice Insurance Limits

- Other than malpractice insurance, there are several other important insurances that are easy (and affordable) to maintain:
 - disability insurance;
 - overhead insurance;
 - liability insurance (for non-malpractice obligations)
 - worker's compensation insurance
 - unowned automobile liability insurance
 - individual automobile liability policies
 - 3M – 5M in umbrella coverage recommended
- Uninsured Motorist Coverage - if the person who hits you in an automobile accident doesn't have enough insurance, your own carrier can pay for your injuries and damages if you have sufficient uninsured motorist coverage

ASSET PROTECTION DEFINITIONS

To understand the subject of asset protection, you must speak the language. The following vocabulary and definitions will provide you with a basic understanding of the fundamental concepts which make up the "art and science" of Florida creditor protection planning.

Debtor - A party who owes money.

Creditor - A party who is owed money by the debtor.

Judgment - A court order establishing that a debtor owes money to a creditor. The existence of a judgment is almost always necessary before a creditor can seize a debtor's property.

Plaintiff - A party suing to get a judgment against a defendant.

Defendant - A party being sued by a plaintiff.

Exempt Assets - Assets that are protected from seizure under the creditor laws. A debtor will be able to keep these assets notwithstanding that a creditor may have a judgment against them.

Non-Exempt Assets - Assets of a debtor that are subject to creditor claims.

Fraudulent Transfer - As explained in Chapter 14, this is the name given to a transfer of assets from a creditor available status to a creditor non-available status if a primary purpose was to avoid known creditors. Under federal and state law, such transfers may be set aside if the assets are within the jurisdiction of an applicable court making such a finding. Outside of Bankruptcy Court, Florida has a statute of limitations on the ability of a creditor to set aside a fraudulent transfer, which in many cases runs 4 years after the applicable transfer. This does not apply under Florida law to a transfer of assets to homestead. Under bankruptcy law, however, a discharge of debt can be denied if there has been a fraudulent transfer made within one year of the bankruptcy filing. Also, the homestead exemption may be limited to \$136,875, if there has been a "fraudulent transfer" to homestead within 10 years of filing bankruptcy. There is also a 10 year set aside rule for "fraudulent transfers to asset protection trusts and similar arrangements" under the 2005 Bankruptcy Act. Oftentimes, clients will be advised to make transfers in exchange for receiving full value to avoid the fraudulent transfer rules while still making the resulting arrangement more creditor protective than it would have been.

ASSET PROTECTION DEFINITIONS

Preferential Transfer - A transfer that may be set aside under state or bankruptcy law, such as a transfer made to any party within 90 days of filing a bankruptcy, or a transfer made to an "insider" within one year of filing the bankruptcy. See also Florida Statute §726 (providing a two year look back on transfers).

Charging Order - A creditor with a judgment cannot reach into a properly structured limited partnership or LLC arrangement, where the debtor does not own the entire entity. Instead, the creditor receives a "charging order" from the court, whereby if and when distributions are made from the entity, the pro rata share of the debtor would be paid to the creditor. There is nothing in the law that allows a court order that a distribution be made. Therefore, someone having a judgment against a debtor whose sole asset is a part ownership interest in a limited partnership or an LLC may have limited leverage to obtain cash or monies from the debtor, although the debtor will also have difficulty receiving distributions when a charging order is in place. This will often result in settlement, or the possibility of the creditor trying to force the debtor into bankruptcy.

Firewall Protection - The concept that the shareholder of a corporation or limited partner in a limited partnership will not be liable for liabilities incurred by the entity. This is why many companies put the more hazardous activities under a separate subsidiary.

Limited Liability Partnerships, Limited Partnerships, Limited Liability Limited Partnerships, Limited Liability Companies, Professional Limited Liability Companies, and Partnerships of the above Entities - The names given to various legal entities which have different effects as to firewall, tax, and charging order versus asset seizure protection. Be cautious as to which entity you choose because they do not all offer the same protection. For example, the creditor of a partner in a Florida limited liability partnership (LLP) can seize the partnership interests, and is not limited to receiving a charging order, but the creditor of a partner in a Florida limited partnership (LP) or a limited liability limited partnership (LLLP) will be limited to the charging order remedy. It is important not to confuse these entities, but this commonly occurs, even among well-meaning lawyers.

Staving Out of Bankruptcy - Many debtors will prefer to stay out of bankruptcy, so it is important for someone with an imminent judgment to understand how this can be achieved. Generally, it takes three creditors to force an individual into bankruptcy, if that individual has at least 12 creditors.

Bankruptcy - A federal process whereby every debtor has the right to file in the bankruptcy court, generally under Chapter 7, Chapter 11, or Chapter 13. Many lawyers say that this is like having the debtor "swim in a fish bowl" because there must be full disclosure of all documentation and information upon filing.

ASSET PROTECTION DEFINITIONS

Joint and Several Liability - The concept that individuals who participate in a negligent or improper act will be totally liable for all damages imposed to the extent that the other "co-defendants" do not pay their fair share. There are limitations on joint and several liability pursuant to Florida Statute Section 768.81.

Vicarious Liability - The concept that an employer is generally responsible for liabilities incurred by an employee acting within the scope of the employee's duties. The Greek term for this phenomenon is "respondere superior."

Under this concept, parents may be responsible for the driving activities of their nannies or errand runners, and doctors may be responsible for unforeseen actions by employees who might aggressively try to help people using prescription scripts, giving medical advice, and/or driving automobiles.

Secured Interest - The concept whereby a creditor can record a mortgage or lien on assets whereby that creditor would be entitled to repossess the assets and sell them at auction to satisfy a debt owed to the creditor. Real estate is liened by the recording of a proper mortgage, and non-real estate assets may be liened by recording UCC-1 Financing Statements based upon appropriately drafted security and/or pledge agreements. If a friendly debtor has a secured interest in a particular asset, then another debtor would have to pay the friendly secured debtor before they would be able to seize the asset secured. This is why doctors will often give the bank with a mortgage on business real estate a lien against medical practice assets, so that a malpractice claimant would have to pay the bank off or take other steps before seizing medical practice assets.

Marshaling of Assets - Whereby a party having a lien against assets may be forced to sacrifice their position if there are plenty of other assets that it has access to, to satisfy the obligation of the debtor. Over-secured creditor issues may also arise.

Asset Protection Trust - A trust arrangement whereby creditors of the grantor may not have access – which is contrary to Florida and basic common law that if the grantor could receive any benefit whatsoever, then creditors may receive all assets.

Bad Faith - The malpractice insurance carrier has an obligation to settle any claim within the limits of coverage of the physician, if reasonably possible. The failure of an insurance carrier to settle within policy limits can result in the carrier being responsible for an "excess verdict." When this occurs, the plaintiff's lawyer will often settle with the defendant by receiving an assignment of the defendant's right to pursue the insurance carrier for the excess amount.

ASSET PROTECTION DEFINITIONS

If the malpractice carrier believes it has a 90% chance winning at trial and a 10% chance of losing with a verdict well over policy limits, then it may make good economic sense for the carrier to take the chance, but not from the point of view of the physician. If the carrier takes the chance then it has acted in bad faith it will be responsible for any excess verdict. Private legal counsel is commonly hired to encourage the carrier to settle within policy limits, and a physician should almost never encourage a carrier not to settle or be without private representation when the carrier or its lawyer recommends private representation! Fortunately, most verdicts exceeding coverage limits result in the physician assigning their bad faith claim to the plaintiff in exchange for a total release, particularly where the physician is otherwise judgment proof.

Automobile Liability – The owner of a motor vehicle in Florida is liable for operation of the vehicle by another driver, except that if the other driver has insurance then the owner's exposure may be limited to \$300,000 per incident. If the driver has \$500,000 of liability insurance, then the owner may not have liability exposure, unless the owner was negligent in allowing the driver to use the vehicle.

Sovereign Liability – The concept whereby an individual working for a governmental agency and the agency itself has limited liability, presently being \$250,000 per incident. This applies to a physician working full time for public hospitals, medical schools, and the Veteran's Administration.

Successor Liability – When a corporation has a liability and a "successor corporation" has identical or similar ownership, identity, customers, employees and/or general identity, a judge may find the new company responsible for the liabilities of the old company, even if there was a legitimate bankruptcy of the old company before the new company was formed and operational.

Reverse Veil Piercing – When a court unwinds transfers made to entities where the transferor is a debtor that had control over the entity, and used the entity to disburse personal assets to keep them beyond the reach of personal creditors.

Concealment – Under the doctrine of concealment an asset "given away" but actually held for the original transferor will be considered as continually owned by the original transferor, notwithstanding title. Concealing assets puts the debtor at risk for losing a bankruptcy discharge.

How to Stop Worring and Start Living – A book written by the late Dale Carnegie, which includes phenomenal advice on how to counsel for and live with concerns about what may happen in the future, what can be done about these potential future problems, and how to handle oneself and others in a logical, sequential, and effective manner.

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Essential Creditor Protection and Retirement Considerations

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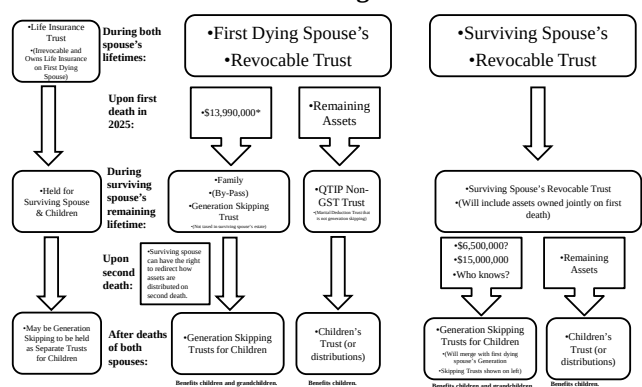
CREDITOR EXEMPT ASSETS	ASSETS THAT ARE DIFFICULT FOR A CREDITOR TO OBTAIN	ASSETS EXPOSED TO CREDITORS
Homestead -Up to half acre if within city limits. -May be immune from fraudulent transfer statute.	Limited partnership and similar entity interests.	Individual money and brokerage accounts.
IRA -Includes ROTH, Rollover, and Voluntary IRAs, but possibly not inherited IRAs.	Foreign trusts and companies.	Joint assets where both spouses owe money.
Permanent Life Insurance -Must be owned by insured.	Note – foreign entities are very rarely recommended and must be reported to IRS -	Personal physical assets, including car, except for \$4,000 exemption (\$1,000 if homestead exemption is claimed in bankruptcy).
401(k) -Maximize these!	Foreign bank accounts.	One-half of any joint assets not TBE where one spouse owes money.
Tenancy by the Entireties (joint where only one spouse is obligated) -Must be properly and specially titled – joint with right of survivorship may not qualify. 529 College Savings Plans Annuity Contracts Wages of Head-of-Household Wage Accounts Up to \$4,000 of personal assets – or less in bankruptcy.	Vocabulary: EXEMPT ASSET – An asset that a creditor cannot reach by reason of Florida law – protects Florida residents. CHARGING ORDER PROTECTION – The creditor of a partner in a limited partnership, limited liability partnership, or properly drafted LLC can only receive distributions as and when they would be paid to the partner. FRAUDULENT TRANSFER – Defined as a transfer made for the purpose of avoiding a creditor. Florida has a 4 year reach back statute on fraudulent transfers. A fraudulent transfer into the homestead may not be set aside unless the debtor is in bankruptcy. It takes 3 creditors of a debtor who has 12 or more creditors to force a bankruptcy. Upon filing a Chapter 7 Bankruptcy, an individual debtor may be able to cancel all debts owed and keep exempt assets, subject to certain exemptions. Annuities and life insurance policies are not always good investments, and can be subject to sales charges and administrative fees. There is a lot more to know – but this chart may be a good first step.	

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Essential Creditor Protection and Retirement Considerations

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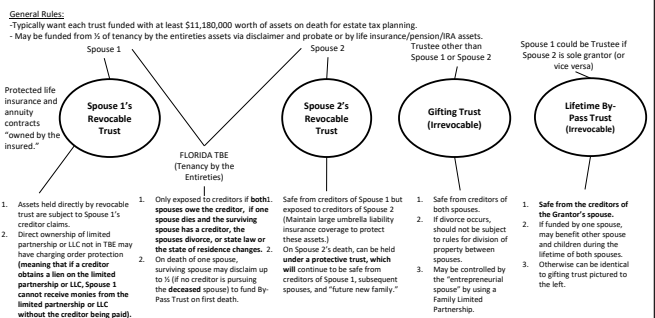
Protective Trust Logical Chart



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DETERMINING HOW TO BEST ALLOCATE ASSETS AS BETWEEN A MARRIED COUPLE - PART I



SEE NEXT PAGE FOR SECOND TIER PLANNING

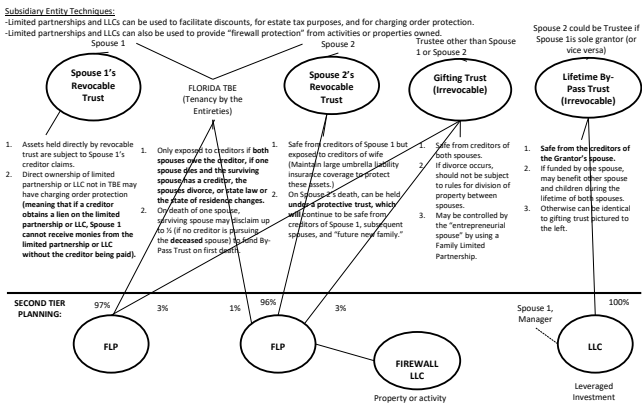
A COMMON SOLUTION - to use a limited partnership or similar mechanisms and have no assets directly in the "high risk" spouse's trust, half to two-thirds of the assets held as tenants by the entireties, and half to two-thirds of the assets directly in the "low risk" spouse's trust.

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DETERMINING HOW TO BEST ALLOCATE ASSETS AS BETWEEN A MARRIED COUPLE - PART II



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Essential Creditor Protection and Retirement Considerations

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Planners may recommend separating community property to avoid all assets being subject to the claims of the creditors of either spouse, or possible use of Alaska or Tennessee Community Property Asset Protection Trusts

(If couple resides in a Community Property State)

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Essential Creditor Protection and Retirement Considerations

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Community Property Trust



- * May offer creditor protection in asset protection state.
- * Step-up basis is more well assured than with JEST - see Zaritsky/Blattmachr articles.
- * Deduct your next trip to Alaska to discuss this with Doug Blattmachr.

** See "Tax Planning with Consensual Community Property: Alaska's New Community Property Law (written by Zaritsky/Blattmachr/Ascher) at:

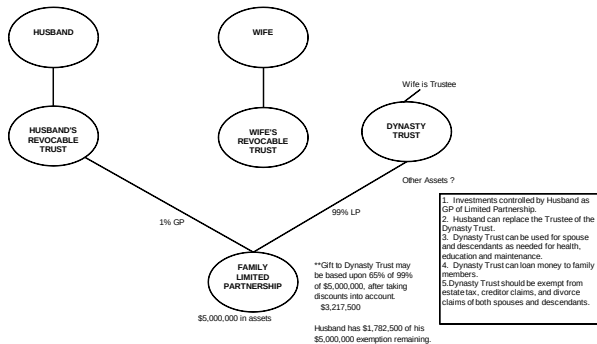
http://www.jstor.org/stable/20782170?seq=1#page_scan_tab_contents

Community Property States

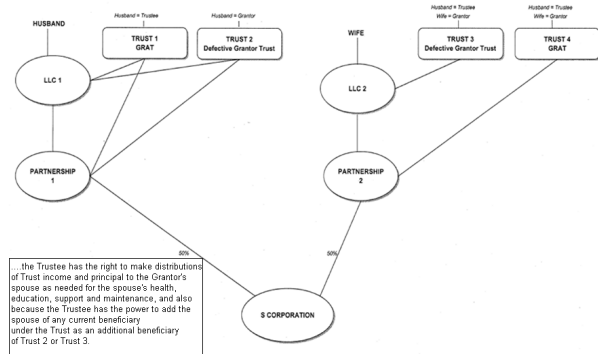
- ✓ Arizona
- ✓ California
- ✓ Idaho
- ✓ Louisiana
- ✓ Nevada
- ✓ New Mexico
- ✓ Texas
- ✓ Washington
- ✓ Wisconsin

•NOTE: Alaska, Tennessee and South Dakota are opt-in community property states that give both parties the option to make their property community property under a trust that can protect from creditors and enable all assets to receive a new fair market value date of death income tax basis if one spouse dies.

Example of a Husband/Wife Dynasty Trust Arrangement



Defective Grantor Trusts & Disregarded Entities Illustrated Flowchart Summarizing Private Letter Ruling 200439028

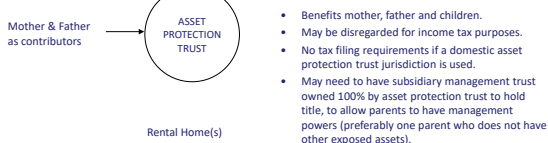


Limited Liability Trust: Asset Protection Trust

BETTER THAN AN LLC TO HOLD INVESTMENT PROPERTY IF LIABILITY INSURANCE COVERAGE AND RATES WILL BE BENEFICIAL

SUCH A TRUST MAY ALSO QUALIFY UNDER AN INDIVIDUAL UMBRELLA POLICY, WHEREAS AN LLC MAY NOT

Trust Company in proper jurisdiction = Trustee or Co-Trustee



- Benefits mother, father and children.
- May be disregarded for income tax purposes.
- No tax filing requirements if a domestic asset protection trust jurisdiction is used.
- May need to have subsidiary management trust owned 100% by asset protection trust to hold title, to allow parents to have management powers (preferably one parent who does not have other exposed assets).

BUYING TERM INSURANCE

AGE 30						
	PREFERRED		STANDARD		STANDARD SMOKER	
	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE
10 Year Term	\$378	\$328	\$658	\$518	\$1,548	\$1,218
15 Year Term	\$458	\$398	\$768	\$688	\$1,918	\$1,438
20 Year Term	\$608	\$478	\$968	\$738	\$2,278	\$1,638
30 Year Term	\$938	\$768	\$1,518	\$1,218	\$3,908	\$3,018

AGE 40						
	PREFERRED		STANDARD		STANDARD SMOKER	
	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE
10 Year Term	\$505	\$435	\$925	\$785	\$2,405	\$2,005
15 Year Term	\$655	\$575	\$1,215	\$1,035	\$3,125	\$2,485
20 Year Term	\$865	\$745	\$1,505	\$1,255	\$4,345	\$3,185
30 Year Term	\$1,495	\$1,135	\$2,465	\$1,985	\$7,175	\$5,275

BUYING TERM INSURANCE

AGE 50						
	PREFERRED		STANDARD		STANDARD SMOKER	
	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE
10 Year Term	\$1,235	\$1,025	\$2,145	\$1,625	\$6,435	\$4,295
15 Year Term	\$1,785	\$1,235	\$2,805	\$2,065	\$7,825	\$5,725
20 Year Term	\$2,225	\$1,625	\$3,425	\$2,715	\$10,425	\$6,865
30 Year Term	\$4,025	\$2,645	\$6,245	\$4,785	\$13,719	\$10,109

AGE 60						
	PREFERRED		STANDARD		STANDARD SMOKER	
	MALE	FEMALE	MALE	FEMALE	MALE	FEMALE
10 Year Term	\$3,098	\$2,198	\$4,808	\$3,278	\$13,028	\$8,308
15 Year Term	\$4,488	\$3,048	\$7,088	\$5,218	\$17,658	\$12,978
20 Year Term	\$5,798	\$4,078	\$9,488	\$6,668	\$22,048	\$15,058
30 Year Term	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available

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Essential Creditor Protection and Retirement Considerations 50

Dynasty Wealth Protection Trust

Trustee



Assets gifted to trust and growth thereon.

Note: Nevada gets a gold star for having a law that says there cannot be an assumed or an oral agreement between the Grantor and the Trustee of a dynasty trust; because of this, the IRS cannot say that the grantor retains certain control.

Grantor can replace the Trustee at any time and for any reason. Protected from creditors of Grantor and family members. Can benefit spouse and descendants as needed for health, education and maintenance.

Per Private Letter Ruling 200944002 the Grantor may be a discretionary beneficiary of the trust and not have it subject to estate tax in his or her estate. But be very careful on this! The Trust would need to be formed in an asset protection jurisdiction and there is no Revenue Procedure on this. Should be grandfathered from future legislative restrictions.

May loan money to Grantor.

May own limited partnership or LLC interests that are managed at arm's-length by the Grantor.

May be subject to income tax at its own bracket, or the Grantor may be subject to income tax on the income of the trust, allowing it to grow income-tax free unless or until desired otherwise. If the Grantor is a beneficiary it must remain a disregarded Grantor Trust.

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Essential Creditor Protection and Retirement Considerations 51

PLANNING FOR A DYNASTY TRUST WHERE THE SPOUSE OF THE SETTLOR/CONTRIBUTOR IS A BENEFICIARY - SPECIAL CONSIDERATIONS

- The settlor's spouse may be a trustee of the trust. As with all irrevocable trusts, administration should be well documented and according to the trust document.
- The settlor's spouse can have the right to receive amounts as reasonably needed for health, education, maintenance, and support. It is best to provide that any such distributions for the spouse will be made only after taking into account the spouse's other assets and resources.

Otherwise, consider whether the spouse might be considered to be gifting to the trust if he or she had the right to receive distributions and did not take them.

Alternatively, limit distributions to the spouse by requiring an independent fiduciary to approve them.

- Marital Deduction Savings Clause.** - The settlor's spouse may be the beneficiary of an outright disposition or General Power of Appointment Marital Trust provision to be funded if total contributions to the trust would otherwise cause gift tax responsibility. Do not use a QTIP trust for this because of the harsh regulations requiring a marital deduction election to be filed for a lifetime QTIP trust gift.
- Typically the trust will be disregarded for income tax purposes, so that the settlor can pay the income tax attributable to the trust's income.

In case the settlor may want to "toggle off" defective grantor trust status (such as by reserving the right to replace trust assets with assets of equal value, and then releasing that right) an adverse party (another substantive beneficiary under the trust) must have the right to approve any distributions to the spouse.

Otherwise the trust will be a defective grantor trust under Internal Revenue Code Section 677, and the settlor will not be able to toggle that off (except by getting divorced!).

- The settlor's spouse may choose to "split the gift" on a gift tax return, which is permitted notwithstanding that the spouse is a beneficiary, so long as it is very unlikely that the spouse will need to receive benefits for health, education, maintenance and support when taking into account the spouse's other assets and resources. See Private Letter Ruling 200345038, William H. Robertson vs. Commissioner, 26 TC 246 (1956), and BNA Portfolios 822-2nd: Estate, Gift and Generation-Skipping Tax Returns and Audits, Section IX.M, and 826-2nd: Life Insurance, Section II.F.

- What if the assets used to fund the trust had recently been owned jointly by the settlor and the spouse, or were owned by the spouse and transferred to the settlor, who then transferred them to the trust? Under the Step Transaction Doctrine, the assets and the economic risk associated therewith should be owned and held exclusively by the settlor for a reasonable period of time. In case the IRS argues that the contribution to the trust was really made by the settlor's spouse (in which event the settlor's spouse may be subject to federal estate tax under Internal Revenue Code Section 2036(a)(1) - retained life interests), it may be important to have trust language which provides that any trust assets considered as transferred to the trust by the spouse beneficiary will be considered to be held in a separate subtrust of which the spouse will not be a beneficiary.

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Essential Creditor Protection and Retirement Considerations 52

PLANNING FOR A DYNASTY TRUST WHERE THE SPOUSE OF THE SETTLOR/CONTRIBUTOR IS A BENEFICIARY - SPECIAL CONSIDERATIONS

- Should the surviving spouse be given a limited power of appointment to direct how trust assets will pass? The grantor cannot be given this power if a completed gift to the trust is desired, but the spouse can. However, the power should not be exercisable in favor of her personally, her creditors, her estate, or creditors of her estate.

At what point should the power of appointment exist and/or be terminated?

- Immediately upon inception of the trust until the death of the surviving spouse?
- Only after the death of the settlor until the death of the surviving spouse?
- Only unless or until the parties are divorced or either party has a child who is not a beneficiary under the trust?

What would prevent the beneficiary spouse from exercising his or her power of appointment to fund a trust for the donor spouse to allow the ability to receive amounts as needed for health education and maintenance - assuming that there is no pre-existing agreement or obligation for this to happen.

- Should there be a divorce clause?

Typically where the drafting lawyer is representing both spouses this can be discussed and a joint representation letter can be put into place. It is likely that the judge will consider the trust assets to be for the benefit of the beneficiary spouse, but this will vary from state to state and judge to judge.

If the settlor's spouse is not a client then consider a clause that will provide that, upon divorce, the beneficiary spouse is no longer a beneficiary, trustee or otherwise entitled under the document.

- If the trust also provides for health, education, maintenance and support or other payments to descendants, how will the trust be protected from a descendant's support claims or other items for which state law permits penetration of a trust?

If the trust's primary beneficiary is your spouse, but your children can reach into it, do you have to worry that one of your children is going to have a nasty divorce and the ex-spouse of a child is going to be able to reach into this trust?

Consider whether there should be a Flee (Cuba) Clause in the trust, or whether the trust should name an independent trust protector or trust protectors with the ability to remove descendant beneficiaries and/or the ability to move the situs of the trust to an appropriately protective jurisdiction.

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Considering Offshore or Domestic Creditor Protection Trusts SHOULD I STAY OR SHOULD I GO?

FACTOR	NEVADA	ALASKA	ISLE OF MAN/JERSEY (Channel Island)	NEVIS	BELIZE
Asset protection law - Statute of Limitations	See Page 46 Strong/2 years - BUT full faith and credit issue	Strong/4 years - BUT full faith and credit issue	No statutory limitation on fraudulent transfer - unless import law of jurisdiction of a Co-Trustee	Strong/2 years	Strong/1 day statute!
Approximate minimal cost to open trust and annual fees.	\$250 to open \$1,500 per year thereafter	\$750 to open \$3,000 per year thereafter	\$1,600 to open \$1,600 - \$3,300 per year thereafter	\$1,750 min to open \$2,500-\$5,000 per year thereafter depending on value of trust	\$700 fee to register; \$1,100 - \$2,300 per year thereafter
Risk of theft.	Very low.	Very low.	Should be very low.	Low, if you use a safe trust company.	Not sure.
Use of subsidiary entities permitted- settlor can be Manager of entity.	YES	YES	YES	YES	YES
Reputation with US courts.	Does the judge gamble?	Does the judge like cruises?	Does the judge know European history?	Does the judge like Four Seasons Hotels or Alexander Hamilton (born there).	Has the judge read SEC v. Banner Fluid International, or like barrier reefs?
Commonality of use of Swiss or Bermuda depositories.	New concept	Not common	Common in these islands for centuries	Common	Common

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Essential Creditor Protection and Retirement Considerations 54

Considering Offshore or Domestic Creditor Protection Trusts SHOULD I STAY OR SHOULD I GO?

FACTOR	NEVADA	ALASKA	ISLE OF MAN/JERSEY (Channel Island)	NEVIS	BELIZE
Use of Trust Protectors.	New concept	New concept	Since the 1700s	Normal	Normal
Quality of service.	High	High- time zone difference	British-style/time zone difference	Small town- usually good.	Mayberry RFD
Allows importation with statute of limitations tolling from inception of trust at where it was imported from?	YES if original situs has substantially similar spendthrift laws	YES	The Statute of Elizabeth provides that fraudulent transfers should be void, not subject to any limitation period	YES	YES
Toggle off is possible?	YES	YES	NOT unless there is one or more U.S. beneficiaries	NOT unless there is one or more U.S. beneficiaries	NOT unless there is one or more U.S. beneficiaries
Provides for contingency fee payments? - Number of lawyers	YES About 10,000 attorneys	YES About 4,000 attorneys	NO, about 170 attorneys in Isle of Man, and 150 in Jersey Most lawyers are conflicted	NO, about 100 attorneys Most lawyers are conflicted	NO, about 150 attorneys Most lawyers are conflicted
Rule Against Perpetuities	365 years	1,000 years	150 years	Does not apply	Abolished

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Essential Creditor Protection and Retirement Considerations 55

A Matter of Opinion – Reasonable Minds Will Differ
HOUSE OF BRICKS/HOUSE OF STICKS/SOAP ON A ROPE

HOUSE OF BRICKS	HOUSE OF STICKS	HOUSE OF STRAW	FORGET IT	SOAP ON A ROPE (PRISON)
Offshore trust in a top offshore jurisdiction?	Domestic in a top domestic jurisdiction?			
Trustee controlled	Most assets under an LLC or partnership controlled by client.	Client as co-trustee and/or loosely managed LLC or partnership		
Small percentage of personal assets	50% of personal assets	The majority of assets		
Business purpose besides creditor protection	Creditor protection is the sole purpose	Creditor protection is the primary purpose and last minute/domestic		
No benefits paid or derived by settlor	Occasional benefits in unexpected situations or expected future retirement benefits	Significant continuing benefits	Debit card	
Fully reported for all tax and disclosure purposes	Reasonable attempts to comply with reporting purposes	Haphazard reporting	Intentional non-reporting	Intentional failure to report income Intentional non-reporting
Disclosure on financial statements and otherwise	No one is misled over the arrangement	No one is intentionally misled over the arrangement	Has intentionally misled creditors (may be a crime)	Has intentionally misled a court or the Internal Revenue Service

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OFFSHORE TRUST – TICKING TIME BOMBS



- Not reporting the trust and trust activities on a Form 3520, upon inception, Form 3520A each year thereafter, TD F 90-22.1 (FBAR) forms annually, and compliance with FATCA (Foreign Account Tax Compliance Act) reporting requirements.
- Not reporting trust income or not reporting income that goes into the trust.
- Being dishonest with any potential creditor, the IRS or any taxing authority with respect to the trust or its underlying operations.
- Not reporting the funding of the trust as a completed gift for gift tax purposes if the grantor has not retained a power with respect to the trust that would cause its funding to be an incomplete gift (such as the testamentary power to appoint trust assets) even if the trust will be subject to estate tax by reason of such power.
- Failure to provide that upon death, any marital deduction devise must override any discretionary power of the trustee or trust protectors to deprive the grantor's spouse of sole lifetime beneficiary/QTIP trust or outright payment rights.
- Getting the trust assets stolen by the trustee.
- Being dishonest with any court with respect to the trust or its operations.

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Do Domestic Asset Protection Trusts Work?

- Nevada, Alaska and Delaware have asset protection trust statutes. But the Full Faith and Credit Clause of the U.S. Constitution provides that a judgment issued by the court in one state will be respected by the court in other states.
- There are many questions regarding the effectiveness of domestic APTs. The case law is not yet fully developed on the question of whether the law of a foreign jurisdiction will apply for the determination of whether a creditor protection trust will shield trust assets from creditors of the grantor who is also a beneficiary.
 - *Hanson v. Denckla*, 357 U.S. 235 1958 – the law of the state where the trust administration occurs will be determinative.
 - *In re Portnoff*, 201 B.R. 685 (Bankr. S.D.N.Y. 1996) and *In re Brooks*, 217 B.R. 98 (Bankr. D. Conn. 1998) – assets placed in offshore APTs were not excluded from the debtor's Bankruptcy estates.

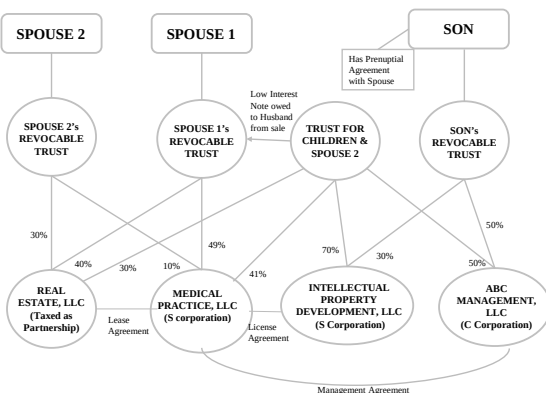
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Avoid Theft

- It is vital that clients utilize reputable trust companies and structures that assure that the assets they place under an APT will not be stolen.
- Sometimes two trust companies from different jurisdictions will serve as Co-Trustees under the trust agreement, or a lawyer or other fiduciary may serve so that two signatures and collusion would be required before monies held in an offshore account could ever be stolen.
- Some jurisdictions, like the Isle of Man and Jersey in the Channel Islands allow for the law of a co-trustee's jurisdiction to apply.
 - There are many well funded and reputable trust companies in the Isle of Man and Jersey willing to serve as managing Co-Trustee of APT formed under the laws of a more recognized APT jurisdiction.

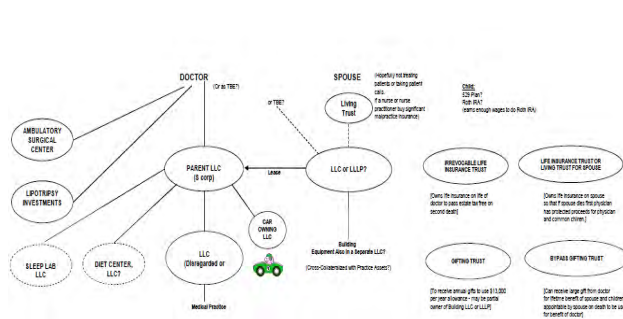
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Possible Family Logistics for a Successful Business and Estate Plan



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SINGLE PHYSICIAN OWNED MEDICAL PRACTICE



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[illegible]

Choices and Factors with Respect to Allocation & Payment of Medical Practice Income for the Practitioner

	PAYEE	CREDITOR PROTECTED IN FLORIDA?	Current Taxes/Expenses	Tax Cuts and Jobs Act
Owned by Physician or as Tenants by the Entities S CORPORATION PRACTICE ENTITY	Pension Plans	Yes	Costs for staff and to maintain plan – spouse on payroll to justify additional contribution. Highest tax – 39.6%. Nonqualified plans subject to 3.8% Medicare tax	Highest tax bracket is 37%. Annual Compensation Limit = \$275,000
	Children on the Payroll	Yes – if goes to Roth IRA in the name of the child.	Child in lower rate (lowest bracket – 10%) but 15.3% employment taxes apply.	Lowest bracket will be 10%. Standard Deduction = \$12,000 Single or \$24,000 MFJ
	Wages paid to Doctor	If Head of Household, Florida State 22 may apply – deposit directly into protected account.	15.3% employment taxes on first \$128,400, and then 2.9% over \$128,400 plus .9% tax on wages exceeding \$200,000 for single person and \$250,000 for married joint filers.	Repeat of additional 0.9% tax not mentioned in new Act
	Dividends to owner of entity.	Only if owner is protected – such as tenants by the entities or a family limited partnership owning the entity.	Not subject to payroll taxes – but can be recharacterized by IRS, and not subject to the 3.8% Medicare tax unless distributions represent income from passive sources.	Business Income Deduction of 20% of Qualified income Repeat of 3.8% Medicare tax not mentioned in new Act
	Spouse on payroll.	Yes, if spouse is safe.	15.3% employment taxes on first \$128,400, and then 2.9% over \$128,400 plus .9% tax on wages exceeding \$200,000 for single person and \$250,000 for married joint filers.	Repeat of additional 0.9% tax not mentioned in new Act
	Rent	Yes, if renting entity is protected. They protect PA assets if landlord has lien to enforce rent on long term lease.	6.8% sales tax Subject to the 3.8% Medicare tax single for taxpayer with MAGI over \$200,000 and MFJ taxpayers with MAGI over \$250,000.	Repeat of 3.8% Medicare tax not mentioned in new Act State sales tax is reduced to 5.8% on commercial real property rentals
Interest owed to related parties.	If related party is protected.	Deductible as interest – receiving party pay interest income	Interest expense not eliminated.	

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A Florida Physician's Guide to Wages and Wage Accounts

Florida law provides limitations upon the access that creditors may have to "wages" and "wage accounts" earned and funded by Florida residents.

Florida Statute Section 222.11 provides that wages earned by a head of household will generally be immune from creditors. Head of household has been defined to mean that the wage earner provides most of the support for themselves and other family members. For example, where the wage earner's spouse earns more than the wage earner, the wage earner may not qualify as "head of household" for creditor exemption purposes unless it can be shown that the actual wages earned by such person provide more than half of the support for at least one other family member.

Wages do not include dividends that are paid attributable to ownership of a professional practice, as opposed to being labeled as wages. Wages are subject to employment taxes.

A family member being supported should be a relative, or maybe a non-relative, who actually resides in the household with the wage earner.

Some courts have indicated that where the wage earner is a shareholder in a closely held corporation, and can thus manipulate between what would be received as wages and what would be received as dividends, then no wages may be protected. These unfortunate bankruptcy court decisions have not been appealed, and point out the importance of taking regular paychecks and having arm's-length employment agreements in place so that wages are paid periodically in a traditional manner to enhance the probability that they will be protected.

If wages are "creditor exempt," then it is important to maintain the creditor exempt status of the wages by depositing them into an account or other investments that will also be creditor exempt.



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A Florida Physician's Guide to Wages and Wage Accounts

Other creditor exempt assets that wages may be "converted to" can include paying down the mortgage on a protected home, investing the paycheck directly into a properly titled annuity contract or life insurance policy, funding a tenancy by the entirety account where the wage earner's spouse would not be used by the same creditor as the wage earner, or making deposits into a wage account.

Physicians who have monies or investments that are not creditor exempt might be well advised to spend down the non creditor exempt savings, while accumulating wages in a wage or other protected account.

The Florida statutes do not explicitly impose any ownership, titling, naming or other specific requirement for an account to qualify as a wage account. A "wage account" can be owned by the physician earner, or may be held as tenancy by the entireties by the physician earner and the physician's spouse.

Most, if not all, married physicians whose spouses do not practice with them will be better protected by depositing their wages into a tenancy by the entireties account so that the wages may be safeguarded for two reasons: (1) the wage exemption rules as described above will apply, and (2) to "invade" a tenancy by the entireties bank account, a creditor must have a judgment against both spouses or show that the transfer into the account was fraudulent transfer. If a wage check is a creditor exempt asset, then the deposit of the wage check directly into a protected tenancy by the entireties account should not be considered a fraudulent transfer.

Many physicians and bankers waste a lot of time opening "wage accounts" where tenancy by the entireties accounts or other vehicles are just as, if not more, protective and would qualify as wage accounts anyway.

The statute simply says that wages are protected for six months in the account so long as they can be traced, and thus are not confused with non-wage or older wage deposits that would not be protected.

It makes sense to have an account funded solely by wages, and to "empty the account" into other exempt investments, at least every six months, so that there would never have to be a tracing and proof analysis as to wage money protection.



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Estate Plan View
Solutions for Physicians

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Chart #1

Professional Practice Lien Structure Logistics

Practice Entity borrows money and distributes to Shareholder professionals

```
graph TD; Bank((Bank)) -- "1. Loans money" --> PPE((Professional Practice Entity)); PPE -- "1. Lien" --> Assets[Accounts Receivable  
Furniture & Equipment]; PPE -- "2. Pays bonus or dividend" --> DrA((Dr. A)); PPE -- "2. Pays bonus or dividend" --> DrB((Dr. B)); DrA -- "3. Pays taxes to IRS" --> IRS((IRS)); DrB -- "3. Pays taxes to IRS" --> IRS;
```

The diagram illustrates the flow of funds and assets in a Professional Practice Lien Structure. A Bank provides a loan to the Professional Practice Entity (PPE). The PPE then places a lien on its assets (Accounts Receivable, Furniture & Equipment). The PPE distributes funds as bonuses or dividends to the professional shareholders, Dr. A and Dr. B. Finally, both Dr. A and Dr. B pay taxes to the IRS.

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Chart #2

Professional Practice Lien Structure Logistics

Shareholders borrow money – Professional Entity provides credit enhancement by collateralizing assets and guaranteeing debt.

The diagram illustrates the flow of funds and collateral in a Professional Practice Lien Structure. A central oval labeled "Professional Practice Entity" is connected to a "Bank" (oval) on the left and two doctors, "Dr. A" and "Dr. B" (ovals), on the right. The "Bank" is connected to the "Professional Practice Entity" by a line labeled "1. Pledges AR, F&E as collateral". The "Professional Practice Entity" is connected to "Dr. A" and "Dr. B" by lines labeled "2. Loans money". "Dr. A" and "Dr. B" are each connected to an oval labeled "IRS" by lines labeled "3. Buys protected investments". The "IRS" oval is connected to a box labeled "Gets nothing". Below the "Professional Practice Entity" oval, the text "Accounts Receivable Furniture & Equipment" is listed, indicating the assets being collateralized.

```
graph LR; PPE([Professional Practice Entity]); Bank((Bank)); DrA((Dr. A)); DrB((Dr. B)); IRS([IRS]); Bank -- "1. Pledges AR, F&E as collateral" --> PPE; PPE -- "2. Loans money" --> DrA; PPE -- "2. Loans money" --> DrB; DrA -- "3. Buys protected investments" --> IRS; DrB -- "3. Buys protected investments" --> IRS; IRS --> Nothing[Gets nothing];
```

Accounts Receivable
Furniture & Equipment

1. Pledges AR, F&E as collateral

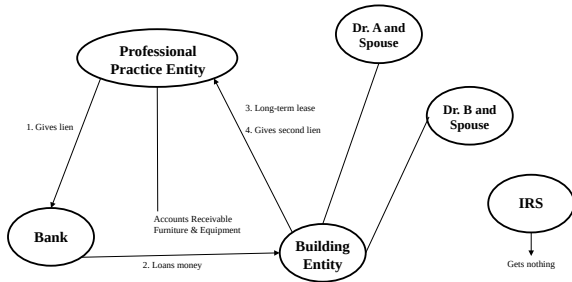
2. Loans money

3. Buys protected investments

Gets nothing

Chart #3 Professional Practice Lien Structure Logistics

Practice Entity assets and guarantee provided under loan to separate Building Entity – Practice and Entity enter into long-term lease.



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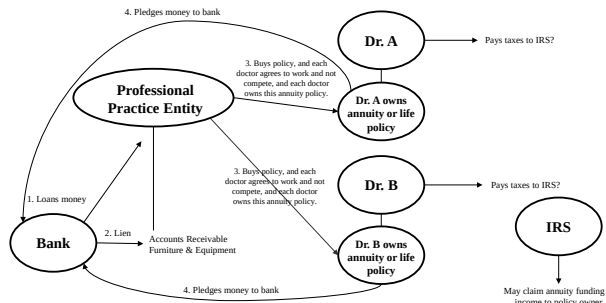


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Chart #4 Professional Practice Lien Structure Logistics

Practice borrows money to purchase deferred compensation annuity or life products purchased for professionals and subject to substantial risks of forfeiture.



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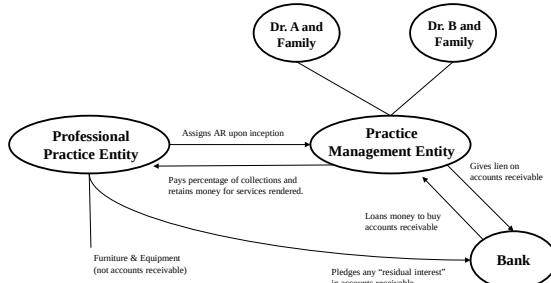


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Chart #5 Professional Practice Lien Structure Logistics

Entity for family members derives income from operating practice management company, which buys accounts receivable from practice on inception by borrowing from bank which receives lien on practice assets.



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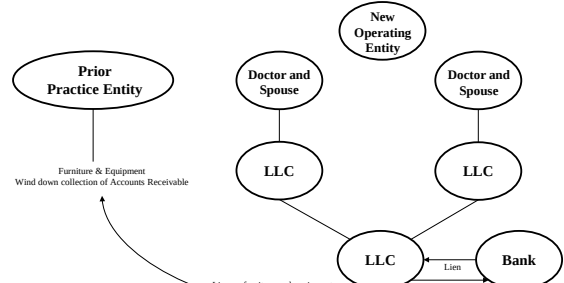


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Chart #6 Professional Practice Lien Structure Logistics

Historical Practice Entity simply holds furniture and equipment for lease to new entity held under partnership structure. New entity can borrow money to pay initial operating expenses. Loan secured by liens against new entity and old entity.



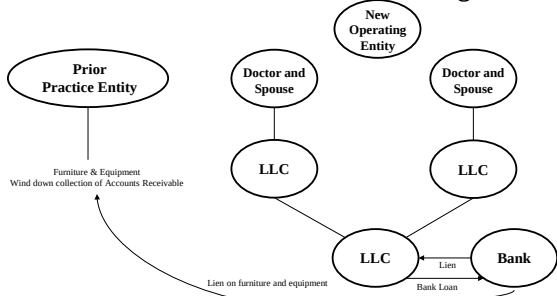
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Chart #7 Professional Practice Lien Structure Logistics



Practice entity gives lien to each doctor to secure his or her right to continued and deferred compensation during the operation of the practice and upon insolvency thereof. Then, if Dr. A gets sued for malpractice, Dr. B may have a valid lien upon his or her applicable portion of the accounts receivable, furniture, and equipment.

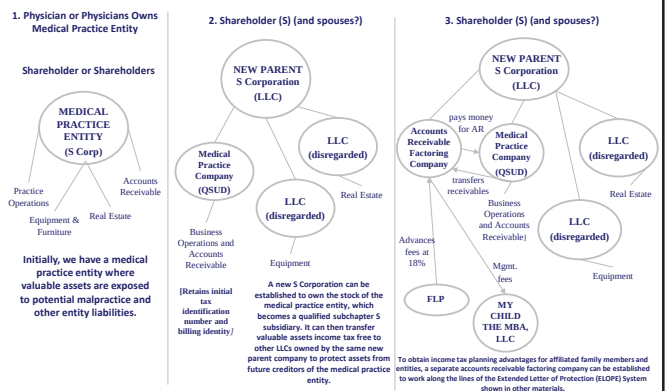
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NEW PARENT F REORGANIZATION SHOWING ACCOUNTS RECEIVABLE FACTORING ARRANGEMENT



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Buy/Sell Agreement Arrangements

There would be a purchase price tax basis for the other shareholders if the Trustee is appropriately characterized as an agent for the other shareholders.

4. The Optimal Solution: Use of a Related Partnership to Facilitate Purchase.

Because of the above concerns, oftentimes a separate limited partnership or limited liability company is established to own and facilitate the life insurance buy-out arrangement. This entity will be taxed as a partnership to avoid the transfer for value rules that would otherwise be problematic if there are more than 2 owners and shifts of ownership in the policy would apply if there was a redemption arrangement.

The transfer for value rules do not apply when there is a reapportionment of entitlement to the proceeds of life insurance for use in a Buy/Sell arrangement between partners under a federal tax partnership. The partnership may have an additional investment besides the life insurance to help assure that it is recognized as a partnership for federal income tax purposes.

If the separate partnership is purchasing the interest in the entity on behalf of its surviving partners, who are the surviving owners of the operating entity, then a creditor of the company would have no claim against the policy proceeds, and a creditor of an individual "partner" in the partnership entity might have a claim against the member or partnership interest of the individual partner, but this would not permit the creditor to reach into the partnership to have a claim against the policy proceeds if appropriate charging order protection applies.

The above strategy was blessed by the IRS in Private Letter Ruling 200747002, which discussed having term insurance held under an LLC taxed as a partnership to facilitate the Buy-Sell arrangement. Under this Private Letter Ruling the manager of the LLC was a trust company that was required to use monies contributed to the LLC to purchase and maintain life insurance to fund a separate cross-purchased Buy-Sell agreement between three related shareholders. It would be possible to have permanent life insurance and to have special allocations of entitlement as to policy values under an LLC/partnership agreement. See The Advanced Tax Planner Volume 5, Issue #1 May-June 2008 at www.zelllaw.com and the ING publication entitled Buy-Sell Planning Using Life Insurance/Buy-Sell Arrangements Using a General Partnership.

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Smart Estate Planning Considerations

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•A.) Important Personal Items

What should be done with important personal items, collectibles, and anything else that might be fought over upon your death?

Item/Collection	Sell	Leave to Specific Heir (If So, Who?)	Go Into a Lottery for Heirs	Donate	Other and Instructions

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•B.) Liquidity Plan

Question to Consider	YES	NO	Action to Take	Who to Delegate To
a.) Do you know how much cash would be needed to settle your estates and trusts and pay estate taxes?				
b.) Will banks or other lenders call loans in the event of your death?				
c.) Are you confident that there is enough life insurance or other assets cordoned off for the exclusive use of your beneficiaries in a way that creditors cannot reach them?				
d.) Do you know how much cash your beneficiaries need each month for the first 24 months after your death?				
e.) Will there be adequate cash and cash flow?				
f.) Have you factored in income taxes and other expenses that may occur upon death?				

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•C.) Minimum and Maximum Needs and Objectives

Question to Consider	YES	NO	Action to Take	Who to Delegate To
a.) Is there going to be enough to go around?				
b.) Will you need to plan for educational needs of young or other family members?				
c.) Do any of your family members have special needs?				
d.) Do you need to plan for special circumstances such as rehab, etc?				
e.) Do you want to prevent ostentatious use of wealth?				
i.) Maseratis				
ii.) Multiple mansions				
iii.) Jet airplane				
iv.) Huge boats/yachts				
v.) \$1,000 bottles of wine				
f.) What is the maximum annual expense amount that a family should spend in today's dollars?				

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•D.) Limits on Availability of Funds and Expenses

Question to Consider	YES	NO	Action to Take	Who to Delegate To
a.) Are you interested in the 4% Rule?				
b.) Are you interested in the \$20,000 a month rule?				
c.) Are you interested in the "must work and contribute to society" requirement?				
d.) Would you like to institute a rule of thumb to make sure the money lasts?				
e.) Would you like to institute a rule of thumb to not ruin the life journey?				
f.) Would you like to make some money available to provide business/entrepreneurial opportunities?				
g.) Would you like to appoint a dynamic advisor to assist in decision making, behaviors, and goal fostering of your beneficiaries?				

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•E.) Family Philosophies & Limitations on Investment Categories

Question to Consider	YES	NO	Action to Take	Who to Delegate To
a.) Do you have any overriding family philosophies that should be considered in deciding your estate or asset protection plan? <i>If yes, please describe:</i>				
b.) Do you have any investment limitations? <i>If yes, please describe:</i>				
c.) Are you confident in stocks of mutual funds?				
d.) Are you confident in bonds?				
e.) Are you confident in annuities?				
f.) Are you confident in life insurance?				
g.) Are you confident in real estate?				
h.) Never invest in the following:				
i.) Always invest in the following:				
j.) Recommended ratios and indicators:				

•Smart Estate Planning Considerations

•F.) Considering Unique Investments

Are the following options a plan that could be considered for your unique investments upon your death?

Action Plan	YES	NO	Action to Take	Who to Delegate To
a.) Authorize your trustee(s) to keep the investments				
b.) Request that your trustee(s) sell your investments				
c.) Appoint a committee to direct your trustee(s) on how to proceed				
d.) Do nothing – hope for the best!				

•Smart Estate Planning Considerations

•G.) Identity of Primary and Secondary Beneficiaries

Question to Consider	YES	NO	Action to Take	Who to Delegate To
a.) Would you like to appoint your spouse as a beneficiary?				
b.) Would you like to appoint your child(ren) as a beneficiary?				
c.) Is there someone else that you would like to appoint as a beneficiary?				
d.) Sharing an inheritance can be very divisive. Would you like to leave your estate to more than one person?				
e.) Would you like to set aside something for your parents?				
f.) Would you like to set aside something for your siblings?				
g.) Would you like to set aside something for your in-laws?				
h.) Do you have any concerns about irresponsible beneficiaries?				
i.) Who will have a Power of Appointment/Disappointment?				
j.) Should children be able to appoint assets directly to irresponsible grandchildren?				
k.) When clients demand outright disposition provisions, consider adding "unless the Trustee determines that the beneficiary would be better served by extending the duration of the trust to age 122."				

•Smart Estate Planning Considerations

•H.) Trusteeship Coordination

Question to Consider	YES	NO	Action to Take	Who to Delegate To
a.) Educate the client that the safest Trustee is a trust company				
b.) If client refuses trust company, require chosen individual trustee to choose a trust company "when the time comes."				
c.) If client says no to (a) and (b) above, suggest that any beneficiary should be able to require addition of a trust				
d.) Review estate plan with trust company during drafting and design stage				

•Smart Estate Planning Considerations

•I.) Avoiding Litigation

Item to Consider	YES	NO	Action to Take	Who to Delegate To
a.) Trusteeship for portion that may be under partial or complete control of beneficiary				
b.) Trusteeship for portion that may be absolutely protected for beneficiary				
c.) Avoiding state law limitations on what can be done				
d.) Beneficiary initiated court changes				
e.) Avoiding loss to litigation				
f.) Avoiding loss to divorce				
g.) Avoiding loss to creditors of beneficiary				
h.) King Solomon and trust protector considerations				

•Smart Estate Planning Considerations

•J.) Considerations for Business Owners

Are the following options a plan that could be considered for your business when you are no longer able to work?

Action Plan	YES	NO	Action to Take	Who to Delegate To
a.) Sell the business to key family members				
b.) Equally divide the business among family members				
c.) Allow the business to be sold to key employees				
d.) Allow the business to be sold to any interested party				
e.) Donate the business to a foundation				
f.) Obtain business advisors that the trustee can rely upon				

•Smart Estate Planning Considerations

•K.) Buy-Sell Agreement Needs and Implementation

Question to Consider	YES	NO	Action to Take	Who to Delegate To
a.) Do you want a Buy-Sell Agreement?				
b.) Should your Buy-Sell Agreement be funded with life insurance?				
c.) Should there be a formula for the price of your Buy-Sell Agreement?				
d.) Should there be financing for your Buy-Sell Agreement or must the parties involved pay cash?				
e.) Shouldn't the life insurance be paid to an escrow agent/trust company to assure proper administration?				
f.) Use trustee buy/sell "LLC/Partnership" cross purchase arrangement to insulate insurance proceeds from creditors				
g.) Other Considerations: <i>(please describe below)</i>				

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SELF EVALUATION

Protecting Assets and Minimizing Legal Risk for Medical Professionals

True/False

1. Physicians should keep their business and personal assets in the same entity for simplicity.
2. Going without malpractice insurance can actually increase your liability exposure.
3. Spouses or significant others should be informed of where all critical planning documents are stored.
4. Using family and friends for business roles is generally recommended for trust and savings.
5. A business partner should be treated like a spouse in terms of care and selection.
6. Business growth without profitability can be just as harmful as business failure.
7. Having a good corporate and personal umbrella insurance policy is unnecessary if you already have malpractice insurance.

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

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Recent Advances in Preventive Cardiology and Lifestyle Medicine

Recent Advances in Preventive Cardiology and Lifestyle Medicine

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OUWB School of Medicine
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No disclosures

Lessons Learned Over The Past 50 Years: Some Seminal Reports In Preventive Cardiology That Got My Attention...*

1975 2000 2025

Physical Activity /Fitness Dietary Choices Cigarette Smoking Psychological Considerations

* Plus cardioprotective medications and genetics

Critical Question: Do You Have Coronary Artery Disease (CAD) ?

Cleveland Clinic studies (using IVUS) show that ~85% of individuals in the U.S. over 50 have atherosclerotic CAD.* Recently, using coronary computed tomography angiography (CCTA) on >25,000 people in Sweden aged 50 to 64 without diagnosed CAD, nearly 50% had silent coronary atherosclerosis.+ For me, the question isn't whether middle-aged and older adults have CAD—they probably do. It's how to **PREVENT** acute catastrophic cardiac events.

Tuzcu EM, et al. Circulation 2003.*
Bergstrom G et al. Circulation 2021 +

The Devastation & Incidence of Sudden Cardiac Death*

Tim Russert (Age 58) James Gandolfini (Age 51)

Members of the population cohort among whom sudden cardiac death is most common:
Men aged 60 ± 5 years

* ~356,000 sudden cardiac deaths/year; nearly 1000 Americans/day; ~ 90% fatal

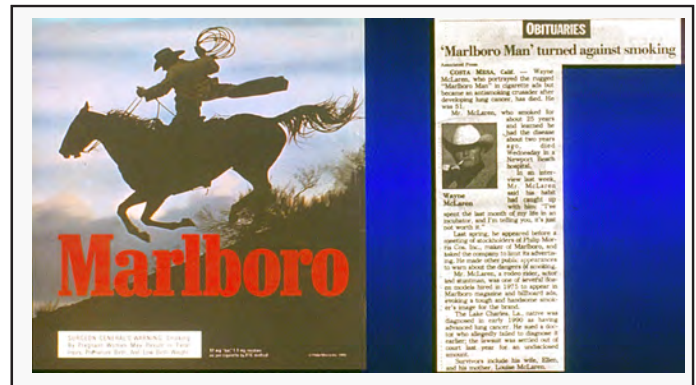
The First-Line Strategy to Prevent Heart Disease

Mozaffarian, Wilson & Kannel, Circulation 2008

Outline (6 Topics)

Topic 1

- ◆ Hazards of Cigarette Smoking and Secondhand Smoke
- ◆ Cardioprotective Medications: HR/BP Goals
- ◆ Evidence-based Dietary Strategies
- ◆ Fitness/Physical Activity: Benefits, Risks, and Prescriptive Considerations
- ◆ Psychosocial Considerations
- ◆ Genetics versus Lifestyle/ Healthy Lifestyle Factors and Life Expectancy



Papers

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

Richard Doll, Richard Peto, Jillian Boreham, Isabelle Sutherland

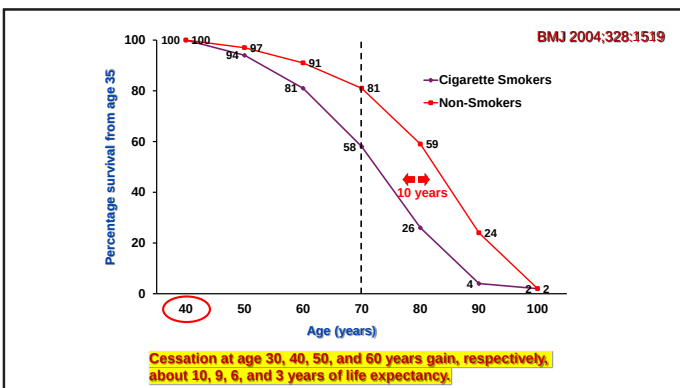
Abstract
During the 19th century much tobacco was smoked in pipes or as cigars and little was smoked as cigarettes, but during the first few decades of the 20th century the consumption of manufactured cigarettes increased greatly. This led eventually to a rapid increase in male lung cancer, particularly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

1951 prospective study
This discovery stimulated much further research into the effects of smoking (not only on lung cancer but also on many other diseases), including a UK prospective study of smoking and death among British doctors that began in 1951 and has now continued for 50 years.¹⁻¹¹ The decision that this study would be conducted

Introduction
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1951 prospective study
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BMJ 2004;328:1519



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

Prabhat Jha, et al. *Journal of the American Medical Association* 2006;295:1900-1906

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

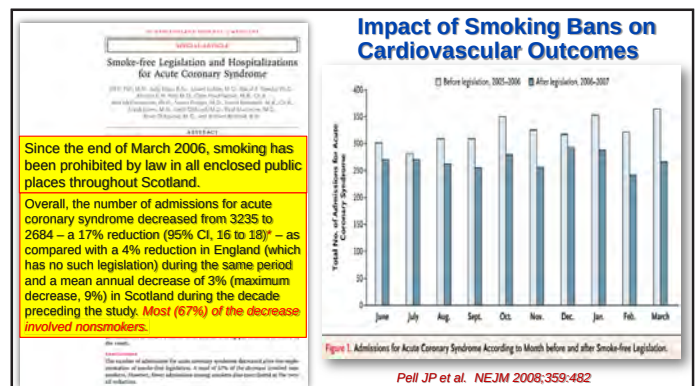
Cessation before the age of 40 years reduced the risk of death associated with continued smoking by about 90%.

Prabhat Jha et al. NEJM 2013;368:341

Cardiovascular Effects of Secondhand Smoke

The effects of even brief periods of SHS are, on average, 80%-90% as deleterious as those from chronic active smoking. SHS increases the risk of coronary heart disease and cardiac events by ~ 30%.

Circulation 2005;111:2684-2698

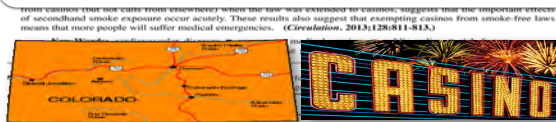


Influence of Secondhand Smoke on the Triggering of Acute Cardiac Events

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

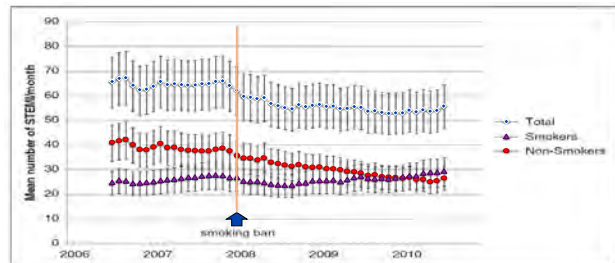
Stanton A. Glantz, PhD; Erin Gibbs, BS

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



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

Smoking Ban in Public Areas: Bremen Germany



The reduction in STEMI may be explained by the protection of non-smokers from SHS and the absence of such an effect in smokers by the dominant effect of active smoking.

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

The Civil Liberty of Smoking Cigarettes

David P. Tuckman, PhD
University of North Carolina
at Chapel Hill, NC 27515
(919) 919-1111

Many smokers argue that others should not have the right to regulate their behavior. *Clearly, innocent nonsmoking bystanders are adversely affected by this toxic inhalation. These data provide compelling rationale for limiting exposure of secondhand smoke to all affected, including children, spouses, friends, and co-workers.*

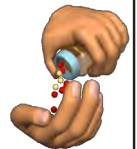
Secondhand smoke is a complex mixture of thousands of chemicals, many of which are known to be carcinogenic. It is a leading cause of lung cancer and heart disease in non-smokers. The World Health Organization estimates that 1.1 million people die each year from diseases caused by secondhand smoke.

Crotty LE et al. Chest 2015 July

Outline (6 Topics)

Topic 2

- ◆ Hazards of Cigarette Smoking and Secondhand Smoke
- ◆ Cardioprotective Medications: HR/BP Goals
- ◆ Evidence-based Dietary Strategies
- ◆ Fitness/Physical Activity: Benefits, Risks, and Prescriptive Considerations
- ◆ Psychosocial Considerations
- ◆ Genetics versus Lifestyle/ Healthy Lifestyle Factors and Life Expectancy



Cardioprotective Medications



Aspirin



Statin
(Cholesterol Lowering)



Beta-blockers
(Post MI,
LV dysfunction)



ACE-I or ARB
(EF ≤ 40%,
DM, HTN)

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

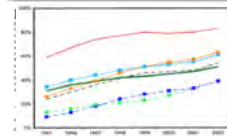
Health Services and Outcomes Research

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

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

In multivariate analysis, nonadherence remained significantly associated with increased all-cause mortality risk (50% - 85%) for β blockers, ACE inhibitors, and statins.

Ho PM et al. Am Heart J 2008



FROM THE EDITOR



Extreme Hypercholesterolemia = Malignant Atherosclerosis



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

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

HEALTH AND BEHAVIOR

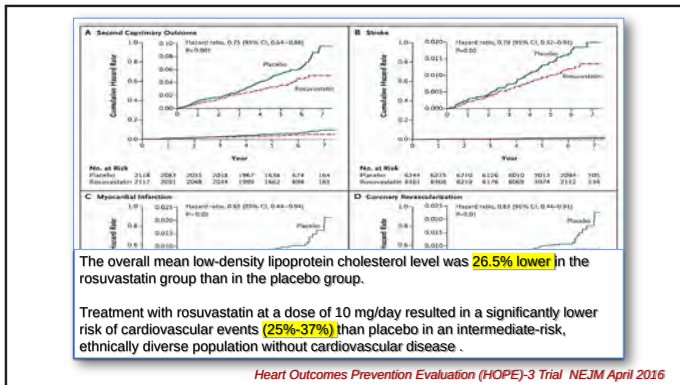
Cholesterol and clogged arteries



Cholesterol-lowering drugs to play larger role in heart health

TC ↓	LDL ↓	HDL ↑
22% - 47%	27% - 60%	7%

"Rule of 5 and 7" for dosing statins. Each doubling of the statin dose results in an additional 5%-7% reduction in the LDL-cholesterol.



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

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



Tenormin
Lopressor
Toprol-XL
Inderal

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

Cucherat M. Eur Heart J 2007;28:3012

Resting Heart Rate: Lower is Better*

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



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

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

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

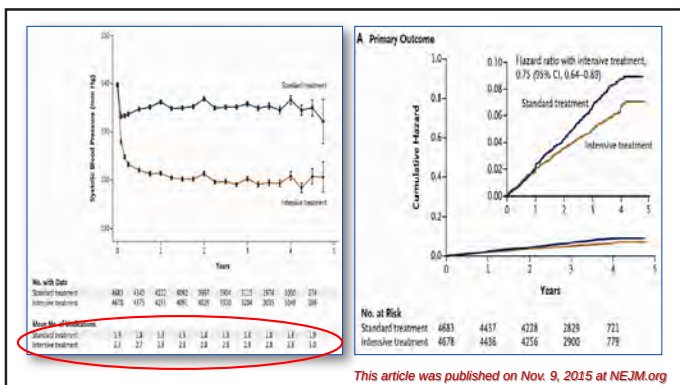
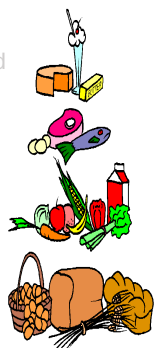
The intervention was stopped early due to a significantly lower rate of the primary composite outcome in the intensive-treatment group than in the standard-treatment group (1.65% per year vs 2.19% per year; **hazard ratio with intensive treatment, 0.75; 95% CI, 0.64 to 0.89; p<0.001**).

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

Outline (6 Topics)

Topic 3

- ◆ Hazards of Cigarette Smoking and Secondhand Smoke
- ◆ Cardioprotective Medications: HR/BP Goals
- ◆ Evidence-based Dietary Strategies
- ◆ Fitness/Physical Activity: Benefits, Risks, and Prescriptive Considerations
- ◆ Psychosocial Considerations
- ◆ Genetics versus Lifestyle/ Healthy Lifestyle Factors and Life Expectancy



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

William C. Roberts, M.D.

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

Is a red meat bad for you? In a word, yes. In this issue, Pan et al describe the outcomes from more than 37,000 men from the Harvard Health Professionals

cohort study that were fed an HPLC diet had

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

we exclude, so substituting healthier foods for red meat provides a double benefit to our health.

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

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

diets) may accelerate atherosclerosis through mechanisms that are unrelated to the classic cardiovascular risk factors. Meat that were fed an HPLC diet had

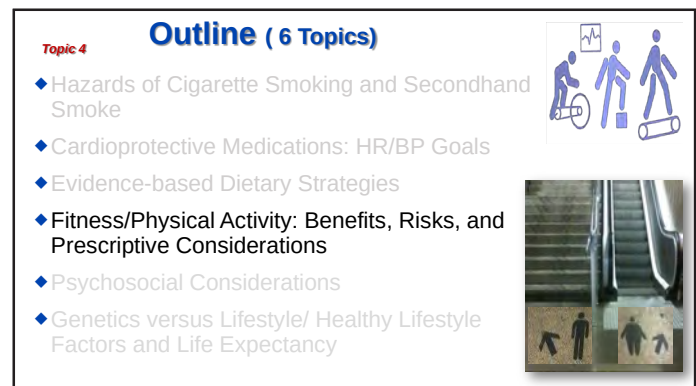
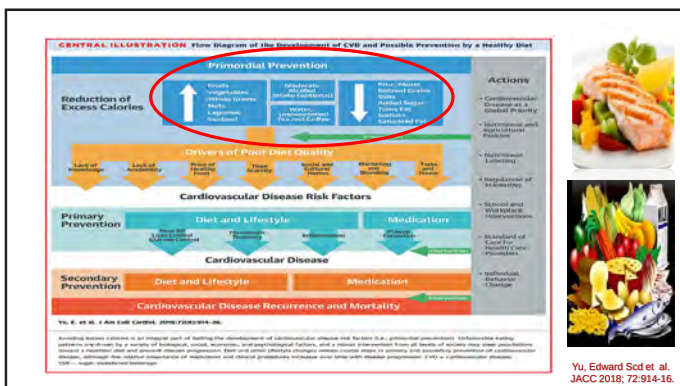
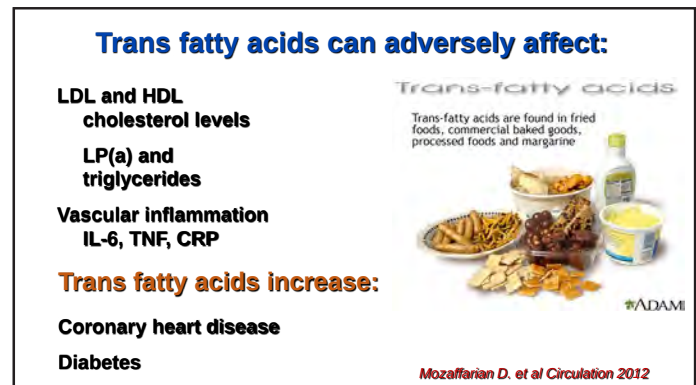
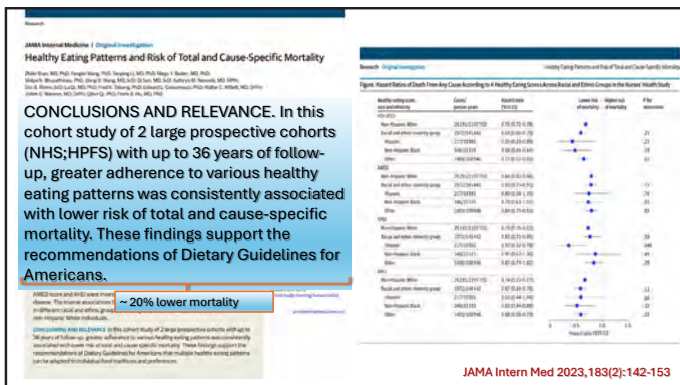
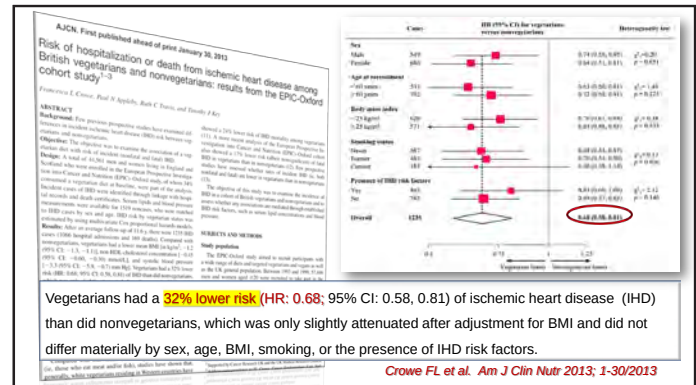
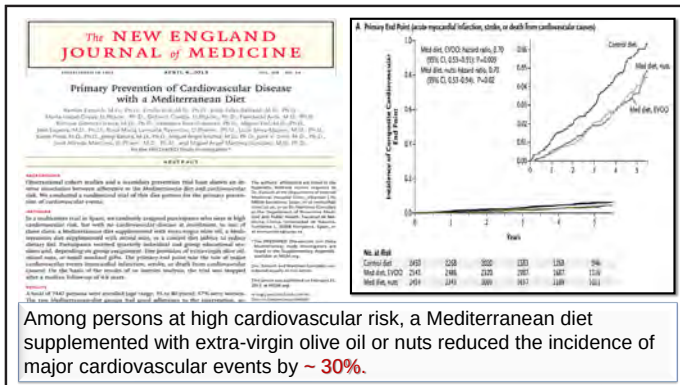
• high in "good fats" (monounsaturated fats, whole grains, legumes, and soy products in their natural forms);

• low in "bad carbs" (simple and refined carbohydrates, such as sugar, high-fructose corn syrup, and white flour);

• high in "good fats" (omega-3 fatty acids found in fish oil, flax oil, and plankton-based oils);

• low in "bad fats" (trans fats, saturated fats, and hydrogenated fats).

Arch Intern Med 2012;172(7):563



Walking: Miraculous Benefits ?*

Thomas Jefferson, the 3rd U.S. president, who lived to be 83 at a time when average life expectancy was about 40 years, firmly believed that physical exercise ensured not only bodily health, but mental health as well. Walking was his preferred activity, purportedly ~ 4 miles per day.

* Early case report



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

METHODS

707 nonsmoking retired men 61 to 81 years of age; distance walked/day

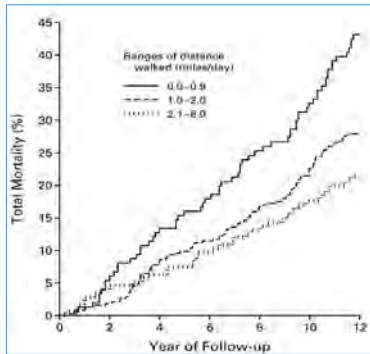
RESULTS

12-year follow-up, 208 deaths; mortality rate among the men who walked < 1 mile/day was nearly twice that among those who walked > 2 miles/day

CONCLUSIONS

Regular walking is associated with a lower overall mortality rate in older, physically capable men

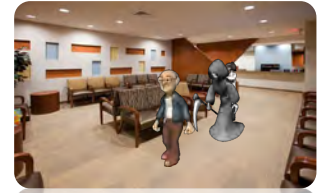
*Hakim AA et al. NEJM 1998;338:94



Hakim AA et al. NEJM 1998;338:94

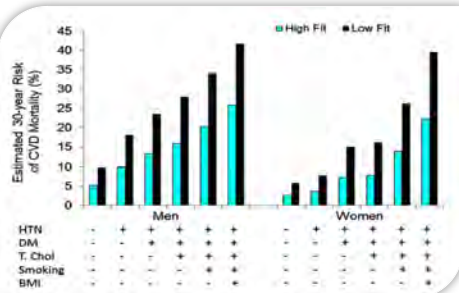
Reduced Walking Speed: An Underappreciated Vital Sign ?

At a minimum, routinely assess physical activity and simply observe your patient's gait speed the next time he/she leaves your office. A tortoise-like pace (**slower than 2 miles per hour**) may provide the most telling "vital sign" of your physical exam that day. **Why > 3mph pace is highly protective ?**



Stenaway FF et al. BMJ 2011 ; Stukenski S, et al. JAMA 2011

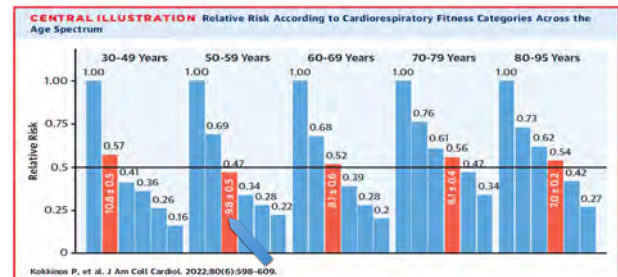
Regardless of the Risk Factor Profile, Low Fit Men and Women have ~ 2x the Mortality



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

Cardiorespiratory Fitness and Mortality Risk Across the Spectra of Age, Race, and Sex (n=750,302) The ETHOS Study

Kokkinos, P., et al. J Am Coll Cardiol 2022; 80 (6):598-609



Kokkinos P, et al. J Am Coll Cardiol. 2022;80(6):598-609.

Health Update:
Exercise Can Kill
You
Details at 11



MARATHON DISASTER: 3 deaths within 5 blocks and 15 minutes of each other

BY KORNIE WILKINS
FREE PRESS STAFF WRITER
Beverly, MA. Three men collapsed and died on Sunday while running in the 37th DPF/Eliot



Cardiac Arrest During Long-Distance Running Races*

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



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

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

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

- > 9 million participants over 30 years
- 135 sudden cardiac deaths (SCDs, 86% men; 13 survivors) – **4 fatalities per year**; incidence of 1.74/100,000 participants versus 1.01/100,000 for marathon running
- Women ~ 15% of the study population, and their incidence of SCD was 3.5 – fold less than men
- Most SCDs occurred during the swim (n=90; 67%) followed by the bicycle, run, and post-race periods, 22, 15, and 8 respectively
- Many of the SCDs (38%) were competing in their first triathlon
- Autopsies performed on 61 of the 135 victims, revealed that 27 (44%) had atherosclerotic CAD and/or cardiomyopathy

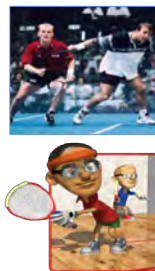


Local deaths
Mark Jahnke: CFO
passionate about service
stood up for his beliefs

Mark Jahnke, 55, died of a heart attack Wednesday while playing racquetball at a local club. He was 55.

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Northcote RJ, Flannigan C, Ballantyne D. Sudden death and vigorous exercise – a study of 60 deaths associated with squash. Br. Heart J 1986;55:198-203

METRO FINAL
City's first snow
Detroit Free Press
DIGGING OUT
A winter's worth in one day



"At least 8 people died Wednesday in the Detroit area after snow-related exertion. In Wayne County alone, 17 heart attack deaths were attributed to exertion since the snow began Tuesday. Most of the victims were older men clearing their driveways and walks."

Cardiac Demands of Heavy Snow Shoveling

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

JAMA 1995;273:880

Acute Myocardial Infarction After Manual or Automated Snow Removal

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

AJC 2001;87:1282

Sudden Cardiac Death After Manual or Automated Snow Removal

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

AJC 2003;92:833



Cardiorespiratory Measurements During Treadmill Testing and Snow Shoveling

$$12 \text{ lifts/min} \times 16 \text{ lbs/lift} \times 10 \text{ min} = 1920 \text{ lbs}$$


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

Cardiovascular Clinical Data in the 5 Sedentary Men*

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

*Persons not participating in a regular exercise program or meeting the minimal physical activity recommendations from the U.S. Surgeon General's report.¹²
AP = angina pectoris; BMI = body mass index; C = cholesterol; CP = chest pain; CS = cigarette smoker; ESI = electric snow thrower; PTCA = percutaneous transluminal coronary angioplasty; SH = systemic hypertension.

AJC 2001;87:1282

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



Sudden Cardiac Death After Manual or Automated Snow Removal

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

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

(Am J Cardiol 2003;92:000)

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

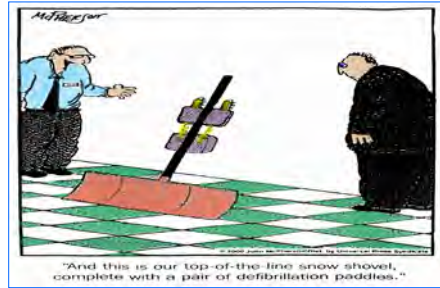
Time Frame	Exertion-Related SCD	Total SCD (%)
Wk before storm	2*	73 (2.7)
Wk of storm	24*	102 (23.5)
Wk after storm	17*	96 (17.7)

* Snow removal related deaths: *1 of 2; *02 of 4; *113 of 17.

snowfall, were obtained from the National Weather Service database.

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

How I Approach Patients who Choose to Disregard My Advice to Avoid Snow Shoveling*



* Franklin BA, et al Mayo Clin Proc 2025

Aerobic Exercise Prescription

Variable	Recommendation
Mode	Aerobic: Rhythmical & continuous in nature
Intensity	Increase in HR to ~ 70-85 % of HRmax Perceived exertion of 11-13 (Fairly Light-Somewhat Hard)
Frequency	"Only on the days you eat " Dr. Joseph Albert
Duration	~ 40 min of continuous or intermittent aerobic activity, accumulated over the day
Progression	The initial training intensity goal is 3 METs or higher ; slowly progress to higher intensities to achieve good fitness, provided you remain asymptomatic



Daily steps ? Initial, 2800/day;
Optimal, 7,000-8,000/day



What should be your initial Training Intensity Goal ? Exercising above 3 METs

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

Corresponding treadmill workloads include . . .

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



ACC.21

ESC European Society of Cardiology (ESC) 2013

RESEARCH LETTER Physical Activity

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

Barry A. Franklin^{1,2}, Ross Arena³, Leonard A. Kaminsky⁴, James E. Peterman⁵, Peter Kokkonen⁶, and Jonathan Myers⁷

¹Barry A. Franklin, PhD, is a professor of Preventive Cardiology, University of Michigan, Ann Arbor, MI, USA. ²Ross Arena, PhD, is an assistant professor of Preventive Cardiology, University of Michigan, Ann Arbor, MI, USA. ³Leonard A. Kaminsky, PhD, is an assistant professor of Preventive Cardiology, University of Michigan, Ann Arbor, MI, USA. ⁴James E. Peterman, PhD, is an assistant professor of Preventive Cardiology, University of Michigan, Ann Arbor, MI, USA. ⁵Peter Kokkonen, PhD, is an assistant professor of Preventive Cardiology, University of Michigan, Ann Arbor, MI, USA. ⁶Jonathan Myers, PhD, is an assistant professor of Preventive Cardiology, University of Michigan, Ann Arbor, MI, USA.

Abstract: We examined the relationship between physical activity (PA) and cardiovascular disease (CVD) risk factors in a large, multi-center, prospective study. We found that individuals who engaged in regular PA had a significantly lower risk of CVD compared to those who did not. This relationship was stronger in individuals who engaged in higher intensity PA. Our findings suggest that individuals should aim for higher intensity PA to maximize the cardioprotective benefits of exercise.

Achieving "Good" Fitness for Age and Sex



ESC European Society of Cardiology (ESC) 2013

RESEARCH LETTER Physical Activity

Barry A. Franklin^{1,2}, Ross Arena³, Leonard A. Kaminsky⁴, James E. Peterman⁵, Peter Kokkonen⁶, and Jonathan Myers⁷

ULTIMATE GOAL EXERCISE TRAINING INTENSITIES FOR MEN AND WOMEN TO ACHIEVE 'GOOD FITNESS'+

	Age Groups				
	30-39	40-49	50-59	60-69	70-79
Men Training METs	8-10	7-9	6-8	5-7	5-6
Women Training METs	6-8	5-7	5-6	4-5	3.5-4.5

+ For men and women > 80 years of age, the training intensity goals are 4 and 3 METs, respectively.

Heart Rate Index—An Alternative Exercise-Based Equation for Estimating Peak VO₂

John B. Wicks, PhD, David B. Clark, PhD, Barry A. Franklin, PhD

Background: The Heart Rate Index (HRI) is a simple, exercise-based equation for estimating peak oxygen consumption (VO₂max). The HRI is calculated as the ratio of heart rate to age, and has been shown to be a strong predictor of VO₂max in healthy individuals. The HRI is a simple, exercise-based equation for estimating peak oxygen consumption (VO₂max). The HRI is calculated as the ratio of heart rate to age, and has been shown to be a strong predictor of VO₂max in healthy individuals.

Key Points: The HRI is a simple, exercise-based equation for estimating peak oxygen consumption (VO₂max). The HRI is calculated as the ratio of heart rate to age, and has been shown to be a strong predictor of VO₂max in healthy individuals. The HRI is a simple, exercise-based equation for estimating peak oxygen consumption (VO₂max). The HRI is calculated as the ratio of heart rate to age, and has been shown to be a strong predictor of VO₂max in healthy individuals.

"Is there a simple, accurate method to estimate METs during submaximal and maximal physical activity?"

Published online, February 2025

Applying The HR Index To Estimate Energy Expenditure During Physical Activity*

FORMULA:
METs = 6 HR Index - 5

HR Index = Activity HR / Rest HR

Example:
Recreational tennis
HR rest = 70 beats/min
HR activity = 140 beats/min

$$(6 \times 2) - 5 = 7 \text{ METs}$$

7 METs



* Wicks JR, et al J Cardio Pulm Rehab 2025 (in press)

Outline (6 Topics)

Topic 5

- ◆ Hazards of Cigarette Smoking and Secondhand Smoke
- ◆ Cardioprotective Medications: HR/BP Goals
- ◆ Evidence-based Dietary Strategies
- ◆ Fitness/Physical Activity: Benefits, Risks, and Prescriptive Considerations
- ◆ Psychosocial Considerations
- ◆ Genetics versus Lifestyle/ Healthy Lifestyle Factors and Life Expectancy

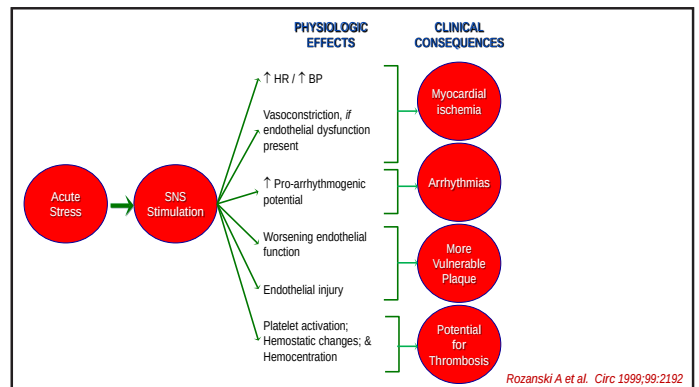
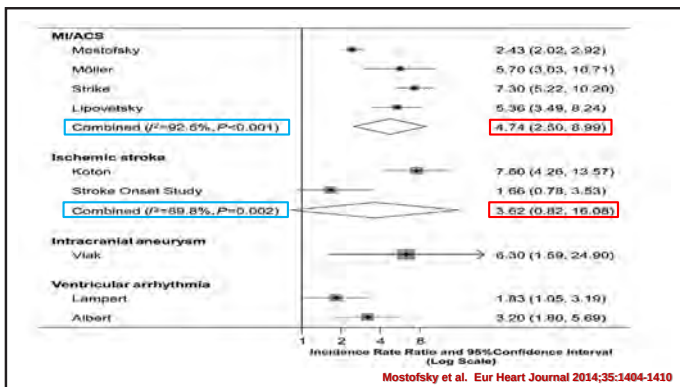


We performed a systematic review of studies evaluating whether outbursts of anger are associated with the short-term risk of heart attacks, strokes, and disturbances in cardiac rhythm that occur in everyday life.

Compared with other times, there was a higher rate of cardiovascular events (**Incidence Rate Ratio, 3.6-4.7 fold increase**) in the 2 hours following outbursts of anger.



Mostofsky et al. Eur Heart Journal 2014;35:1404-1410



The New England Journal of Medicine
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 Volume 334 FEBRUARY 15, 1996 Number 7

SUDDEN CARDIAC DEATH TRIGGERED BY AN EARTHQUAKE
 JONATHAN LEOR, M.D., W. KENNETH POOLE, Ph.D., AND ROBERT A. KLOFFER, M.D., Ph.D.

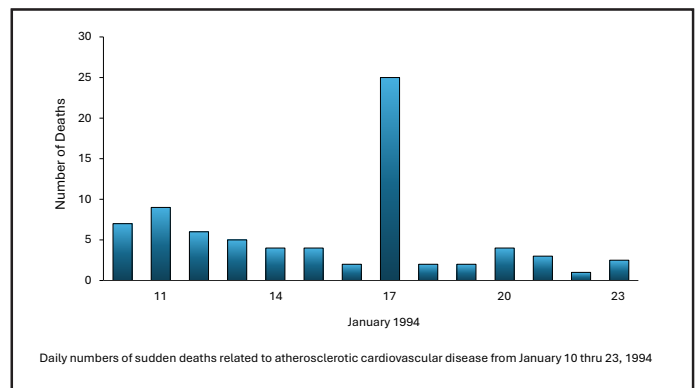
Abstract Background. The earthquake that struck the Los Angeles area at 4:31 a.m. on January 17, 1994, was one of the strongest earthquakes ever recorded in a major city in North America. Once the life-threatening situation was over, the Northridge earthquake, so called because its epicenter was near Northridge, California, just north of Los Angeles, provided investigators an unusual opportunity to examine the relation between emotional stress and sudden cardiac death.

Methods. We reviewed the records of the Department of Coroner of Los Angeles County for the week before the earthquake, the day of the earthquake, the six days after the earthquake, and corresponding control periods in 1991, 1992, and 1993.

Results. On the day of the earthquake, there was a sharp increase in the number of sudden deaths from cardiac causes that were related to atherosclerotic cardiovascular disease, from a daily average ($\pm$ SD) of 4.6 ± 2.1 in the preceding week to 24 on the day of the earthquake ($z = 4.41$, $P < 0.001$). Sixteen victims of sudden death either died or had premonitory symptoms, usually chest pain, within the first hour after the initial tremor. Only three sudden deaths occurred during or immediately after unusual physical exertion. During the six days after the earthquake, the number of sudden deaths declined to below the base-line value, to an average of 2.7 ± 1.2 per day.

Conclusions. The Northridge earthquake was a significant trigger of sudden death due to cardiac causes, independently of physical exertion. This finding, along with the unusually low incidence of such deaths in the week after the earthquake, suggests that emotional stress may precipitate cardiac events in people who are predisposed to such events. (N Engl J Med 1996;334:413-9.)

©1996, Massachusetts Medical Society.



NEJM 2008;358:475-83

Cardiovascular Events during World Cup Soccer

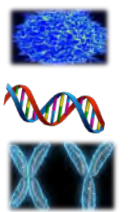
Abstract Cardiovascular events occurring in patients in the general Munich area were prospectively assessed by emergency physicians during the World Cup. We compared these events with those that occurred during the control period (July 3 to June 9 and July 10 to July 15, 2006, and May 1 to July 15, 2006, and 2006).

Results. Cardiovascular events were assessed in 4200 patients. The day of matches, from 10 a.m. to 11 p.m., was the time of highest incidence of cardiovascular events. During the control period (July 3 to June 9, 2006, and July 10 to July 15, 2006), the incidence was 1.0 per 1000 patients per day. During the World Cup period (May 1 to July 15, 2006), the incidence was 3.26 per 1000 patients per day ($P < 0.001$). For men, the incidence was 3.26 times that during the control period ($P < 0.001$), and for women, it was 1.82 times that during the control period ($P < 0.001$). Viewing a stressful soccer match more than doubles the risk of an acute cardiac event.

Outline (6 Topics)

Topic 6

- ◆ Hazards of Cigarette Smoking and Secondhand Smoke
- ◆ Cardioprotective Medications: HR/BP Goals
- ◆ Evidence-based Dietary Strategies
- ◆ Fitness/Physical Activity: Benefits, Risks, and Prescriptive Considerations
- ◆ Psychosocial Considerations
- ◆ Genetics versus Lifestyle/ Healthy Lifestyle Factors and Life Expectancy



Conclusions



Last 3 slides...

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

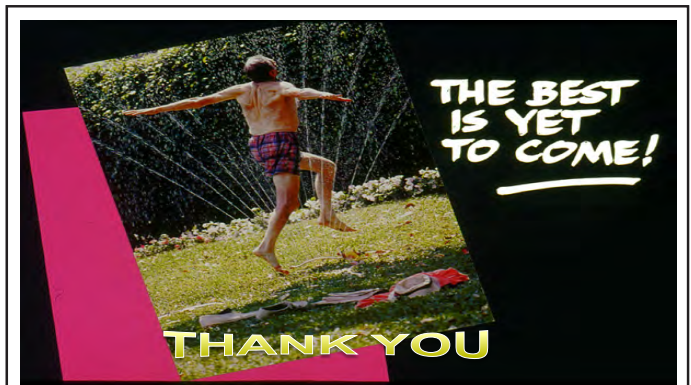


Health care will soon account for \$1 out of every \$5 spent in the U.S. If these trends continue, health care will soon become unaffordable, unless we find ways to implement effective preventive interventions.

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

In Closing--Beyond Acute and Palliative Care...

- Contemporary healthcare providers need to become champions of achieving healthy lifestyle overhauls in the patients we serve---well beyond the acute and palliative care provided in our emergency centers, surgical suites, cath labs, hospital rooms, and physician offices. The "paradigm shift" needs to move from not only helping patients when they are ill, injured, or sick, to "helping patients help themselves (24/7) ." Moreover, patients need to assume greater self-responsibility for their health outcomes.*



SELF EVALUATION

Recent Advances in Preventive Cardiology and Lifestyle Medicine

1. A landmark study showed that ~____% of individuals in the U.S. over 50 have atherosclerotic coronary artery disease.
 - a. 55
 - b. 65
 - c. 75
 - d. 85
 - e. None of the above
2. According to 2 landmark studies, individuals who continued cigarette smoking lost, on average, _____ years of life expectancy.
 - a. 7 to 9
 - b. 10 to 12
 - c. 13 to 15
 - d. 16.5
 - e. None of the above
3. T/F - According to a widely cited study in cardiac patients, each 10 beat reduction in resting heart rate is estimated to reduce the relative risk of cardiac death by about 15%.
4. Trans fatty acids, commonly found in fried foods, commercial baked goods, some processed foods and margarines can adversely affect...
 - a. LDL and HDL cholesterol levels
 - b. LP (a)
 - c. Triglycerides
 - d. Indices of vascular inflammation (e.g., C-reactive protein)
 - e. All of the above
5. Which of the following are not associated with the increased cardiac demands and simultaneous decreased coronary blood flow associated with snow shoveling?
 - a. Leg exertion
 - b. Upright posture
 - c. Superimposed static exertion
 - d. Valsalva maneuver
 - e. Inhalation of and exposure to cold air
6. T/F - According to a landmark study, men and women in the U.S. with 5 of 5 low-risk lifestyle factors gained 8 – 10 additional years.

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

FACULTY

Bert Orlov, MBA

Bert Orlov, MBA, of New York, New York, is a Managing Director of Eisner Amper Healthcare Consulting Group with 25 years of experience as a management consultant in the healthcare industry. Mr. Orlov earned his MBA from Yale School of Management and specializes in strategy, transactions, operations and project management for physician groups and hospital systems, as well as not-for-profits. Mr. Orlov has been published in many books and articles including the Beckers Hospital Review. He also collaborates with the University of Pennsylvania on strategy for primary care practices.

You may contact Mr. Orlov with your questions or comments at 212-324-2297, or by email at [bert.orlov@eisneramper.com](mailto:orlov@eisneramper.com).

THE
2026-27

Medical-Dental-Legal
UPDATE

Optimizing Revenue Cycle Management

Bert Orlov, MBA



Strategic Context

- Improvement in Revenue Cycle Performance drives up Practice value and better positions the Practice for effective leverage of any strategy – independent, partnered, or acquired

Strengths	Opportunities
Weaknesses	Threats

Slide 2

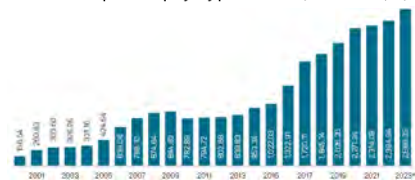
Slide 2

Strategic Context: Private Equity

- "Dry Powder" stands at an all time high at \$2.5 trillion – according to S&P Global
- Approximately \$100 Billion is ear-marked for investment in the Healthcare sector

- PE investors seek to complement existing platform investments via acquisitions that increase scale and efficiencies in the following sectors:
 - Physician Practices
 - Healthcare Information Technology
 - BioPharma
 - Home Healthcare
 - Behavioral Health

Global private equity dry powder trend, 2000-2023 (\$B)



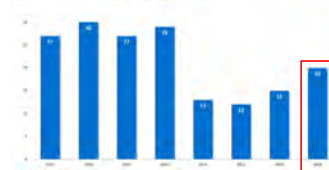
* Year to date through Dec 1, 2023.
 Dry powder data is extrapolated by PwC.
 Source: S&P Global Market Intelligence
 © 2023 S&P Global

Slide 3

Strategic Context: Hospital Partner

- According to [Kaufman Hall](#), Q1 2024 showed a significant uptick in M&A activity and represents the strongest Q1 since 2020
- A key highlight of the quarter was the diversity of transactions, showcasing a variety of trends that have been shaping the health care landscape:
 - Cross-Market Transactions
 - Community Health Systems seek larger partners
 - Portfolio realignment
 - A new partnership model
 - Academic health systems build community networks
- Since 2012, direct hospital employment of physicians has nearly doubled (as a % of physician workforce)

Figure 1: Number of Q1 announced transactions by year: 2017-2024



2024 Q1

Slide 4

Slide 4

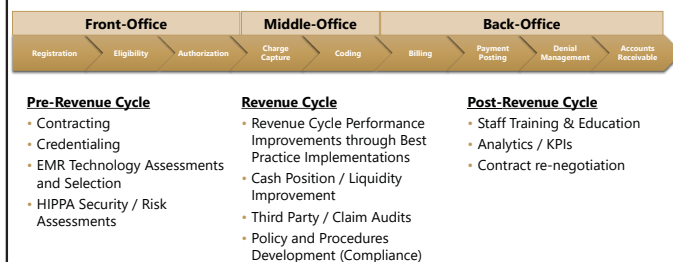
Strategic Context: MD Practice Industry

- According to the [American Medical Association](#), in 2023, the U.S. physician group market size was estimated at \$325 billion and expected to grow to \$461 billion by 2030
 - Initiatives to improve revenue to physician groups
 - Shift towards value-based care
 - Growing trend of solo practitioners joining larger physician groups
- Practice Ownership (2012-2022)
 - The share of physicians working in private practices fell from 60.1% to 46.7%.
 - The share of physicians working in hospitals as direct employees or contractors increased from 5.6% to 9.6%.
- Practice Size (2012-2022)
 - The share of physicians in small practices (10 or fewer physicians) shrank from 61.4% to 51.8% between 2012 and 2022
 - Large practices (50 physicians or more) grew from 12.2% to 18.3%
 - Mid-sized practices (those with 11 – 49 physicians) remained stable
- Employment Status (2012-2022)
 - The share of physicians who were self-employed fell by 9 percentage points from 53.2% to 44%.
 - The share of physicians who were employed grew from 41.8% to 49.7%
 - The share of physicians under the age of 45 who were self-employed fell from 44.3% to 31.7%.

Slide 5

Slide 5

Revenue Cycle Management: Operations Overview



Slide 6

Slide 6

Case Study: Project Process

Situation:

- Initially, multi-specialty group with 200+ providers
- Combined with independently-owned (PE) practices in other specialties to develop a large multi-specialty group with 500+ provider's
- Expanded group saw revenue decline and AR surge, requiring:
 - Problem diagnosis and remediation strategy
 - KPI development for management to drive stronger financial performance
 - Physician coding education, for compliance

Interim Management:

- Deploy experienced RCM professionals to remedy gaps in front, middle, and back-office operations to increase cash flow
 - AR recovery to increase cash flow
 - AR clean up
 - Denial management processes
- Address long-term RCM performance
 - KPI/Dashboarding tools
 - New write off policy
 - Prospective improvements
 - Coding Education

Case Study: Results

Results

- AR recovery (one-time gain) = \$1.0M
- Improvement in AR = Reduced by \$7.0M
- Gains in net collection rate = Increased by 2%
- Clean up of old AR = 1300 Accounts totaling \$600k
- New AR write-off policy
- New reporting structures
- KPI Dashboard
- New policies for
 - Patient Eligibility and Authorizations
 - Applying Timely Filing limits to AR prioritization
 - Clinical Decision Support Tool

Process Overview

Core Outputs

- Improvement Opportunity (AR/one-time and prospective)
- KPI Dashboard (de novo development) to track performance

Quantitative Assessments

- Clean Claim Rates
- Charge Lag Time
- Collection Rates
- Collections/wRVU
- Aging Accounts Receivable
- Average Days in AR
- Denial Analysis (CARC code)
- Cost to Collect

Qualitative Reviews

- Key Interviews
- Staff Interviews
- Process & Procedure Mapping and Reviews
- Coding & Documentation Reviews

Financial Opportunity Estimate

Opportunity Area	Value Range Est.	Note
One Time Opportunity:		
AR Push Effort	\$0.9M - \$1.6M	Range estimate for a one-time push to collect Aging AR*
Ongoing Opportunities:		
RCM Performance / Net Collection Rate	\$3.7M - \$9.2M	Net collection rates appear low vs. benchmark; 1%-2.5% improve could drive non-trivial ongoing benefit
Billing Costs	Limited, costs appear in line	Costs appear to be approximately 3.37%, which is within EisnerAmper expected range
Subtotal Ongoing	\$3.7M - \$9.2M	

*AR Push: This is a conservative estimate based on gross charges.
 **Production Improvement: All physicians are considered fulltime based on the staffing detail report received, Master File Information(download)-2023 Ver B.xlsx spreadsheet

Dashboards

- Dashboards allow management to track performance over specific periods of time and proactively flag any under performance

RCM Key Performance Indicators			
	2022	2023	MGMA Benchmark
Clean Claim Rate	99%	99%	95%*
Denial Rate (First Time Pass)	14%	10%	8%
DOS to Charge Lag Time	18 Days	8 Days	4 Days*
Average Days in AR	38 Days	35 Days	46 Days
Total AR 120+ Days	9%	9%	12%
Net Collection Rate	96%	98%	98%
Gross Collection Rate	46%	51%	51%

AR Report Date:	11/28/2023	12/12/2023	12/28/2023	1/8/2024	1/15/2024
Total Prioritized Claim Amount	\$2,036k	\$1,465k	\$1,290k	\$3,134k	\$4,795k
Performance as of:	12/12/2023	12/28/2023	1/8/2024	1/15/2024	1/22/2024
Adjusted	\$96k	\$42k	\$11k	\$22k	\$1,745k
Collected	\$254k	\$234k	\$212k	\$113k	\$415k
Unpaid Prioritized Claims	\$1,995k	\$1,006k	\$744k	\$2,801k	\$4,050k

Total Collection by Bucket	\$254k	\$234k	\$212k	\$113k	\$415k
0-30	\$51k	\$4k	\$18k	\$4k	\$4k
31-60	\$11k	\$21k	\$40k	\$7k	\$8k
61-90	\$150k	\$134k	\$113k	\$60k	\$300k
91-120	\$48k	\$60k	\$14k	\$1k	\$125k
>120	\$36k	\$43k	\$39k	\$32k	\$91k

Collection Rates

- Gross Collection Rate is 46%
- 5 percentage points below the MGMA Benchmarked Median
- Aggregate Net Collection Rates is 96.5%
- 1.5 percentage points below the MGMA Benchmarked Median
- On a revenue base of \$367M, a 1-2.5% improvement in net collections translates to an incremental revenue opportunity of \$3.7 – \$9.2M

Collection Rate vs. Benchmarks	
	2022
Charges	\$ 794,650,727
Payments	\$ 367,444,181
Adjustments	\$ 413,824,718
Gross Collection Rate	46.24%
MGMA Median	52%
Net Collection Rate	96.5%
MGMA Median	98%

Source: 20230619 DOS Data 202201-4.csv Reports
 Opportunity: 1-2.5%, \$3.7M - \$9.2M

- Note: Collection Rates calculation
- Gross Collection Rate = Payments / Charges
- Net Collection Rate = Payments / (Charges-Adjustments)

Denial Analysis

- Denial analyses are performed via root cause analysis
- This allows the Practice to identify major trends within your denials and lead a focused effort in denial reduction to ultimately increase collections

collections				
CARC Category	Revenue Cycle	CARC	\$ Amount	% of Grand Total
1. Authorization/Referral	Front Office	CO/PR-187	\$2,292k	9%
2. Eligibility		CO/PR-22	\$593k	2%
3. Eligibility		CO/DA-109	\$542k	2%
4. Eligibility		CO/PR-27	\$354k	1%
5. Eligibility		CO/PR-31	\$232k	1%
6. Clinical/Medical Necessity	Middle Office	CO-151	\$1,333k	5%
7. Clinical/Medical Necessity		CO/PR-06	\$1,746k	7%
8. Clinical/Medical Necessity		CO/PR-10	\$1,609k	6%
9. Clinical/Medical Necessity		CO/PR-204	\$232k	2%
10. Coding		CO-87	\$1,093k	8%
11. Coding		CO-234	\$235k	1%
12. Coding		CO-236	\$240k	1%
13. Billing	Back Office	CO-A1	\$2,740k	11%
14. Billing		CO-16	\$1,234k	5%
15. Billing		CO-252	\$1,036k	4%
		List Total	\$16,801k	65%

Key Process Flows: Example 1

Current Process

Patient Eligibility and Authorizations

Example:

- Incomplete Patient Scheduling and authorizations

Situation:

- Patient eligibility and authorizations are not being regularly run or confirmed prior to scheduling

Recommendation:

- Perform eligibility verification and authorizations prior to all visit scheduling

Improved Process



Source: Fast Billing Solutions

Optimizing Revenue Cycle Management

Key Process Flows: Example 2

Current Process

Applying Timely Filing Limits to AR prioritization

Example:

- Outstanding claim prioritization

Situation:

- Timely filing limits for insurance carriers are not applied to individual claims for prioritization purposes

Recommendation:

- Implement workflows to prioritize claims into buckets based on timely filing deadlines

Improved Process



Key Process Flows: Example 3

Current Process

Clinical Decision Support Tool:

Example:

- Fracture Care Workflow

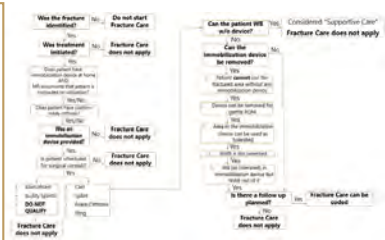
Situation:

- Current fracture care workflow doesn't take into consideration local coverage and determination policies

Recommendation:

- Enhance fracture care workflow with local coverage and determination policies

Improved Process



Aged AR by Bucket vs. Benchmarks

- The following Aged AR summary is based on gross charges and was run February 2023
- Overall AR performance is better than MGMA Benchmarks
- The Total AR Balance is \$82.1M (\$17M Non-Ortho)
- Average Charges per day is \$2.2M
- Average Days in AR is 37.7

AR Specialty Distribution			Aged AR Buckets vs. Benchmarks					
	Ortho	Non-Ortho	Total	Current	\$1.4B	\$1.4B	\$1.1B	Total A.R.
Ortho AR Balance	\$40,481K	\$6,620K	\$47,101K	\$40,481K	\$6,620K	\$47,101K	\$40,481K	\$47,101K
Non-Ortho AR Balance	\$12,410K	\$1,397K	\$13,807K	\$12,410K	\$1,397K	\$13,807K	\$12,410K	\$13,807K
Total	\$52,891K	\$8,017K	\$60,908K	\$52,891K	\$8,017K	\$60,908K	\$52,891K	\$60,908K
% of Total AR	72%	13%	85%	72%	13%	85%	72%	85%
MGMA Benchmarks	62%	12%	74%	62%	12%	74%	62%	74%
Reasonable Collectability				45%	30%	15%	15%	Total Opp Est
Non-Ortho Collectable Value	\$477K	\$220K	\$697K	\$477K	\$220K	\$697K	\$477K	\$697K
Ortho Collectable Value	\$40,004K	\$7,797K	\$47,801K	\$40,004K	\$7,797K	\$47,801K	\$40,004K	\$47,801K

Note: Ortho 61-90 day not included in opportunity due to longer collectable time period of Workers Comp and No-Fault

AR Parameters

- AR management should be prioritized based on specific parameters
- How old is too old?
- Depending on specialty building out models to prioritize claims based on three categories:
 - Timed Out
 - At Risk
 - Workable

Run Date: 2/26/2023	Rejections	Denials	AR Aging	AR Patient Responsibility	Total Accounts Receivable
Total	\$2,134	\$53	\$8,080K	\$5,563	\$38,425K
AR Risk (Next 90 Days)	\$17K	\$7	\$1,265K	\$1,179	\$3,185K
Workable	\$2,098	\$46	\$6,815K	\$4,384	\$35,240K

AR Clean Up

- A viability analysis identifies claims <\$500 older than January 2023 for write off

- Write Off Amount: \$194K
- Viability Estimate: \$404K

ROI Calculation (3/4/2024)					
	<\$100	\$100-\$500	\$500-\$2500	\$2500-\$5000	>\$5000
Avg Charge Per Claim	\$ 42.71	\$ 282.25	\$ 1,157.37	\$ 3,567.96	\$13,450.49
Estimated Collection Per Claim (50% Collection Rate)	\$ 21.36	\$ 141.13	\$ 578.69	\$ 1,783.98	\$ 6,725.25
# of claims	447	619	137	35	39
Total Minutes (12 + 30 Minutes per claim)	18774	25998	5754	1470	1638
Total Hours	312.9	433.3	95.9	24.5	27.3
Total Cost (\$30/Hr)	\$ 9,387.00	\$ 12,999.00	\$ 2,877.00	\$ 735.00	\$ 819.00
Estimate of Viable Claims (10%)	44.7	61.9	13.7	3.5	3.9
Total Revenue	\$ 954.57	\$ 8,735.64	\$ 7,927.98	\$ 6,243.93	\$26,228.46
ROI @ \$30/Hr	\$ (8,432.43)	\$ (4,263.36)	\$ 5,050.98	\$ 5,508.93	\$25,409.46
Total Cost (\$10/Hr)	\$ 3,129.00	\$ 4,333.00	\$ 959.00	\$ 245.00	\$ 273.00
ROI @ \$10/Hr	\$ (2,174.43)	\$ 4,402.64	\$ 6,968.98	\$ 5,998.93	\$25,955.46

Note: Analysis does not include Work Comp claims

ROI Viability (Previous)					
	<\$100	\$100-\$500	\$500-\$2500	\$2500-\$5000	>\$5000
# of claims	540	995	328	61	48
ROI @ \$30/Hr	\$ (10,190.00)	\$ (6,795.00)	\$10,062.00	\$ 9,569.00	\$29,292.00
ROI @ \$10/Hr	\$ (2,630.00)	\$ 7,135.00	\$14,654.00	\$ 10,423.00	\$29,964.00

Implementation: Overview

- One-time AR Recovery and clean-up
- Process redesign for:
 - Front-office
 - Middle-office
 - Back-office
- Follow-up:
 - Provider education
 - Rate negotiation

Implementation: Back End

- AR Swat to Pursue Outstanding AR (One Time Opportunity)
 - Focus
 - AR Prioritization (Adjudication Timeframe & Dollar Amount)
 - Staff assignments, regular auditing and monitoring of progress
 - Assistance
 - Oversight with option of outside billers to assist
 - Staff assignments, auditing and monitoring

Implementation: Redesign

- Front & Middle Office Redesign (Annual Ongoing Opportunity)
 - Focus
 - Process (Re)Design
 - Implementation of Electronic Scheduling Platform
 - Eligibility Process Review & Runs
 - Surgical Request Process & Reconciliation
 - Reconciliation/Outreach Process
 - Charge Capture & Entry Reconciliation/Outreach Process
 - Assistance
 - Process Implementation & Redesign Lead
 - Project Management
 - Auditing/Measurement
 - Concurrent RCM Director Recruitment

Implementation: Redesign

- Back Office Redesign (Ongoing Opportunity)
 - Focus
 - AR Assignment, Prioritization
 - Denial Management Assignment & Prioritization
 - Perform Productivity Audits of current staff members to ensure quality of claim touches
 - Perform Denial Origination Identification Audits
 - Patient Access
 - Eligibility
 - Process (Re)Design of Payment Posting & Policies
 - Process & Control Design for Contractual and Bad Debt Write offs
 - Assistance
 - Process Implementation & Redesign Lead
 - Project Management
 - Auditing/Measurement
 - Concurrent RCM Director Recruitment

Implementation: Education, Denials

- Denial Education following root cause assessments can improve a practices' understanding of high-volume denials and most importantly how to prevent future denials

Summarized Front-Office Findings

Authorization Denials

1. CO/PR-197: Precertification/Auth absent
2. CO/PR-22: May be covered by another payor
3. CO/OA-109: Claim/service not covered by this payor
4. CO/PR-27: Expense incurred after coverage was terminated
5. CO/PR-31: Patient cannot be identified as our insured

Eligibility Denials

2. CO/PR-22: May be covered by another payor
3. CO/OA-109: Claim/service not covered by this payor
4. CO/PR-27: Expense incurred after coverage was terminated
5. CO/PR-31: Patient cannot be identified as our insured

Target Locations

Orthopedic Surgery Centers

- Orthopedic SC (1)
- Crosstown SC
- Orthopedic SC (2)

Education Summary

Authorization Denials

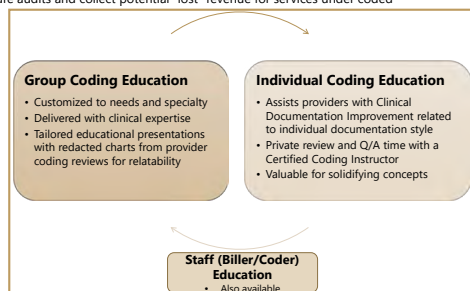
- Cheat Sheet by payor inclusive of major procedures requiring Auth vs. No Auth required
- Adoption of electronic authorization tools/software to streamline the authorization process and help ensure compliance with payor requirements
- Provision of appeals including additional information / documentation to support the medical necessity of the service
- Electronic communication pre-surgery / post-surgery by Clinical Coordinators and Providers to confirm procedures performed vs. additional procedures added/changed to allow for a timely retro-authorization request (for payors that allow).

Eligibility Denials

- Redesign of process recommended

Implementation: Education, Coding & Documentation

- Education following Coding & Documentation Reviews can improve a practices' coding and billing accuracy, prevent future audits and collect potential "lost" revenue for services under coded



Implementation: Rate Negotiation

- **Rate Negotiations and Contractual Allowance Reviews** to improve your practices' payor contracts

Payor Contract Negotiations

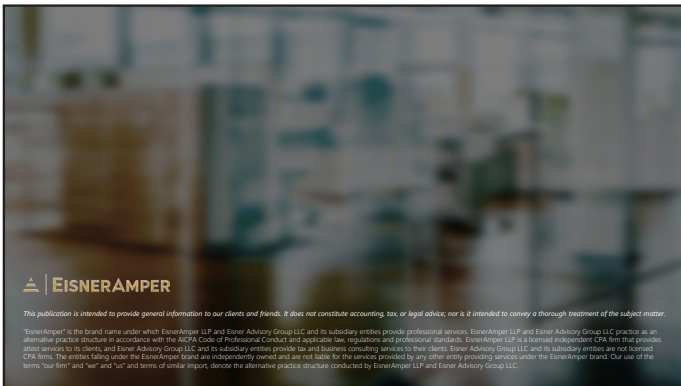
- Reimbursement rates of payor contracts should be reviewed annually
- Underperforming contracts should be identified
 - Negotiations should be initiated for underperforming contracts

Contractual Allowance Reviews

- Contractual allowances should be reviewed to ensure the validity of outstanding accounts / Accounts Receivable on a regular basis
- These procedures reduce practice exposure to underpayments and improper write-offs

Lessons Learned: Take-away

Whether you are considering remaining independent or doing a deal with private equity, a hospital/system, or other Practices, there is tremendous value in improving your Revenue Cycle performance with the appropriate support



SELF EVALUATION

Optimizing Revenue Cycle Management

1. How much money is PE sitting on:
 - a. \$10M
 - b. \$100M
 - c. \$1B
 - d. \$20B
2. T/F - EVERY partner should participate in the planning process for a deal?
3. Which of the following is not part of RCM
 - a. Patient scheduling
 - b. EMR close-out
 - c. Managed care contract negotiations
 - d. Patient balance billing
4. T/F - Gross collection rate is a better metric than net collections in measuring performance
5. T/F - Higher days in AR indicates better performance.
6. T/F - Prioritizing AR work-down should be based on size of claim
7. T/F - Claims posters should write-off a claim if it gets denied in the first pass
8. T/F - Outsourcing and insourcing are equally viable alternatives

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

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Gout Revisited: Optimizing Diagnosis and Management

Gout Revisited: Optimizing Diagnosis and Management

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Gainesville, FL 32605
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Should be the same as.....

Management of Gout in Rheumatology

Should be the same as.....

Management of Gout by Goutologists

Should be the same as.....

Management of Gout by Specialists of the Great Toe

ACR: The Most Recent US Gout Guideline

AMERICAN COLLEGE
of RHEUMATOLOGY
Empowering Rheumatology Professionals

Arthritis Care & Research
Vol. 72, No. 6, June 2020, pp 744-760
DOI 10.1002/acr.24180
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ACR GUIDELINE FOR MANAGEMENT OF GOUT

2020 American College of Rheumatology Guideline for the Management of Gout

John D. Fitzgerald,¹ Nicola Dalbeth,² Ted Mikuls,³ Romina Brignardello-Petersen,⁴ Gordon Guyatt,⁵

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

Gout Primary Care Management 2025

Sx Consistent with Acute Gout

If possible, confirm with
microscopy

Serum Uric Acid now and/or
> 2 weeks post-flare

Anti-inflammatory Rx

Colchicine

Steroids

NSAID

LTULT (Goal Uric Acid <6.0 mg/dL)

#1 Allopurinol

#2 Febuxostat

#3 Probenecid

Refer for Pegloticase

Why Bother?

Where to Begin, and Why

"While the etiology of gout is well-understood and there are effective and inexpensive medications to Rx gout, gaps in quality of care persist."

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

Where to Begin, and Why Urate Lowering Treatment (ULT)

"Despite [ACR] recommendations, over the past 2 decades there has been no ↑ in ULT utilization. Adherence to ULT remains poor and is the lowest... among...7 common medical conditions.

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ULT: Comparative Adherence (Year 1 of Drug Therapy)

Disorder	% Adherent*
HTN	72.3%
Hypothyroid	68.4%
T2DM	65.4%
Epilepsy	60.8%
Hypercholesterolemia	54.6%
Osteoporosis	51.2%
Gout	36.8%

*Defined as ≥80% Rx fill rate

N = 706, 032

Briesacher BA, et al. *Pharmacotherapy* 2008;28:437-443

Historical

What Are These
Dermatoses?

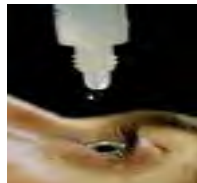


What Are the Directions
for These Eyedrops?

Gout: Definition

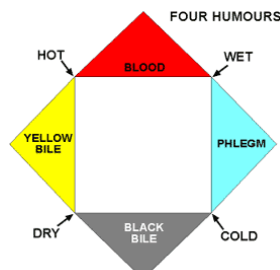
Gout (gowt) [L. *gutta* a drop, because of the ancient belief that the disease was due to a 'noxa' falling drop by drop into the joint]

Dorland's Illustrated Medical Dictionary
26th Edition 1981 Saunders (Philadelphia)



4 gtts q.i.d.

Scope of the Problem



“ our Greek ancestors believed that the attacks were caused by the dropping of evil humours in the body towards the toe, so that they could then be expressed from the body.”

Arthritis Research Campaign 2004 - Registered Charity No. 207711

Demographics

- most common crystal-induced arthropathy
- 2% of all persons > age 45
- Men : women = 20 : 1*
- Rare in women prior to menopause
- Most common patient: male > age 30
- If urate >9.0 mg/dL: incidence = 5%/year

Kerolus G, Schumacher HR "Crystal-Induced Arthropathies" *Drug Therapy* 1987:61-70
*Usatine RP, Sacks B, Sorci J "A swollen knee" *J Fam Pract* 2003;52(1):53-55

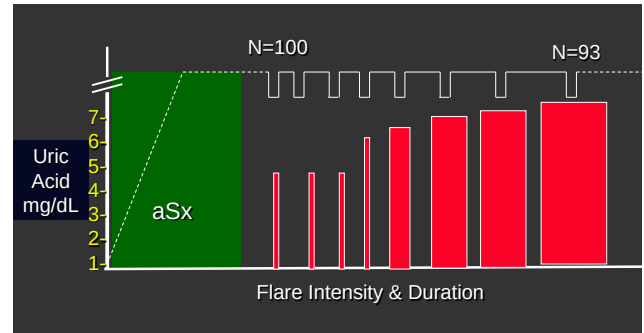
Clinical Course

The Three Overlapping Phases of Gout

- A long phase of asymptomatic hyperuricemia
- A period of recurrent acute gout attacks separated by Sx-free intervals
- Development of tophi and chronic tophaceous gouty arthritis (10-20%)

Fam AG "Gout and Hyperuricemia" Conn's Current Therapy 2006 Rakel, Bope, eds. (Saunders Elsevier, Philadelphia)

Natural Hx of Gout



Singh H. "Dx and Management of Gout in the Long-Term Care Setting" Annals of Long-Term Care 2007;15(5):34-40

Joints Affected: Decreasing Order of Frequency

- Great toe
- Forefoot
- Ankle
- Heel
- Knee
- Wrist
- Finger
- Elbow

Usatine RP, Sacks B, Sorci J "A Swollen Knee" J Fam Pract 2003;52(1):53-55

Olecranon Bursitis



Wikipedia "Gout Elbow" accessed 025-5-26

Dx

Clinical Presentation

- Initial attack often nocturnal
- Usually monarticular
- 1st MTP in 60%
- Atraumatic, $\leq 10/10$ pain
- Joint hot, red, tender, swollen
- May mimic cellulitis

Kerolus G, Schumacher HR "Crystal-Induced Arthropathies" Drug Therapy 1987:61-70

Gout Dx: Crystals 1987

“Even if clinical signs and Sx strongly suggest gout, needle aspiration of an acutely inflamed joint is necessary to confirm the Dx.”

Kerolus G, et al. "Crystal-Induced Arthropathies" *Drug Therapy* 1987:61-70

Gout Dx: Crystals 2011

“The **gold standard** for Dx of gout is demonstration of MSU crystals by polarized light microscopy either in joint fluid aspirated during an acute attack or between attacks, or from...tophi.”

Chohan S "Hyperuricemia and Gout" *Conn's Current Therapy* 2011 Elsevier

Gout Dx: Crystals 2022

“...EULAR has provided a frameworkcentered on the identification of MSU crystals in aspirates of synovial fluids or tophi.”

Mikuls TR *NEJM* 2022;387:1877-1887

Gout Dx: 2025

WORKUP

Arthrocentesis and examination of synovial fluid

Garci JP, Reginato AM. "Gout" *Ferri's Clinical Advisor* 2025:476-479

Why Bother with Joint Aspiration?

“It is important to make the distinction, because patients with gout usually require lifetime therapy with potentially toxic drugs.”

Kerolus G, Schumacher HR "Crystal-Induced Arthropathies" *Drug Therapy* 1987 61-70

Urate Crystals WHEN & WHERE?

“Often, urate crystals can be demonstrated in the 1st MTP joint or a knee joint that is not acutely involved. In fact, needle aspiration of aSx joints can be useful in establishing the Dx between attacks.”*

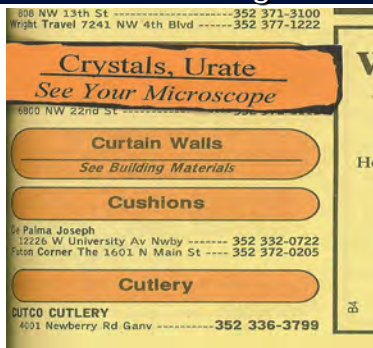
*Agudelo CA, et al "Definitive Dx of gout by identification of urate crystals in aSx MTP joints" *Arthritis Rheum* 1979;22:559-560

How to Find Urate Crystals

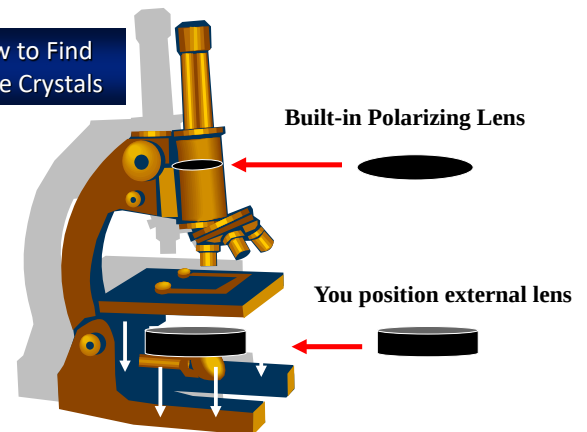
How to Find Urate Crystals: The Yellow Pages



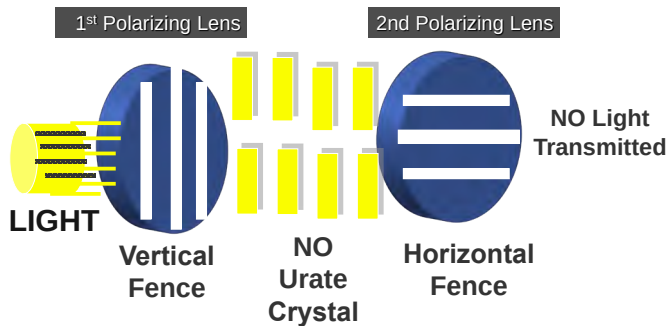
How to Find Urate Crystals: The Yellow Pages



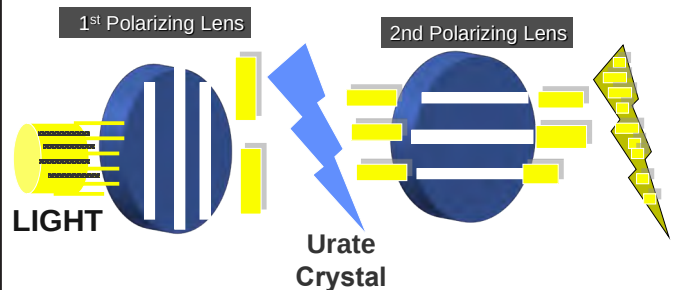
How to Find Urate Crystals



What the Heck is Birefringence?



What the Heck is Birefringence?



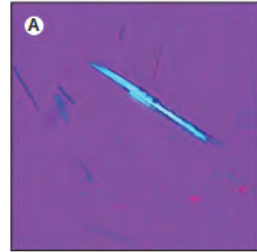
Steps in Urate Microscopy

- Obtain joint fluid (preferable) or tissue fluid aspirate
- Place on slide with coverslip PROMPTLY
 - Crystals dissolve with time
- Seek intracellular crystal needles
- Exclaim "EUREKA" when crystals seen, if alone
- Pretend professorial complacency when crystals encountered while in presence of colleagues....

"ah, yes, here are the typical crystals confirming the Dx..."

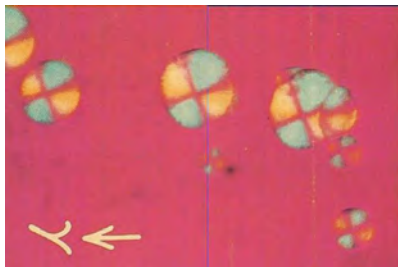
Gout Dx:

Color-Compensated Polarized Light Microscopy



Dalbeth N, et al Lancet 2021;397:1843-1855

Spherulite Uric Acid Crystal Color-Compensated Microscopy



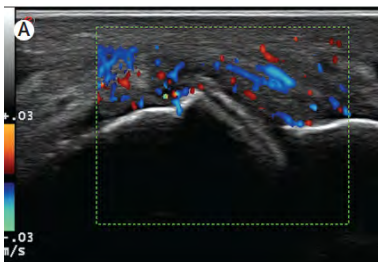
Fiechtner JJ, et al. "Urate Spherulites in Gouty Synovia" JAMA 1981;245(15):1533-1536

Urate Crystals: Tophus Aspiration Color-Compensated Microscopy



Pittman JR, et al. Dx and Management of Gout Am Fam Phys 1999;59(7):1799-1806

Gout Dx: Colour Duplex Ultrasound: Double Contour Sign



Dalbeth N, et al Lancet 2021;397:1843-1855

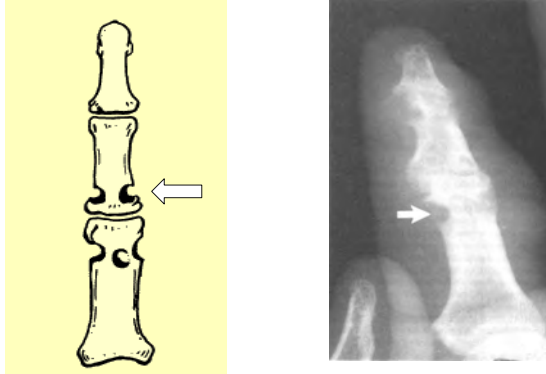
Gout Dx: Dual-Energy CT



Uric acid
crystals

Dalbeth N, et al Lancet 2021;397:1843-1855

Gout "Rat Bite" Lesion: Plain Films



Does Colchicine Responsivity Prove Gout?

"Among those disorders in which colchicine has documented efficacy are pseudogout, familial Mediterranean fever, sarcoidosis, and Behcet syndrome. Therefore, a therapeutic response to colchicine does not prove a diagnosis of gout."

Rothschild BM "Colchicine test disputed" *Geriatric Consultant* 1985;Jan/Feb:Page 7

Criteria for Dx of Gout American Rheumatism Association 1977

A. Characteristic urate crystals in joint fluid

And/Or

B. Tophus proved to contain urate crystals

And/Or

C. ≥ 6 of 12 clinical, lab, or x-ray findings

Wallace SL, et al. "Preliminary criteria for the classification of the acute arthritis of primary gout." *Arthritis Rheum* 1977;20(3):895-900

THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

Cardiovascular Safety of Febuxostat or Allopurinol in Patients with Gout

William B. White, M.D., Kenneth G. Saag, M.D., Michael A. Becker, M.D.,
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Barbara Hunt, M.S., Majin Castillo, M.D., and Chansoo Gonwardhana, M.D., Ph.D.,
for the CAES Investigators*

White WB, et al. *NEJM* 2018;378:1200-1210

"Patients were eligible for enrollment in the trial if they had a Dx of gout fulfilling the American Rheumatism Association criteria⁹"

ties. *Am Heart J* 2012;164:14-20.
9. Wallace SL, Robinson H, Masi AT, Decker JL, McCarty DJ, Yu TF. Preliminary criteria for the classification of the acute arthritis of primary gout. *Arthritis Rheum* 1977;20:895-900.
10. Hicks KA, Tchong JE, Bozkurt E, et al.

Criteria for Dx of Gout American Rheumatism Association 1977

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1. >1 attack of acute arthritis
 2. Maximum inflammation developed within 1 day
 3. Monoarthritis
 4. Redness over joint
 5. 1st MTP painful or swollen
 6. Unilateral 1st MTP joint attack
 7. Unilateral tarsal joint attack
 8. Tophus (proven or suspected)
 9. Lab: Hyperuricemia
 10. X-ray: Asymmetric swelling within a joint
 11. X-ray: subcortical cysts without erosions
 12. Joint fluid during attack: Culture negative for organisms
- Wallace SL, et al. "Preliminary criteria for the classification of the acute arthritis of primary gout." *Arthritis Rheum* 1977;20(3):895-900

**Dx of Gout:
 ≥ 6 Criteria +**

ACR: The Most Recent US Gout Guideline

AMERICAN COLLEGE
of RHEUMATOLOGY
Empowering Rheumatology Professionals

Arthritis Care & Research
Vol. 72, No. 6, June 2020, pp 744-760
DOI 10.1002/acr.24189
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ACR GUIDELINE FOR MANAGEMENT OF GOUT

2020 American College of Rheumatology Guideline for the Management of Gout

John D. Fitzgerald,¹ Nicola Dalbeth,² Ted Mikuls,¹ Romina Brignardello-Petersen,⁴ Gordon Guyatt,⁴

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR Recommendations STRONG vs CONDITIONAL

- **Strong Recommendation:** moderate-high certainty evidence that benefits consistently > risks; with rare exceptions, an informed patient and provider would concur
- **Conditional Recommendation:** benefits and risks more closely balanced and/or low certainty of evidence and/or no data available

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR Recommendations (Strong) When to Initiate ULT

- ANY radiographic evidence of joint damage
- ≥2 acute gout attacks/yr
- Any tophi

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR Recommendations (Conditional) When to Initiate ULT

- 2 prior flares, but infrequent recurrences (<2/yr)
- Factors to consider: Urate >9 mg/dL, CKD, CVD

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR Recommendations (Conditional) When NOT to Initiate ULT

“For patients experiencing their 1st flare, we conditionally recommend *against* initiating ULT.”

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR Recommendations (Conditional) When to Initiate ULT

- Even at 1st flare IF
 - Uric acid > 9 mg/dL
 - CKD ≥Stage 3
 - Urolithiasis

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR Recommendations
Urolithiasis Meant Uric Acid Stones, Right?

“Among patients with **calcium oxalate** stones and hyperuricosuria, allopurinol (300 mg/d) is superior to placebo in reducing the 3-year incidence of stone-related events.”

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR Recommendations
aSx Hyperuricemia (Conditional)

“Initiating ULT is conditionally recommended **against** in patients with aSx hyperuricemia.”

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR Recommendations
Rx aSx Hyperuricemia: Why NOT

“...among patients with aSx hyperuricemia with serum urate concentrations of **≥ 9 mg/dl**, only **20%** went on to develop gout **within 5 years**.”

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR Recommendations: aSx Hyperuricemia
NOT: Even for “Subclinical Gout”

“This is also the case for aSx hyperuricemia with MSU crystal deposition as noted on ...ultrasound or dual-energy CT.”

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR Recommendations (Strong)
Initial Rx: Allopurinol Preferred

“Rx with allopurinol as the preferred 1st line agent, over all other ULTs, is strongly recommended for all patients, including those with moderate-severe CKD ($\geq$ stage 3)”

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR Recommendations
Allopurinol Don't Forget Dose Range

“...allopurinol...when dosed appropriately (often requires doses >300 mg/d up to the maximum **FDA-approved dose of 800 mg/d**).”

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR Recommendations (STRONG)
ULT with Moderate-Severe CKD ($\geq$ CKD-3)

Initial ULT Dosing

- allopurinol ≤ 100 mg/d
- febuxostat 40 mg/d
- probenecid 500 mg qd-b.i.d.

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR 2020 Recommendations (STRONG)
ULT: ≥ 3 -6 months anti-inflammatory Prophylaxis

- Anti-inflammatory prophylaxis + ULT X < 6 months
 - Colchicine
 - NSAIDs
 - Prednisone/prednisolone
- After 6 months, anti-inflammatory as-needed

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR Recommendations
Pegloticase NOT 1st Line

“The choice of pegloticase as a first-line therapy is strongly recommended against.”

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR 2020 Recommendations (Conditional)
ULT: Old Dogma No Start During Flare

“...starting ULT during the gout flare over starting ULT after the gout flare has resolved is conditionally recommended....Two small RCTs and an observational study support the hypothesis that ULT during a flare does **not** significantly extend flare duration or severity.”

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR 2020 Recommendations (Strong)
Serum Uric Acid Target < 6 mg/dl

“Achieving and maintaining a...target < 6 mg/dl...is strongly recommended for all patients...[and] titration should occur over a reasonable time frame e.g., weeks to months, not years.”

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR 2020 Recommendations (Conditional)
ULT: Indefinitely?

“Continuing ULT indefinitely over stopping ULT is conditionally recommended.”

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR 2020 Recommendations (Conditional) WHY ULT Indefinitely?: Recurrences

“...[when] ULT was withheld in patients in clinical remission...only 13% of patients (27/211) whose serum urate concentration remained at <7 mg/dL while not receiving ULT had no flares with 5 years.”

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR 2020 Recommendations Screening for Allopurinol Hypersensitivity: YES

HLA-B*5801 Allele Screening

- Southeast Asian descent (e.g., Han Chinese, Korean, Thai)
- African American

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR 2020 Recommendations HLA-B*5801 Prevalence

- Han Chinese, Korean, Thai: 7.4%
- African American: 3.8%
- Hispanic: 0.7%
- White: 0.7%

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR 2020 Recommendations Dietary Constituents

- “We conditionally recommend*, regardless of disease activity, limiting...”
 - Alcohol
 - Purines
 - High-fructose corn syrup

*Evidence certainty **low** or **very low** for each

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR 2020 Recommendations Alcohol

- Alcohol users urate 1.6 mg/dL > non-drinkers
- 1-2 drinks → ↑flare rate by 40%

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR 2020 Recommendations Dietary Constituents

- “We conditionally recommend*, regardless of disease activity, limiting...”
 - Alcohol
 - Purines
 - High-fructose corn syrup
- We conditionally recommend* weight loss

*Evidence certainty **low** or **very low** for each

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR 2020 Recommendations Collateral Pharmacotherapy

- We conditionally recommend, regardless of disease activity, AGAINST
 - Adding Vit C
 - Adding or switching to fenofibrate
 - Stopping low dose ASA

*Evidence level **low** or **very low** for each

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR 2020 Recommendations Collateral HTN Rx

- We conditionally recommend, regardless of disease activity
 - Switching from HCTZ to another agent
 - Choosing losartan

*Evidence certainty **very low** for each

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR 2020 Recommendations Febuxostat: It's Complicated

"Switching to an alternative oral ULT agent...is conditionally recommended for patients taking febuxostat with a Hx of CVD or a new CVD-related event."

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

Febuxostat: CV Risk Message 2018

THE NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Cardiovascular Safety of Febuxostat or Allopurinol in Patients with Gout

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Barbara Hunt, M.S., Majin Castillo, M.D., and Lhanoo Gunawardhana, M.D., Ph.D.,
for the CARES Investigators*

White WB, et al. *NEJM* 2018;378:1200-1210

Febuxostat vs Allopurinol: CV Risk The CARES Trial 2018

- Study: RDBT gout patients (n = 6,190)
- Inclusion: gout with a 'Hx of major CVD'
- Rx (for up to 85 months)
 - Allopurinol up to 600 mg/d
 - Febuxostat up to 80 mg/d
- Endpoints
 - 1^o: CV death, nonfatal MI/stroke, unstable angina
 - 2^o: Individual components of 1^o

White WB, et al. *NEJM* 2018;378:1200-1210

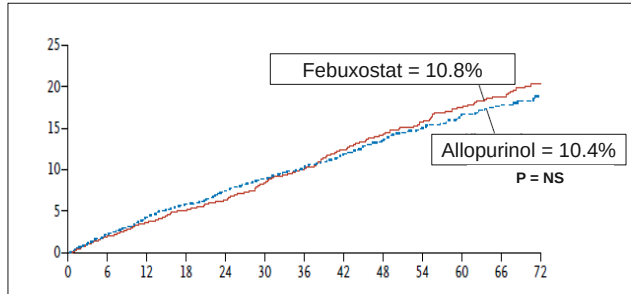
Febuxostat vs Allopurinol: CV Risk The CARES Trial 2018: Inclusion

What does "a Hx of Major CVD" mean?

- MI
- Stroke
- PAD
- Hospitalization for unstable angina or TIA
- DM with micro- or macrovascular disease

White WB, et al. *NEJM* 2018;378:1200-1210

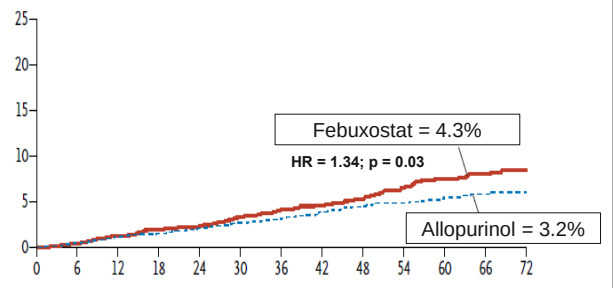
Febuxostat vs Allopurinol: 1^o Endpoint (CV death, nonfatal MI/stroke, unstable angina*)



*with urgent revascularization

White WB, et al. *NEJM* 2018;378:1200-1210

Febuxostat vs Allopurinol: CV Death



White WB, et al. *NEJM* 2018;378:1200-1210

Febuxostat: CV Risk Update 2020

Long-term cardiovascular safety of febuxostat compared with allopurinol in patients with gout (FAST): a multicentre, prospective, randomised, open-label, non-inferiority trial

Julia S Mackenzie, Ian Ford, George Nuki, Jasper Hallas, Christopher J Morley, John Webster, Stuart H Robinson, Matthew Walters, Michele Robertson, Raffaele De Lorenzo, Evelyn Findlay, Fernando Perez-Rua, John J V McMurphy, Thomas M MacDonald, on behalf of the FAST Study Group*

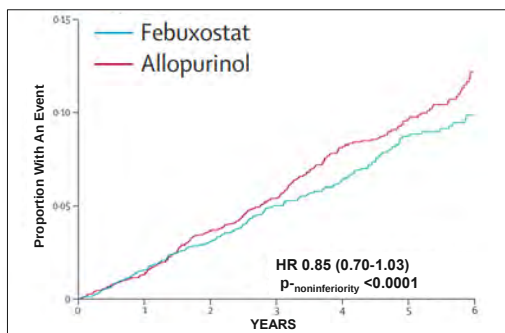
Mackenzie JS, et al *Lancet* 2020;396:1745-1757

Febuxostat vs Allopurinol 2020: FAST Trial 1^o Endpoint (CV death, nonfatal MI/Stroke, ACS)

- Study: PRSB gout patients (n =6,128)
- Inclusion: gout with “at least 1 CV risk factor”
- Rx (for up to 8 years)
 - Allopurinol up to 600 mg/d
 - Febuxostat 80-120 mg/d
- Endpoints
 - 1^o: CV death, nonfatal MI/stroke, ACS
 - 2^o: Individual components of 1^o

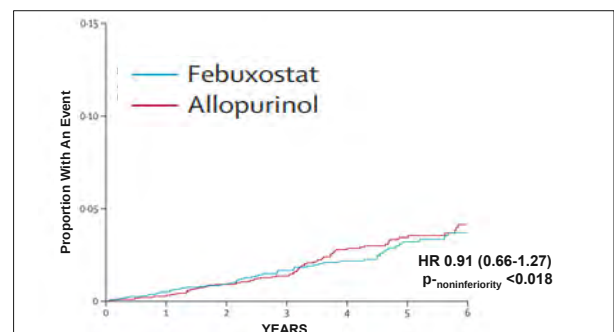
Mackenzie JS, et al *Lancet* 2020;396:1745-1757

Febuxostat vs Allopurinol 2020: The FAST Trial 1^o Endpoint (CV Death, nonfatal MI/stroke, ACS)



Mackenzie JS, et al *Lancet* 2020;396:1745-1757

Febuxostat vs Allopurinol 2020: The FAST Trial CV Death (on Rx analysis)



Mackenzie JS, et al *Lancet* 2020;396:1745-1757

Febuxostat vs Allopurinol: CV Risk The FAST Trial: Conclusions

"In contrast to a previous large study, we found no signal of ↑ all-cause or CV deaths with febuxostat. In light of these findings, regulatory advice to avoid the use of febuxostat in patients with CVD should be reconsidered and modified."

Mackenzie IS, et al *Lancet* 2020;396:1745-1757

ACR 2020 Recommendations Acute Rx of Last Resort: Interleukin-1 inhibitors

- anakinra
- canakinumab
- rilonacept

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR 2020 Recommendations Acute Flare Rx: Equal Efficacy

- Colchicine (1.2 mg f/u 0.6 mg)
- NSAIDs
- Steroids (PO, IM, IA)

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

Acute Flare Rx: Day 2 thru 7-10

- Colchicine: 0.5 mg-0.6 mg qd
- Prednisone: 5mg-10mg/qd
- NSAID: low dose (e.g., naproxen 220-250mg b.i.d.)

Mikuls TR *NEJM* 2022;387:1877-1887

Acute Gout Rx Choices

- NSAIDs: ANY
 - Indomethacin 50 mg q.i.d.
 - Ibuprofen 800 mg t.i.d.
 - Naproxen 500 mg b.i.d.
 - Celecoxib 200 mg b.i.d.
- Colchicine: Acute: 1.2 mg + 0.6 mg 1 hr later
- Prednisone 40 mg/d X 3 then 10 day taper

Garci JP, Reginato AM. "Gout" *Ferri's Clinical Advisor* 2025:476-479

ACR 2020 Recommendations What is the Role of Pegloticase?

- AND {
- Failed xanthine oxidase inhibitors
 - Failed uricosurics
 - Continue have gout flares (2 yr)
- OR • SQ tophi

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR 2020 Recommendations Why the Limits on Pegloticase?

“[Pegloticase benefits]...come with high costs, twice-monthly infusions, and the potential for serious allergic reactions.”

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

ACR 2020 Recommendations Lifestyle

- Limit alcohol
- Limit purine intake
- Limit high-fructose corn syrup
- Weight management (overweight/obese)

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

High Purine Foods

- All meats (esp organ meats), & meat extracts
- Seafood
- Gravies
- Yeast and yeast extracts
- Beer and other alcoholic beverages
- Beans, peas, lentils
- Oatmeal,
- Spinach, asparagus, cauliflower, mushrooms

Wood AJJ "The Management of Gout" *NEJM* 1996;334(7):445-451

ACR 2020 Recommendations Concurrent Meds

- Thiazides: De-select when possible
- Losartan: Select preferentially
- Appropriately indicated ASA: Don't Stop
- Fenofibrate: don't bother

FitzGerald JD et al. *Arthritis Care Research* 2020;72(6):744-760

Gout Primary Care Management 2025

Sx Consistent with Acute Gout

If possible, confirm with
microscopy

Serum Uric Acid now and/or
> 2 weeks post-flare

Anti-inflammatory Rx

Colchicine

Steroids

NSAID

LTULT (Goal Uric Acid <6.0 mg/dL)

#1 Allopurinol

#2 Febuxostat

#3 Probenecid

Refer for Pegloticase

SELF EVALUATION

Gout Revisited - Optimizing Diagnosis and Management

1. What is the gold standard for diagnosing gout?
 - a. Elevated serum uric acid level
 - b. X-ray showing joint erosions
 - c. Identification of monosodium urate crystals on polarized microscopy
 - d. Response to colchicine
2. T/F - A therapeutic response to colchicine confirms the diagnosis of gout.
3. According to ACR recommendations, what is the target serum uric acid level for patients on urate-lowering therapy?
 - a. <8 mg/dL
 - b. <7 mg/dL
 - c. <6 mg/dL
 - d. <5 mg/dL
4. Which medication is recommended as first-line urate-lowering therapy?
 - a. Febuxostat
 - b. Probenecid
 - c. Pegloticase
 - d. Allopurinol
5. T/F - Urate-lowering therapy should always be initiated after the first gout flare.

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

Anatomy of the Chief Medical Officer

Mark D. Olszyk, MD, MBA, FACEP

Anatomy of the Chief Medical Officer

What is a CMO and why it is the best job in medicine

Welcome to CMO Anatomy Lab

- Today's question: What is a Chief Medical Officer?
 - We'll explore the 'anatomy' of the role using organ systems.
 - You'll leave with a practical mental model and a pocket guide.

Gross Anatomy: Where the CMO Lives

- Sits at the intersection of patients, clinicians, and the health system.
 - Bridges medical staff, administration, board, and regulators.
 - Clinical accountability: where "the buck stops" for care quality.



The Bones: Governance and Credentialing

- Medical staff bylaws and policies are the skeleton of the organization.
 - Credentialing, privileging, OPPE/FPPE: defining who can do what, safely.
 - Committees and MEC: the joints where decisions flex and move.



The Heart: Culture and Trust

- The CMO pumps trust through the organization.
 - Presence in the physician lounge, OR, and nursing stations matters.
 - Culture is shaped more by conversations than by policies.



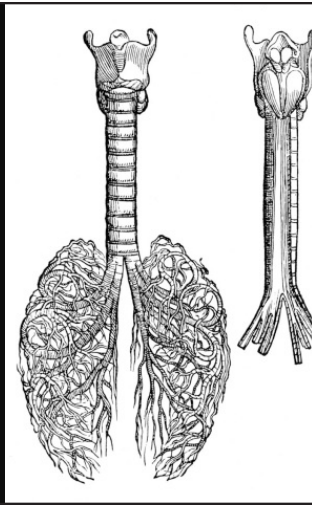
The Brain and Nerves: Strategy and Signals

- Connects strategy (boardroom) to reality (bedside).
 - Uses data, dashboards, and AI as 'neural signals.'
 - Translates complex information into clear decisions and priorities.



The Lungs: Communication as Oxygen

- Upward: honest clinical reality to CEO and board.
 - Downward: translating strategy into meaningful actions.
- Outward: communicating with community, media, and regulators.



Hands and Feet: Operational Leadership

- Rounding on units, ED, OR: leadership by walking around.
 - Throughput, length of stay, sepsis bundles, discharge planning.
- Partnering with nursing, case management, and hospitalists at the frontline.



Immune System: Quality, Safety, and Risk

- Peer review, incident reports, and root cause analyses as antibodies.
 - Just Culture: learning from harm instead of hunting for blame.
- Partnering with risk management and legal to protect patients and staff.



Skin and Senses: Experience and Warning Signs

- Patient experience and physician/nurse engagement as sensory input.
 - Burnout, turnover, and complaints are 'rashes' and 'pain signals.'
- The CMO must be attuned to quiet signals, not just loud alarms.



GI and Metabolism: Margin Feeds Mission

- Understanding how money flows through the system.
 - Clinical decisions drive revenue, cost, and value outcomes.
- CMO translates clinical value into financial language without losing mission.



Embryology: How a CMO Develops

- Pathway: curious clinician → informal leader → formal leadership roles.
 - Key traits: curiosity, humility, resilience, systems thinking.
- Experiences: committees, QI projects, teaching, crisis leadership.



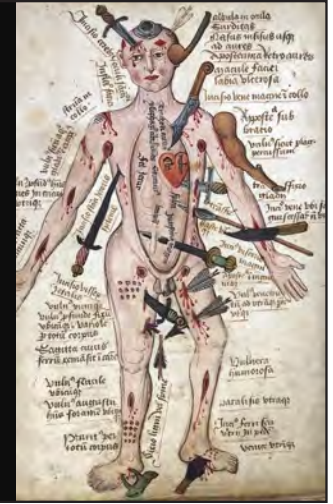
Histology: Micro-Skills of the CMO

- Listening deeply before reacting.
 - Asking good questions instead of giving quick answers.
 - Giving credit, taking blame; coaching more than commanding.



Pathology: When the CMO Role Goes Wrong

- Organ rejection: poor cultural or values fit.
 - Isolation from frontline clinicians and teams.
 - Over-identifying with either administration or medical staff.
 - CMO burnout and moral injury.



The Fire Chief: Leading When the House Is on Fire

- Healthcare is on fire: workforce, finance, regulation, technology shocks.
 - CMOs and fire chiefs both run toward the flames, not away.
 - Calm in chaos: triage, incident command, and protecting the team.



Future Anatomy: AI and Hybrid Care

- New 'organs': AI governance, digital health, and virtual teams.
 - Trustworthy AI: data quality, bias, explainability, and safety.
 - The next-gen CMO: data-fluent, ethically grounded, globally aware.



Case Lab: One Patient, One System, One CMO

- Tell a short story where multiple 'systems' fired at once.
 - Map which organs you used: heart, brain, immune system, hands & feet.
 - Highlight lessons: what worked, what you'd do differently.



CMO Pocket Card: Take-Home Anatomy

- CMO is the heart of culture and brain of clinical strategy.
 - Also the immune system for safety, skin for experience, and hands & feet for operations.
 - Choose one 'organ system' to strengthen in your leadership this month.

SELF EVALUATION

Anatomy of the Chief Medical Officer

1. Where does the presentation say the CMO “lives” in the organization?
 - a. Primarily within the IT department
 - b. At the intersection of patients, clinicians, and the health system
 - c. Exclusively in the boardroom
 - d. Only within the finance office
2. In the anatomy metaphor, what do “the bones” represent?
 - a. Patient satisfaction scripting
 - b. Governance and credentialing structures
 - c. Marketing and branding
 - d. Social media communications
3. What does the presentation identify as the “heart” of the CMO role?
 - a. Budgeting and margin management
 - b. Culture and trust
 - c. Supply chain optimization
 - d. Contracting strategy
4. In the metaphor, what do the “brain and nerves” emphasize?
 - a. Scheduling and coverage
 - b. Strategy translated into signals using data, dashboards, and AI
 - c. Patient billing and coding
 - d. Construction and facilities planning
5. The presentation calls communication the “lungs.” Which direction(s) of communication does it highlight?
 - a. Only outward to media
 - b. Only downward to staff
 - c. Upward, downward, and outward
 - d. Only lateral within the medical staff
6. Which item below best matches the “immune system” in the talk?
 - a. Social events to improve morale
 - b. Peer review, incident reporting, RCA, and Just Culture
 - c. Recruiting new specialists
 - d. Website redesign
7. What does the “pathology” section warn can happen when the CMO role goes wrong?
 - a. Too many dashboards
 - b. Poor cultural/values fit and isolation from frontline teams
 - c. Overuse of committee charters
 - d. Excessive patient rounding

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

FACULTY

Cullen Ruff, MD, FACR

Cullen Ruff, MD, FACR, of Fairfax, VA is a board-certified radiologist and published author of the Amazon best-selling book *“Looking Within: Understanding Ourselves Through Human Imaging”*. He is in private practice with Fairfax Radiology Centers and is an associate professor of medical education at the University of Virginia. Dr. Ruff has authored numerous publications and articles in his field, and is the recipient of several teaching awards.

You may contact Dr. Ruff with your questions or comments by email at cullen.ruff@frcpc.org.

THE
2026-27

Medical-Dental-Legal
UPDATE

Radiology Update - What to Order and Why

Radiology Update: *What to Order and Why*

Cullen Ruff MD, FACR
Associate Professor of Medical Education
University of Virginia School of Medicine
Fairfax, VA

American College of Radiology

www.acr.org

Study appropriateness criteria
Accreditation
Manual on Contrast Media
Radiation concerns
Educational resources

Imaging Cons

- Cost
- Discomfort
- Radiation exposure
- IV contrast risk: renal, allergy
- Interventional procedure complications

Consider:

How will the results of the test affect the treatment of my patient?

No Contrast CT

Intracranial hemorrhage

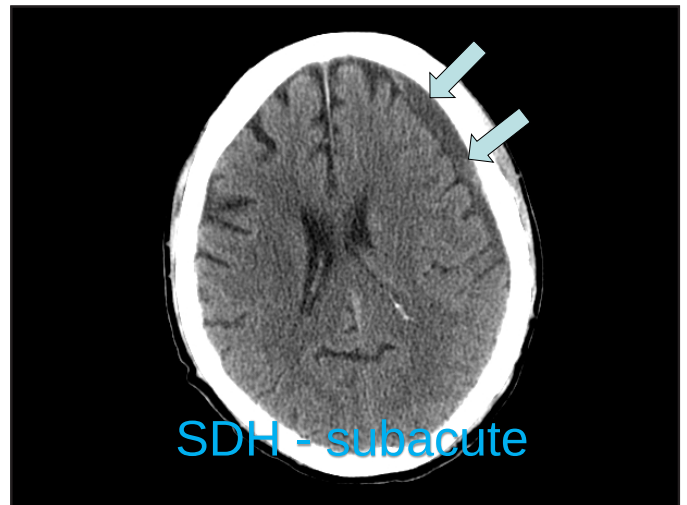
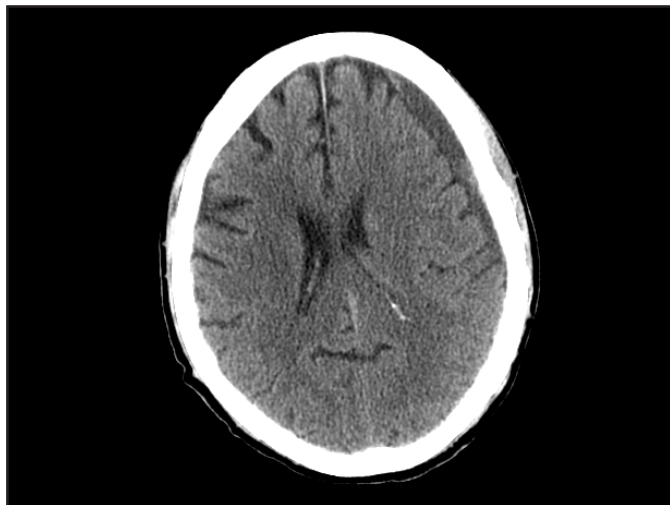
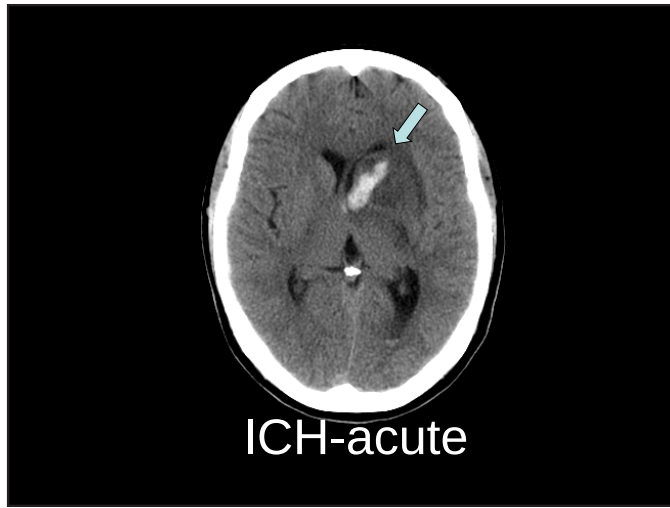
Kidney stones

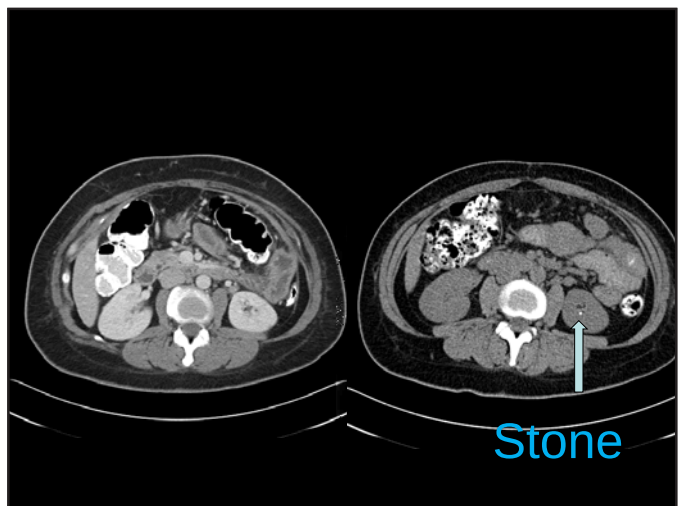
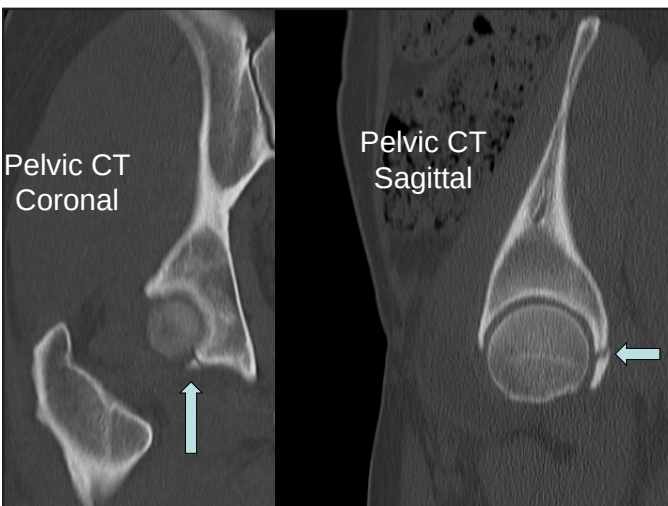
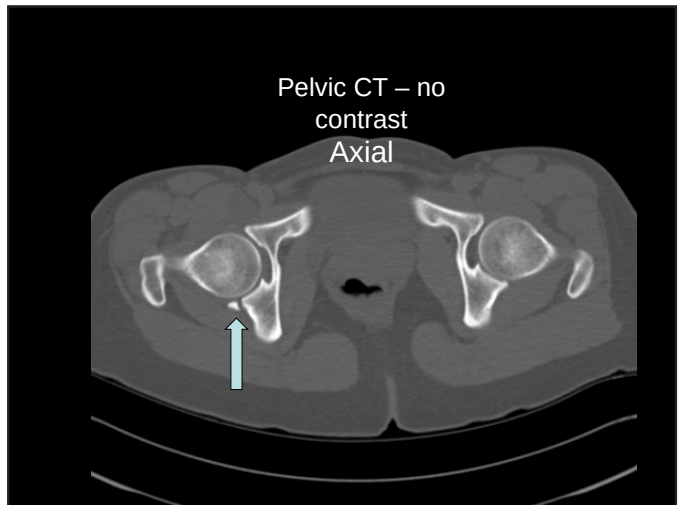
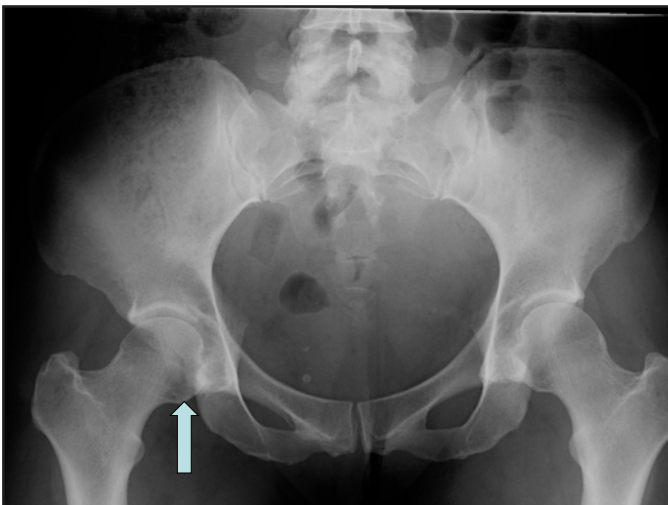
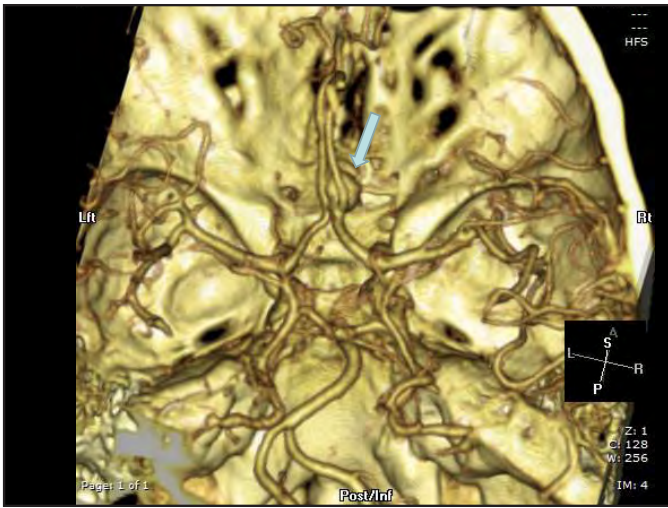
Lung disease, including nodule follow up

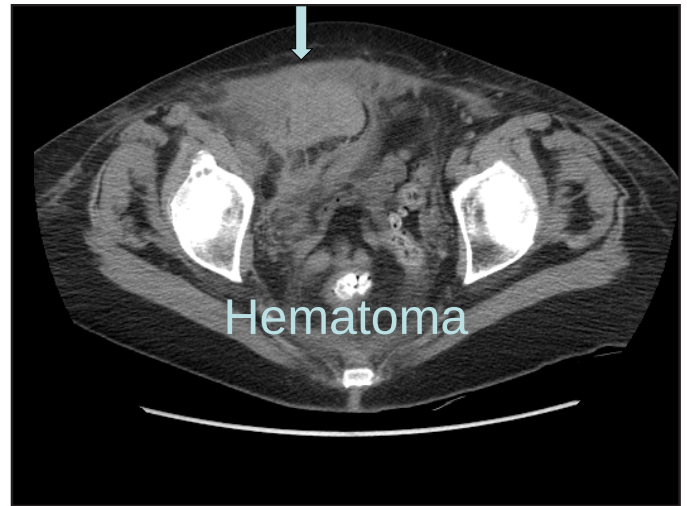
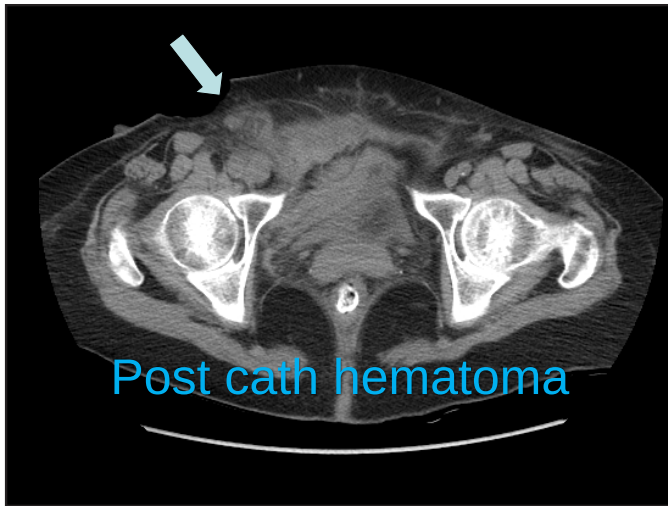
Fractures

Hematoma presence







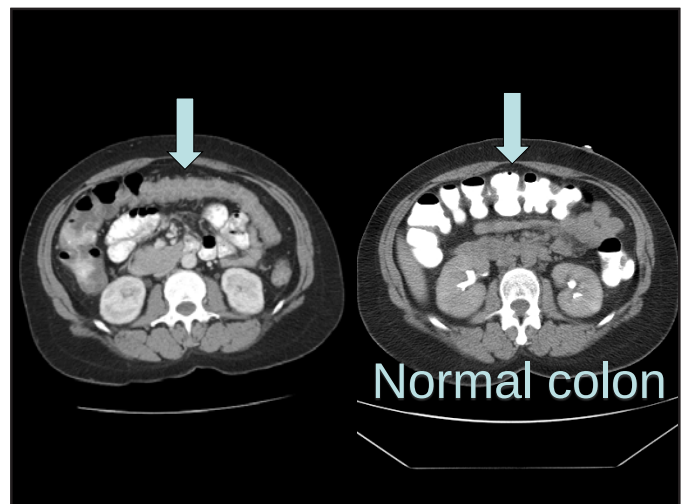
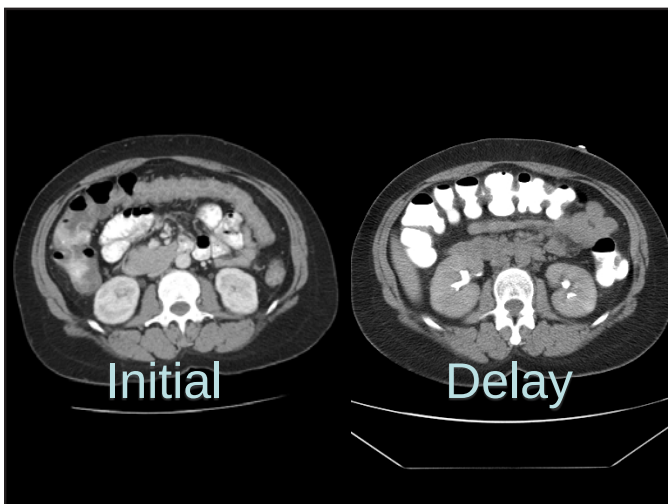


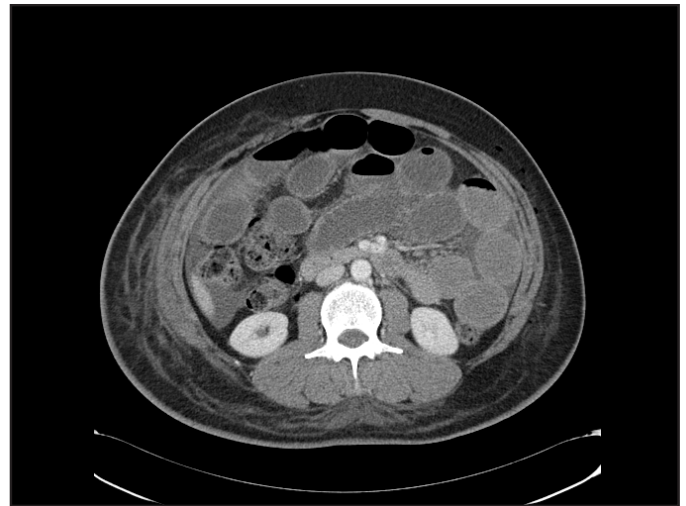
Oral Contrast

- 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 (pain, cancer, etc.)
- Exceptions:
 - Trauma
 - Bowel obstruction (if cannot tolerate)
 - Kidney stone protocol
 - CT angiogram (CTA)
 - CT urogram





IV Contrast

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

IV Contrast Complications

Iodine based (CT, angio):

- Allergy
- Nephrotoxicity

Gadolinium based (MRI):

- Nephrogenic systemic fibrosis (NSF)
- Allergy (rare)
- Tissue deposition

Renal Function

- Cutoff for CT contrast $\text{GFR} \geq 30$ ml/min/1.73 m²

Renal Function

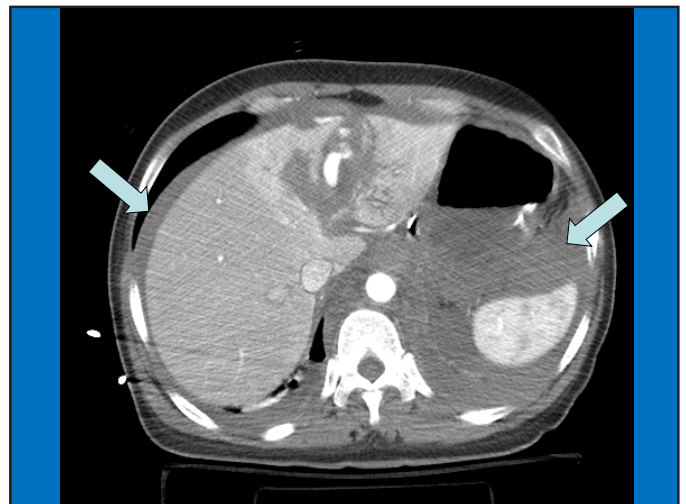
- Cutoff for CT contrast $\text{GFR} \geq 30$ ml/min/1.73 m²
- No issues if on permanent dialysis

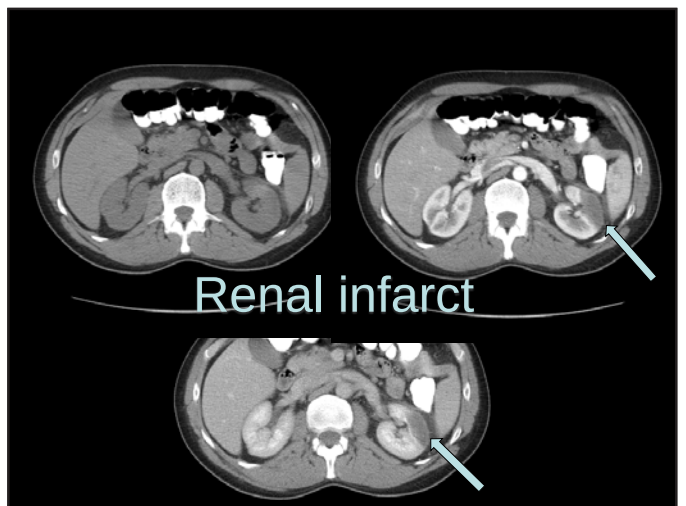
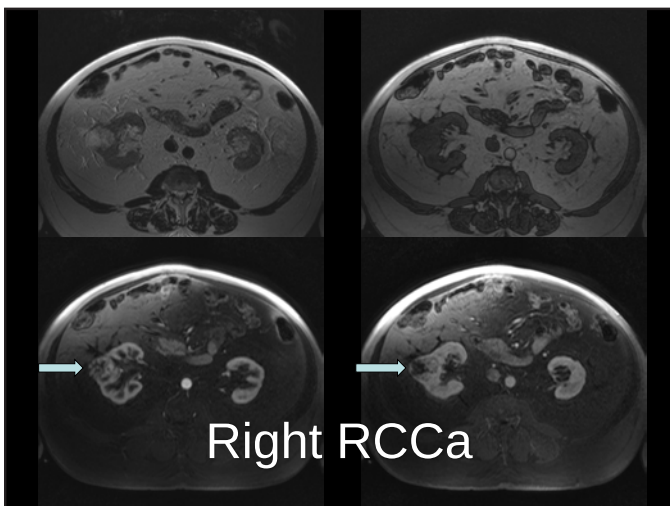
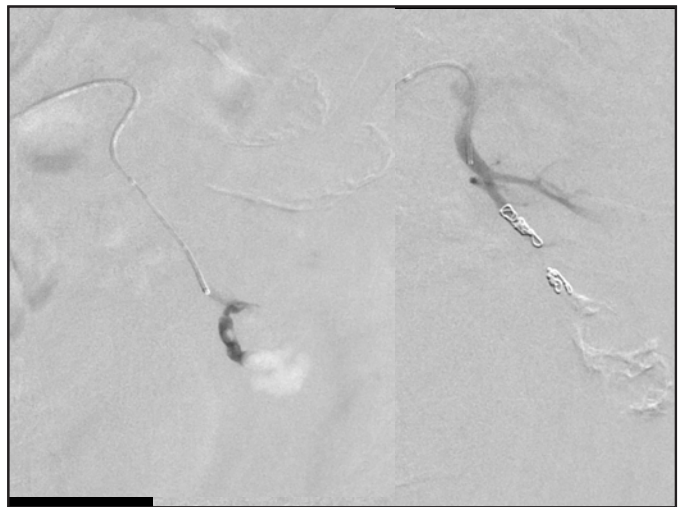
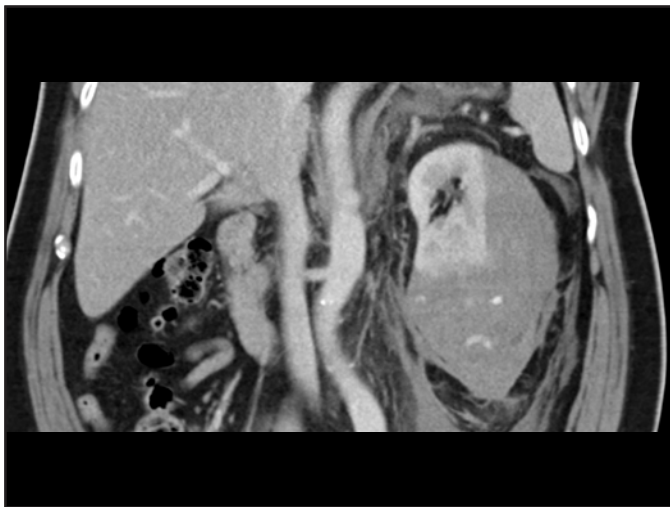
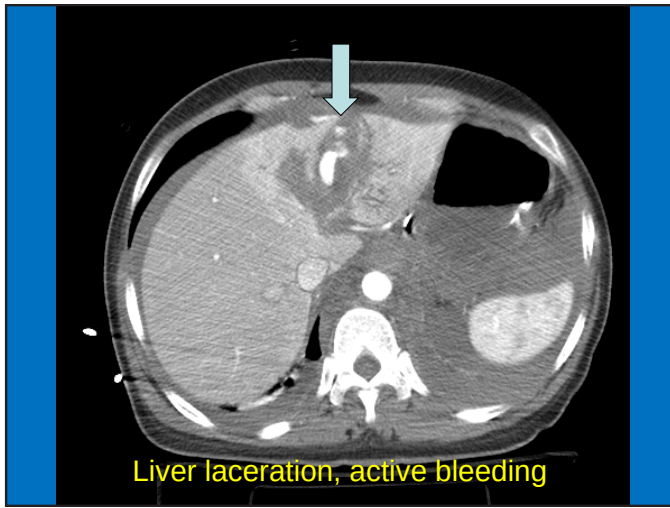
Renal Function

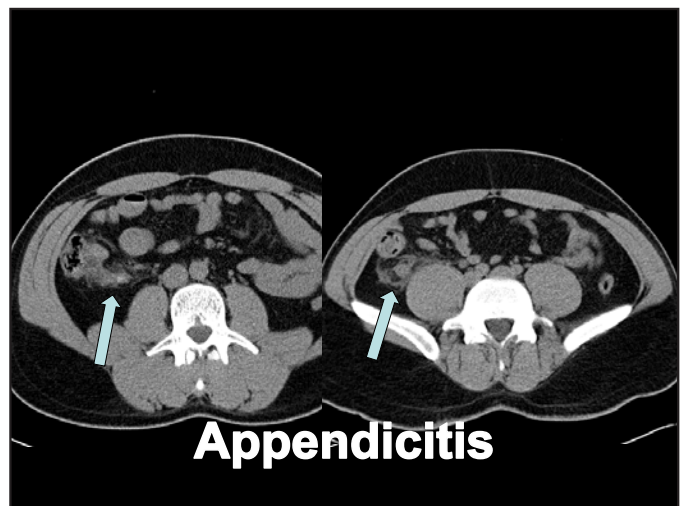
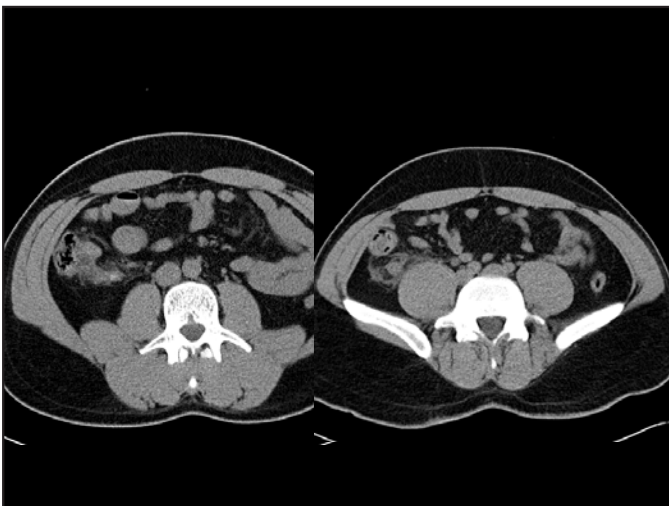
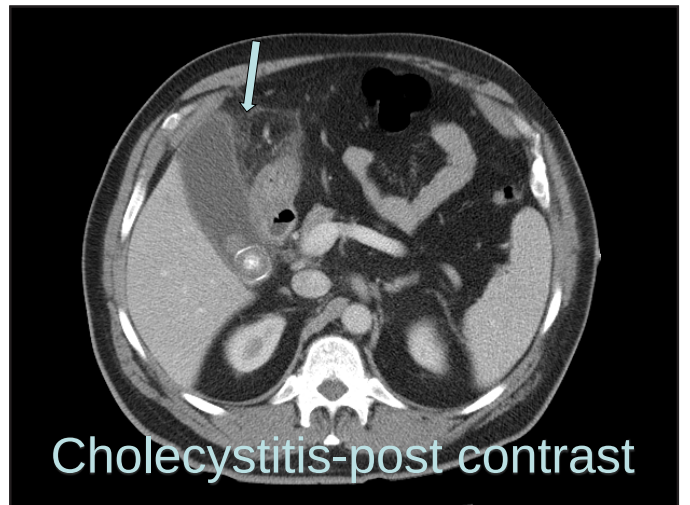
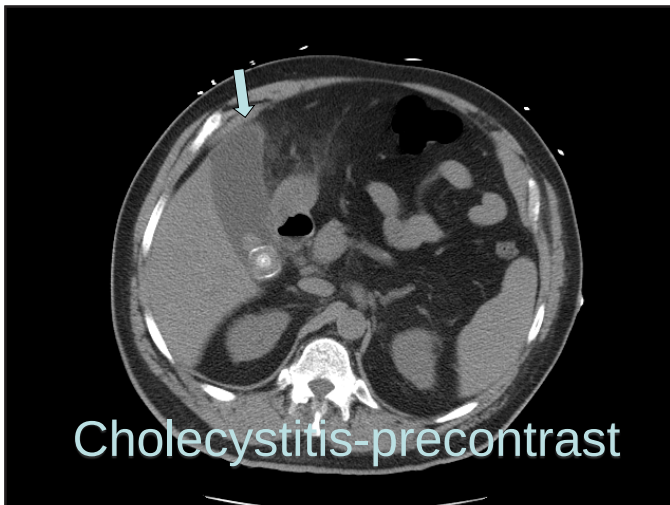
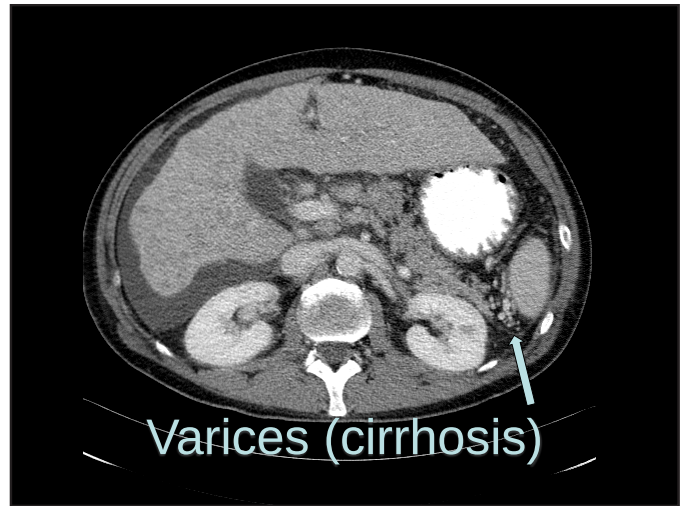
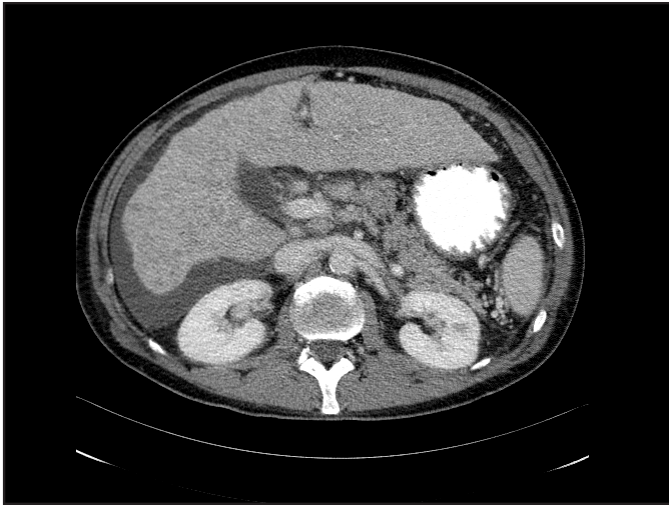
- Cutoff for CT contrast $\text{GFR} \geq 30$ ml/min/1.73 m²
- No issues if on permanent dialysis
- No GFR limits for most MRI contrast

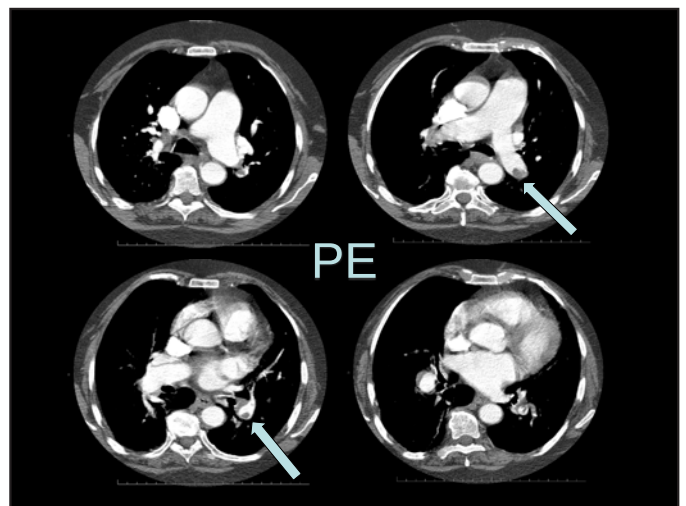
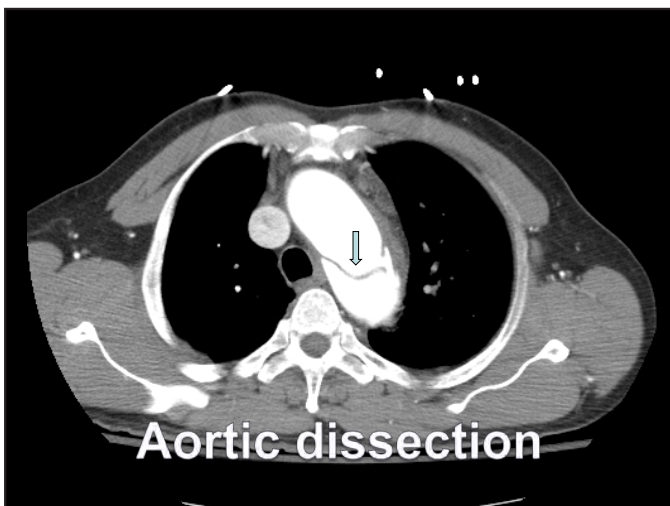
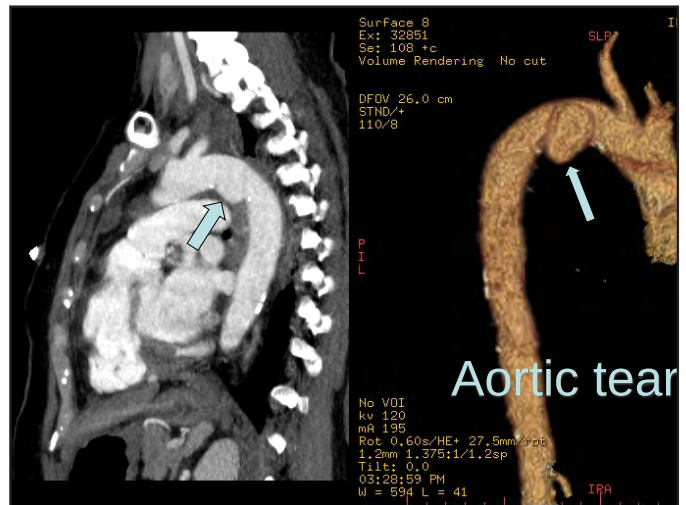
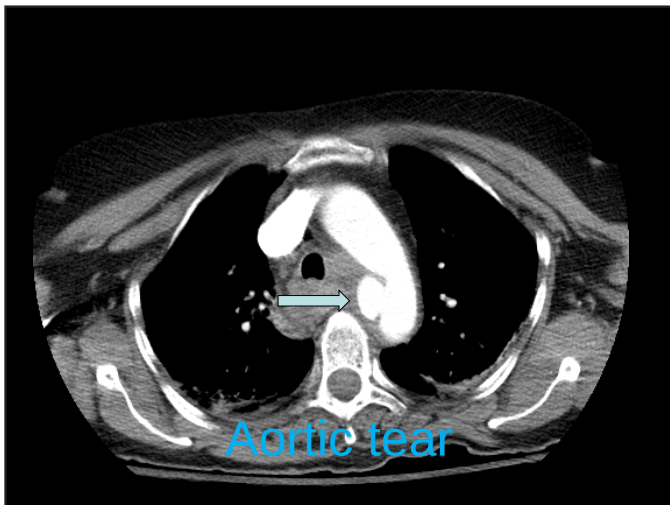
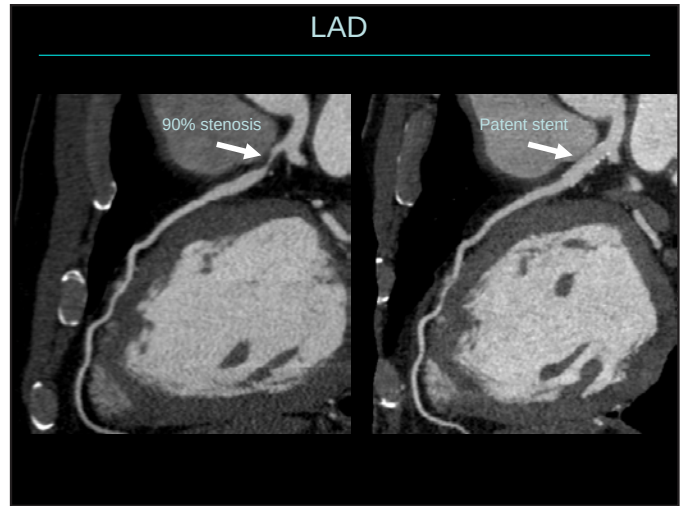
Renal Function

- Cutoff for CT contrast $\text{GFR} \geq 30$ ml/min/1.73 m²
- No issues if on permanent dialysis
- No GFR limits for most MRI contrast
- GFR no longer checked for Gadavist, Prohance, Clariscan due to negligible risk of nephrogenic systemic fibrosis (NSF)









Question

Lung nodule on chest CT, too small for PET or bx. F/U CT recommended.

The F/U chest CT should be done with IV contrast:

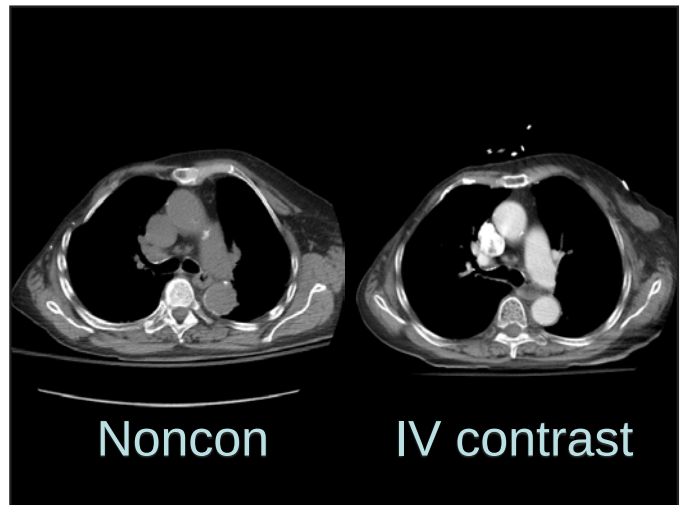
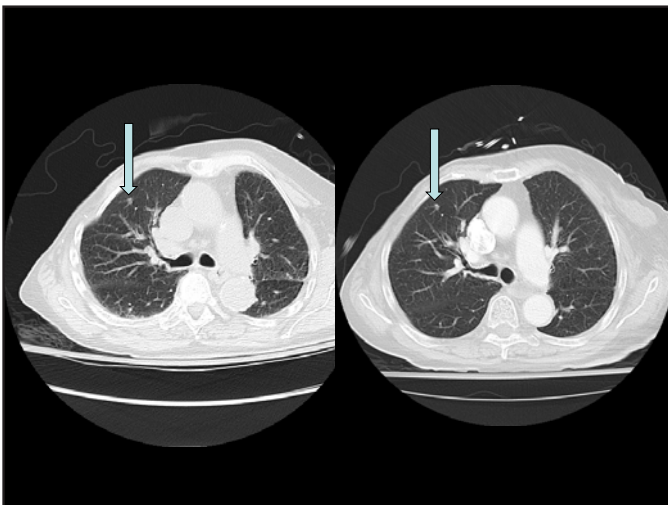
- A. True
- B. False

Question

Lung nodule on chest CT, too small for PET or bx. F/U CT recommended.

The F/U chest CT should be done with IV contrast:

- A. True
- B. False



With & without IV Contrast

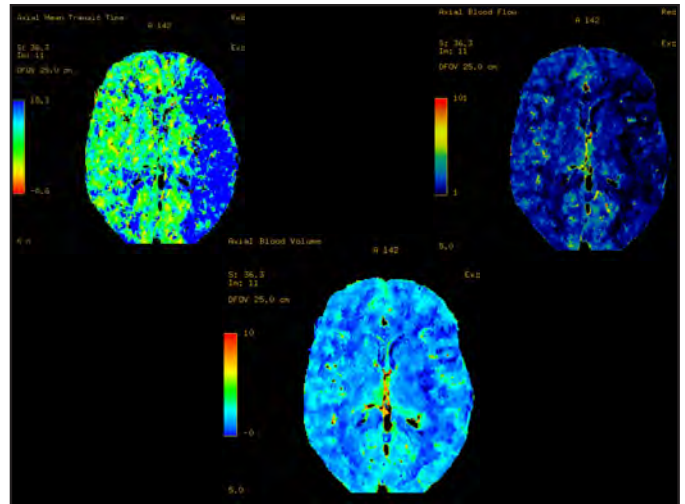
- Common in neuro, body MRI
- MSK MRI if tumor or infection
- Certain CT: endoleak, urogram, GI bleed, cardiac, brain perfusion

Endoleak

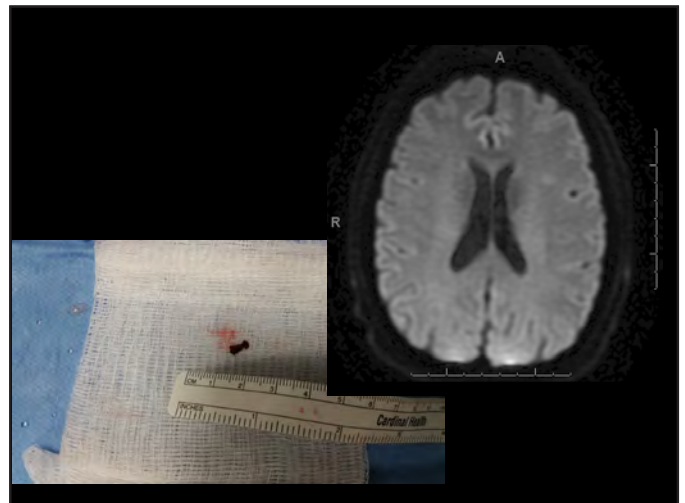
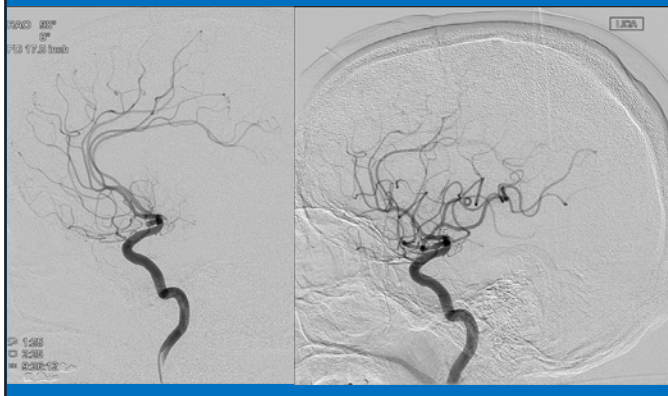


Acute Stroke Case

- 7:30 a.m.: 71M sudden onset aphasia + right sided weakness
- NIHSS = 18. Came to ER
- 8:30 a.m: NCCT done tPA given
- 9:00 a.m: CTA/P performed shows LMCA M1 occlusion and tissue at risk
- 9:30 a.m: Interv. Neuroradiology

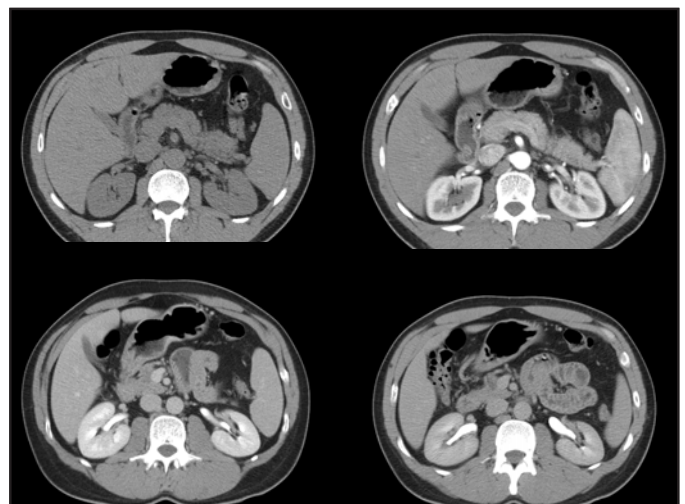


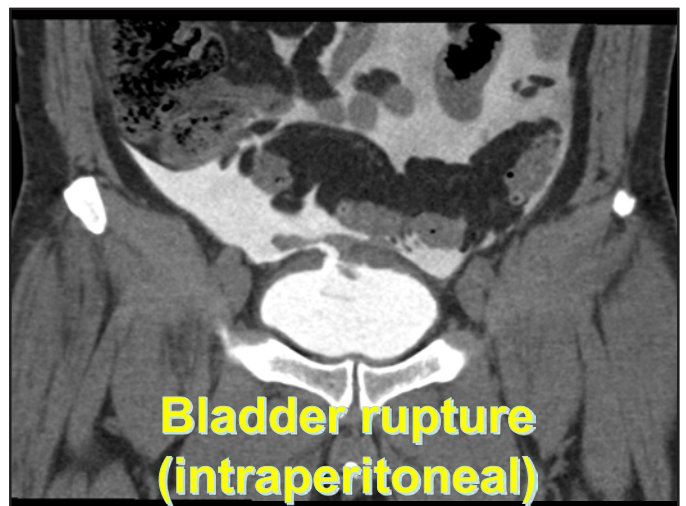
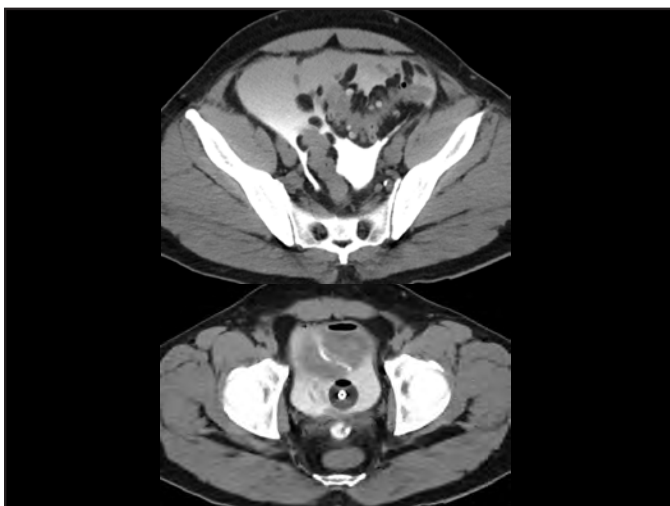
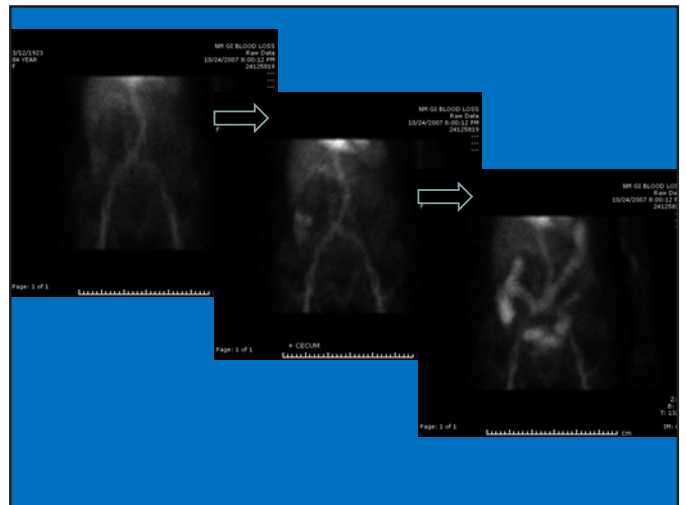
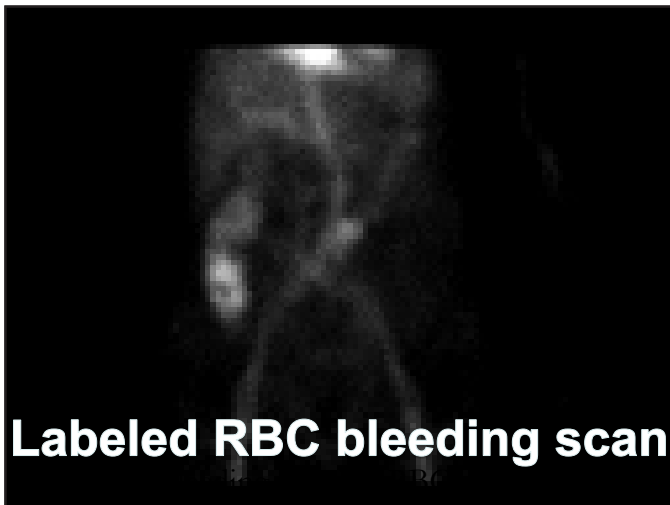
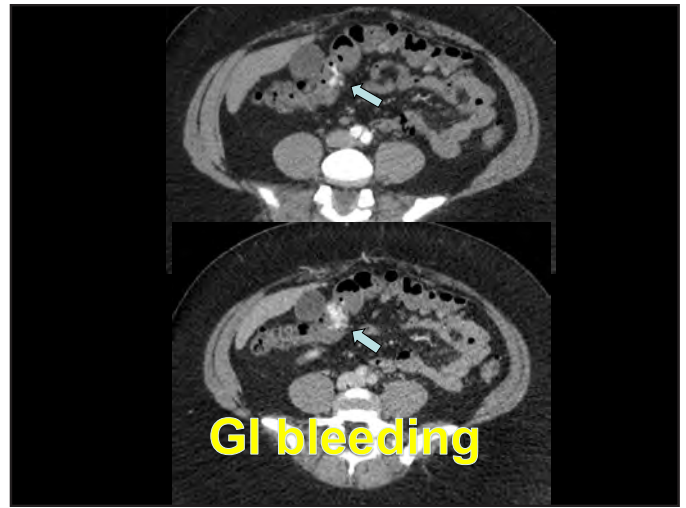
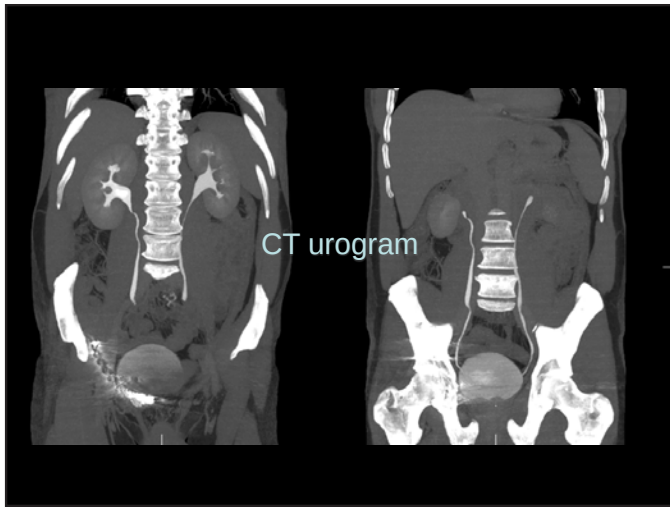
Neurointervention

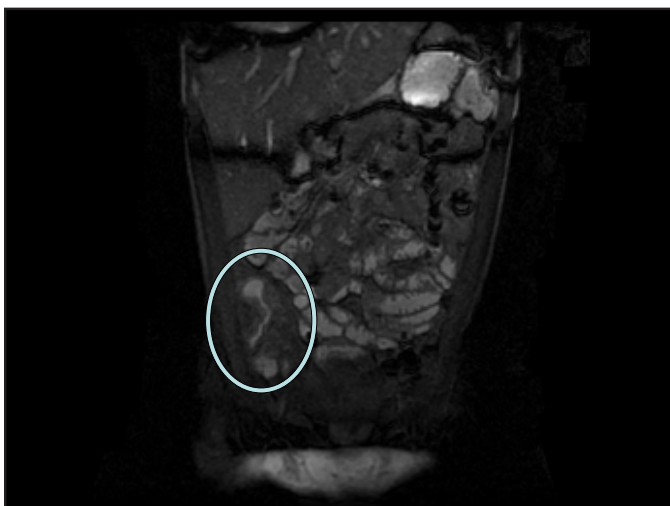
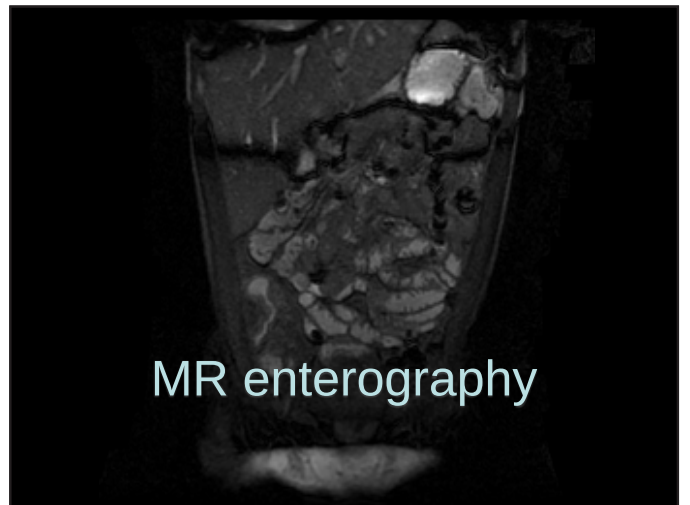
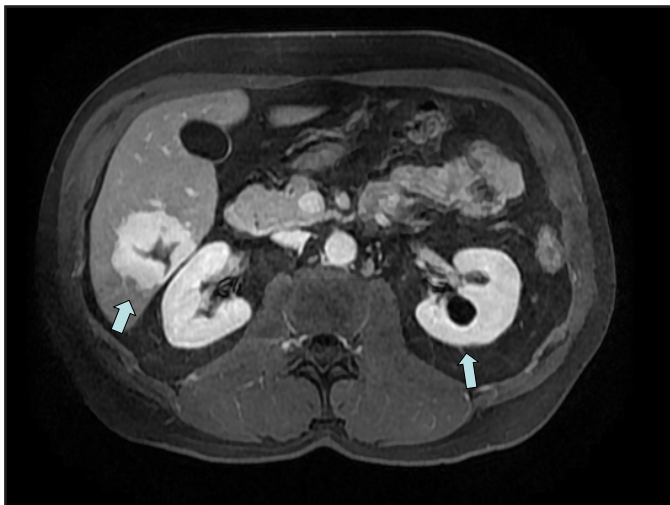
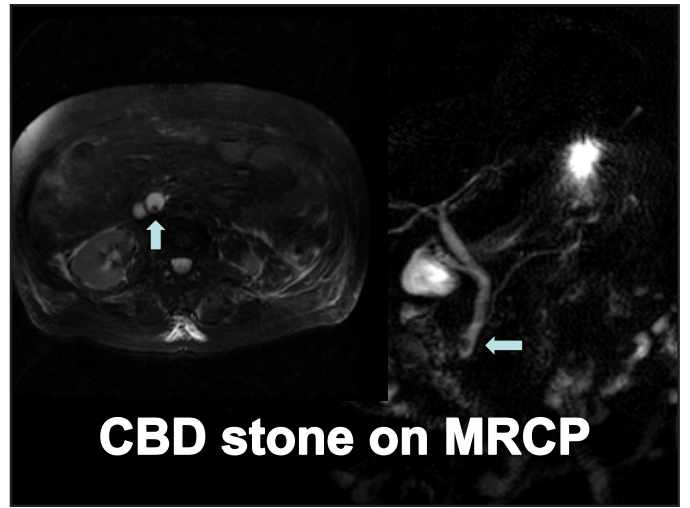
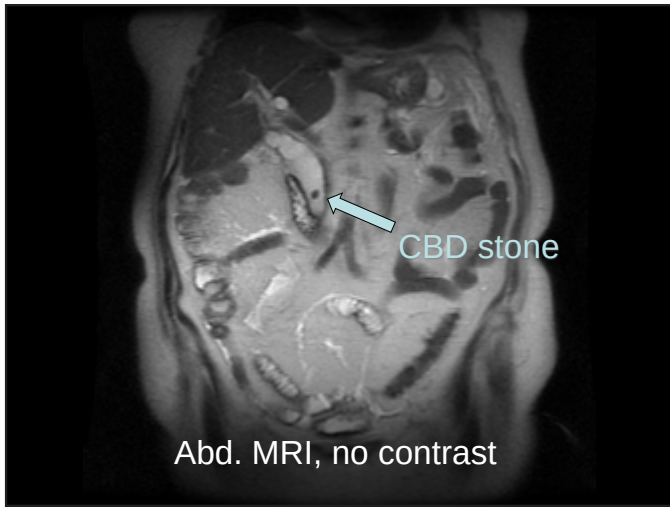


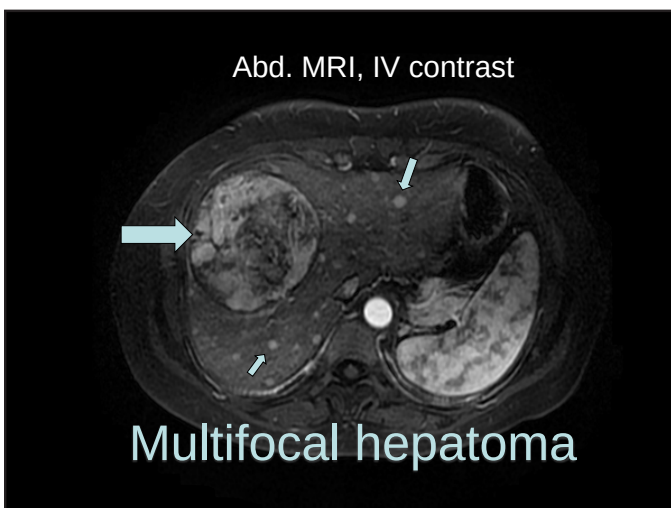
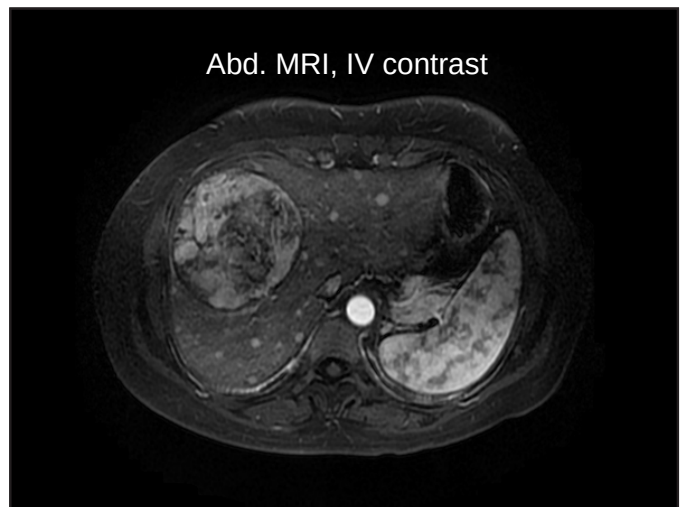
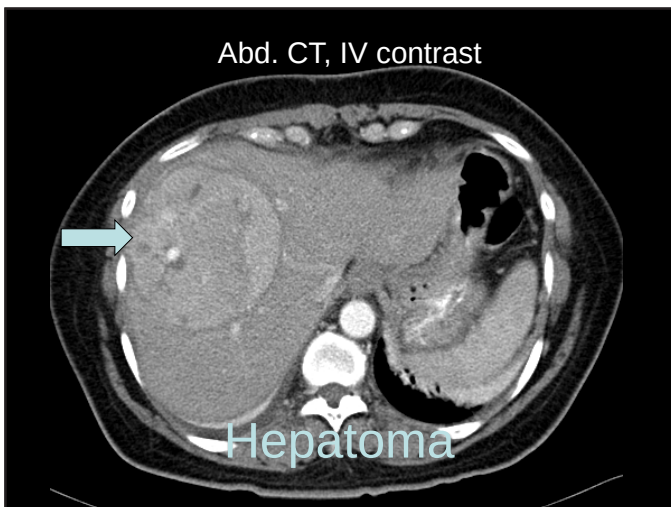
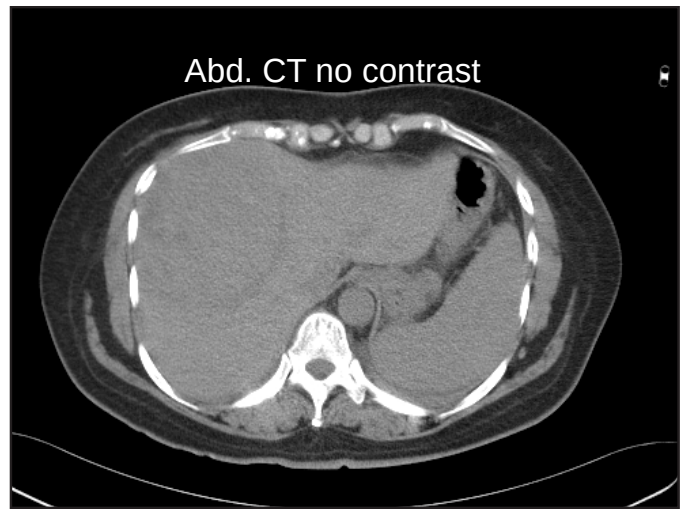
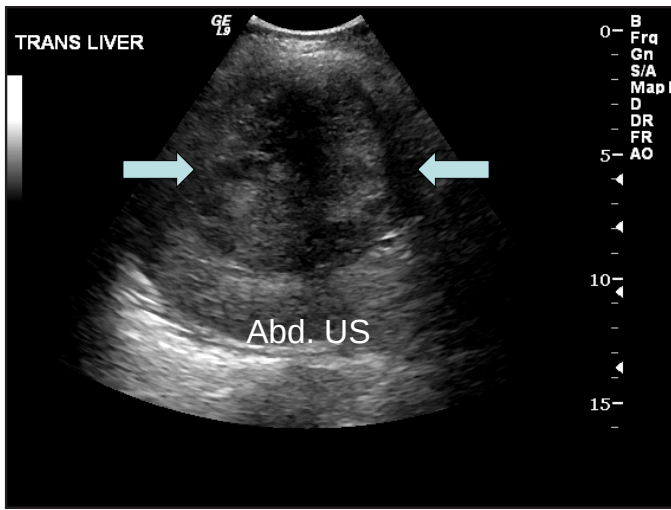
CT urogram

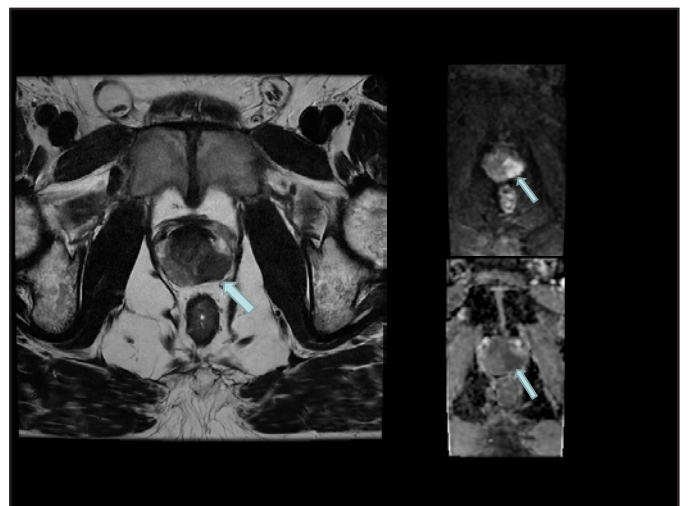
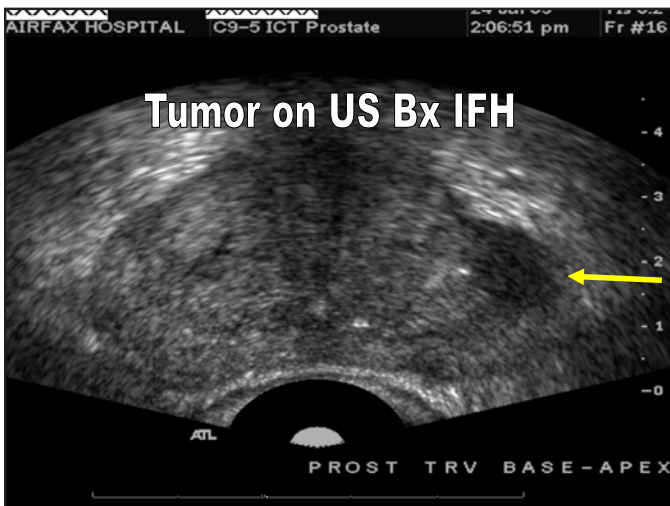
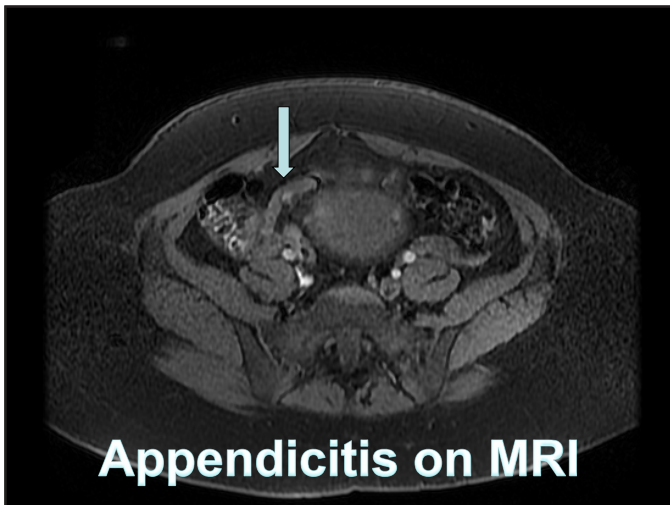
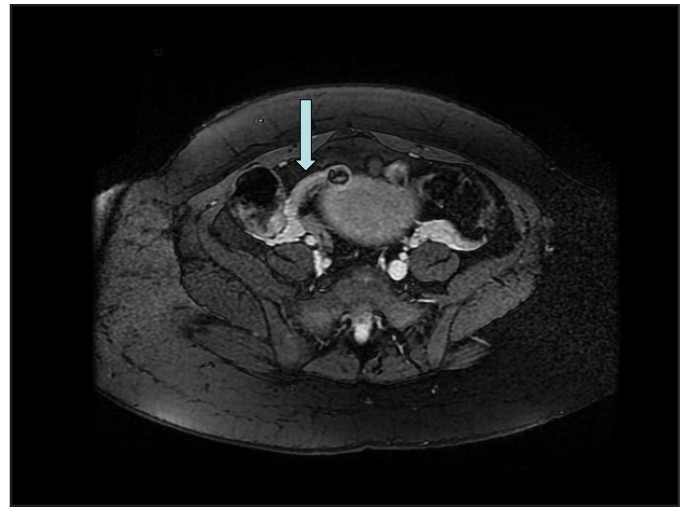
- Hematuria workup
- Simultaneously evaluates for stones, renal and urothelial masses



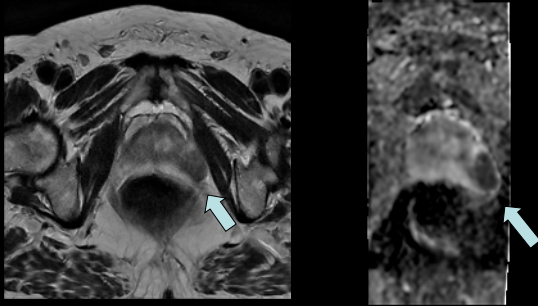






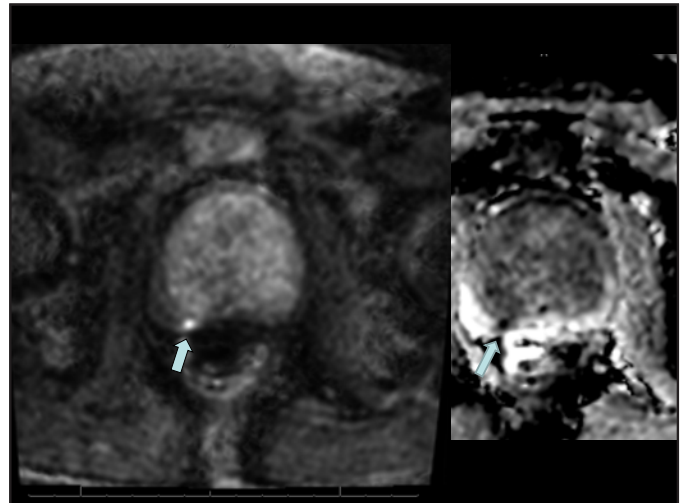
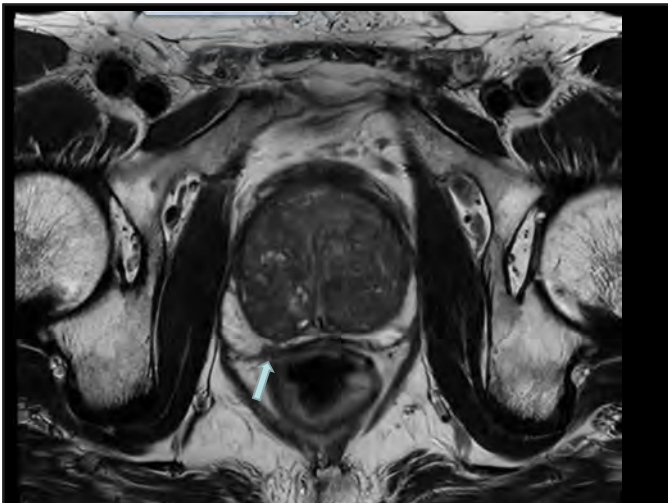
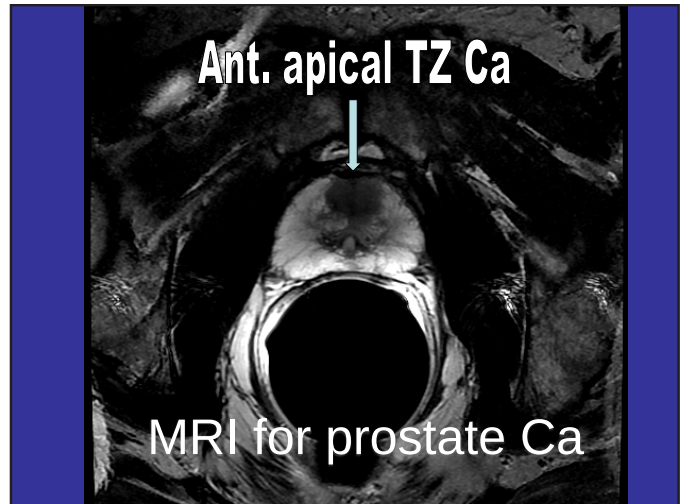


Prostate Ca with extracapsular extension

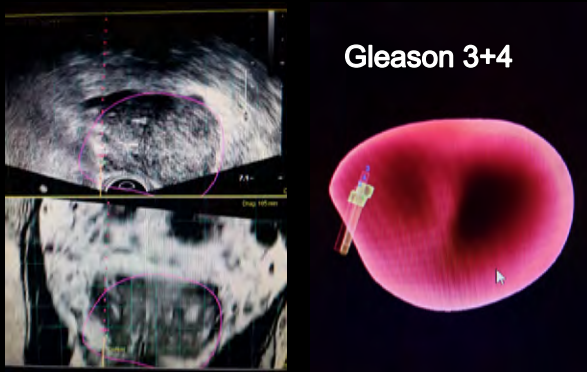


Ant. apical TZ Ca

MRI for prostate Ca



Gleason 3+4



Points:

- Different ways to do CT or MRI of same body part
- Good history benefits patient, ordering clinician, technologist & radiologist

Patients may be allergic to:

- A. Carbon
- B. Oxygen
- C. Iodine
- D. None of the above

Patients may be allergic to:

- A. Carbon
- B. Oxygen
- C. Iodine
- D. None of the above

“Iodine” Update

70-year pharmacological research
review confirms that
iodine is not an allergen

Wulf et al, *American Journal of Health-
System Pharmacy* 2021
(First Databank study)

Nobody is allergic to iodine

- “Iodine allergy” is nonsensical

Nobody is allergic to iodine

- “Iodine allergy” is nonsensical
- Slang for unrelated allergies:
 - 1) iodinated contrast agents
 - 2) iodine based soap
 - 3) shellfish (tropomyosin protein)

Iodinated contrast is not a single
substance, but a drug class:

- Ionic/hyperosmolar (older, more allergenic)
- Nonionic/low osmolar (newer, less
allergenic)

TERMINOLOGY IMPORTANT

Example Allergic to:

Drug Penicillin-G

TERMINOLOGY IMPORTANT

Example Allergic to:

Drug Penicillin-G

Drug class Antibiotics

TERMINOLOGY IMPORTANT

Example Allergic to:

Drug Penicillin-G

Drug class Antibiotics

Slang "Carbon"

TERMINOLOGY IMPORTANT

Example Allergic to: Allergic to:

Drug Penicillin-G

Iothalamate (Conray)

Drug class Antibiotics

Slang "Carbon"

TERMINOLOGY IMPORTANT

Example Allergic to: Allergic to:

Drug Penicillin-G Iothalamate (Conray)

Drug class Antibiotics Iodinated contrast

Slang "Carbon"

TERMINOLOGY IMPORTANT

Example Allergic to: Allergic to:

Drug Penicillin-G

Iothalamate (Conray)

Drug class Antibiotics

Iodinated contrast

Slang "Carbon"

"Iodine"

Avoid term “Allergic to Gadolinium”

Similar principles:

- More than one kind of MRI contrast
- Better to call agents by name, so may give substitute if someone is allergic to an agent

DISCUSSION

- By using accurate terminology, “Are you allergic to iodine based intravenous contrast” instead of “Are you allergic to iodine,” CT technologists found improved patient review prior to performing contrast CT ($p < 0.001$)

Ruff C and Overdeck D, “Improved CT Workflow Efficiency by Eliminating the Term *Iodine Allergy*”, American College of Radiology 2020 Annual Conference on Quality & Safety.

What Were Your Allergic Symptoms?

- Those who can name the symptoms of their reaction: 265 (86.3%)
- Those who provided no info on symptoms: 41 (13.7%)
- Most common reported prior reactions:
 - Hives and/or rash 153 (49.8%)
 - Dyspnea 30 (9.8%)
 - Anaphylaxis/throat closure 27 (8.8%)

When did allergic reaction occur?

(relevant to distinguish old ionic vs. nonionic)

- Year estimate reaction occurred: 113 (36.8%)
- “A long time ago”: 20 (6.5%)
- No info when reaction occurred: 173 (56.7%)

Where did reaction occur? *(relevant for retrieving old records)*

- Facility name or city/state provided: 125 (40.7%)
- Could not provide: 182 (59.3%)

Name the Contrast Agent Allergic to:

Name the Contrast Agent Allergic to:

- Other studies estimate 60-70% patient accuracy naming their drug allergies, improves to >90% with pharmacist counseling

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- 60% of our cohort would predict 184/307 patients could name their contrast allergy

Name the Contrast Agent Allergic to:

- 60-70% patient accuracy naming their drug allergies, improves to >90% with pharmacist counseling
- 60% of our cohort would predict 184/307 patients could name their contrast allergy
- Results: 5 of 307 (1.6%) ($p < 0.00001$)
(3 Ioversol [Optiray], 2 Iodixanol [Visipaque]. One additional patient knew "non-ionic contrast")

Ruff C, Banayan E, Overdeck D: "Patients Have Very Limited Knowledge of Their Contrast Allergies," *Clinical Imaging* Vol. 79 Nov. 2021, 319-322.
<https://doi.org/10.1016/j.clinim.2021.11.002>

Why is it important to know which agent?

- 1. Mild reactions to older agents may not require premedication

Why is it important to know which agent?

- 1. Mild reactions to older agents may not require premedication
- 2. Switching agents is more effective than premedication

Premedication for prior contrast reaction:

Three doses Prednisone 50 mg po 13, 7, & 1 hrs. before contrast, + Benadryl po 1 hr prior

Rapid alternative: Solumedrol 40 mg IV 5 hrs and 1 hr. before contrast, + oral Benadryl 1 hr. prior

Prior mild reaction (90% allergy-like 10% GI)

1178 pts/3533 repeat injections, no steroid prep
31% recurrence if re-exposed to same agent
12% recurrence if different agent
7.6% recurrence if different agent + antihistamine

Park SJ et al. Immediate Mild Reactions to CT with Iodinated Contrast Media: Strategy of Contrast Media Readministration without Corticosteroids, *Radiology* Vol. 288, No. 3, 2018

Prior moderate to severe reaction

150 pts/328 repeat injections
19.5% recurrence
Steroids did not decrease rate of severe reaction
*67% lower reactions when switched agents

Park HJ et al. Re-exposure to low osmolar iodinated contrast media in patients with prior moderate-to-severe hypersensitivity reactions: A multicentre retrospective cohort study. *Eur Radiol* 2017 Jul 27(7): 2886-2893.

Prior moderate to severe reaction

**Premedication ineffective at preventing recurrent severe reactions to CT contrast.
Switching agents more effective.**

McDonald J et al, *Radiology* August 2021. Prevention of Allergic-Like Reactions at Repeat CT: Steroid Pretreatment vs. Contrast Material Substitution.

Abe S, Fukuda H, Tobe K, Ibukuro K. Protective effect against repeat adverse reactions to iodinated contrast medium: Premedication vs. changing the contrast medium. *Eur Radiol* 2016; 26(7):2148–2154.

Cha MJ et al. Hypersensitivity Reactions to Iodinated Contrast Media: A Multicenter Study of 196,081 Patients. *Radiology* 2019; 293:117-124.

MRI Contrast Hypersensitivity Reactions

- Incidence acute reactions 0.4%
- Delayed reactions 0.04%
- Switching agents more effective in preventing acute reactions
- Premedication also helps prevent acute reactions
- Premedication more effective at preventing delayed reactions
- Patients with CT contrast allergy 4.6 times more likely to react to MR contrast

Yoon Hae Ahn et al. Allergic-like Hypersensitivity Reactions to Gadolinium-based Contrast Agents: An 8-year Cohort Study of 154 539 Patients

Radiology vol. 303, no. 2, 2022.

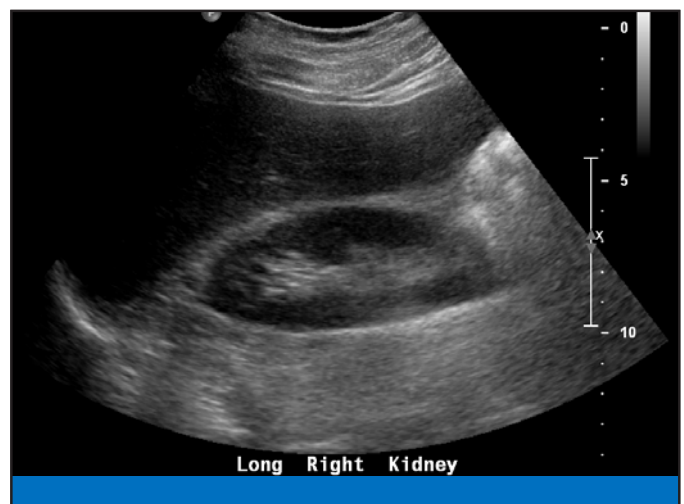
<https://doi.org/10.1148/radiol.2020545>

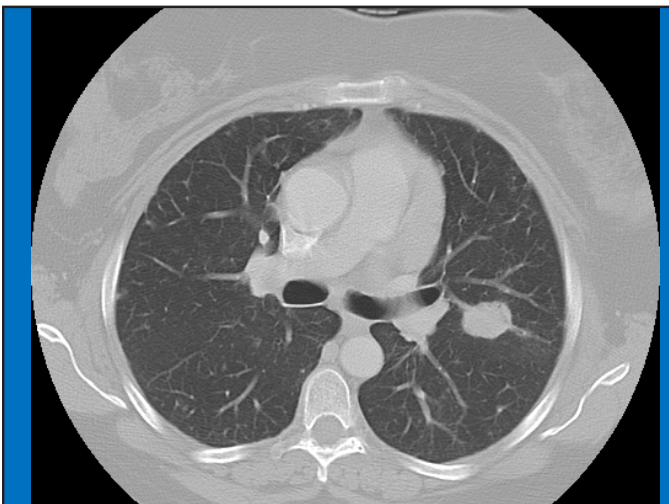
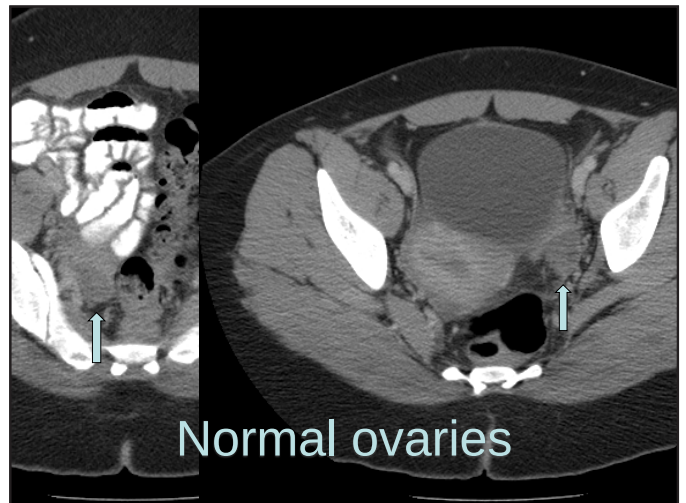
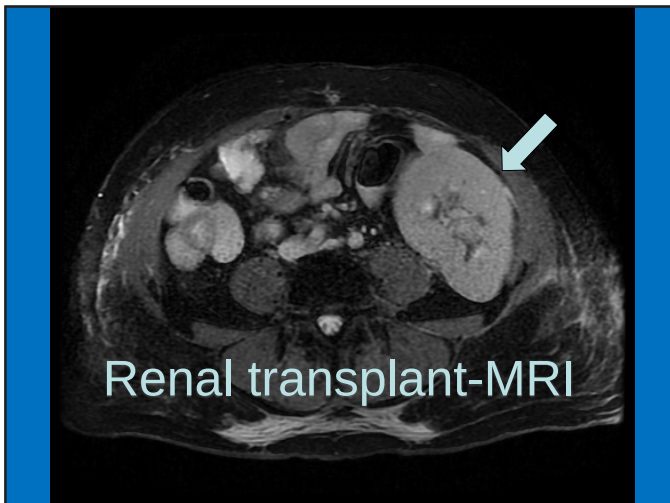
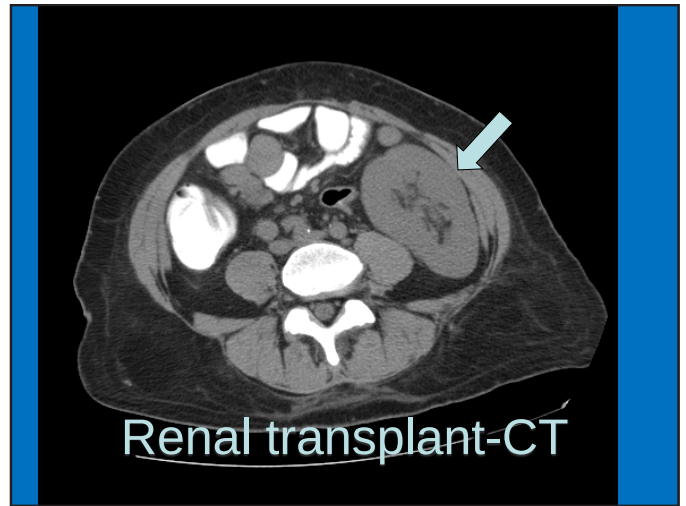
Question

A patient has renal insufficiency. A recent CT/MRI was performed without contrast.

Q. Renal US should be performed to rule out hydronephrosis/obstruction.

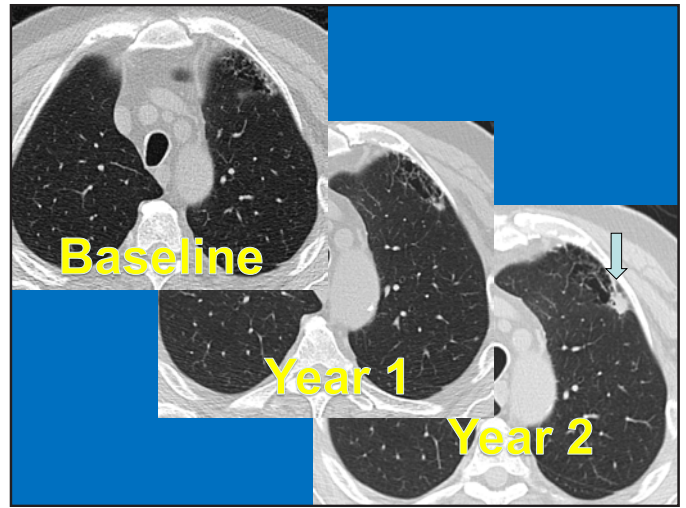
- A. True
- B. False





Cancer Screening/Workup

Lung
Colon
Breast
Thyroid



Fleischner Society Lung Nodules

Nodule follow up recommendations revised
in 2017

Higher threshold, follow nodules ≥ 6 mm

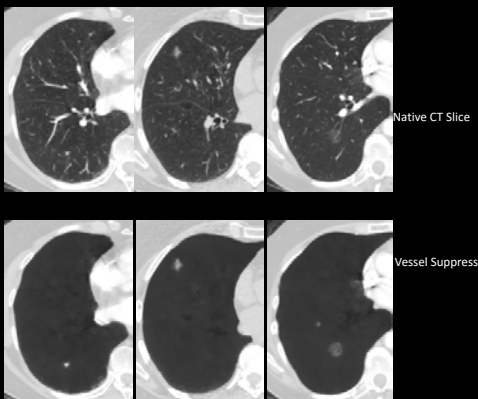
Guidelines for Management of Incidental Pulmonary Nodules Detected on CT
Images: From the Fleischner Society 2017
(Radiology July 2017 volume 284 issue 1)

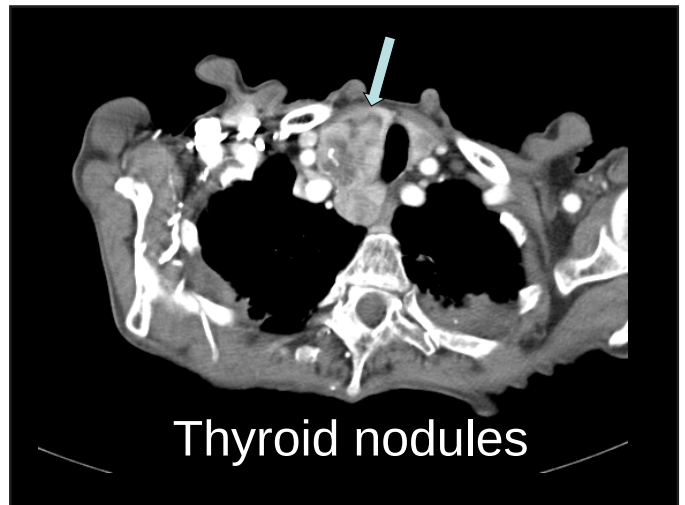
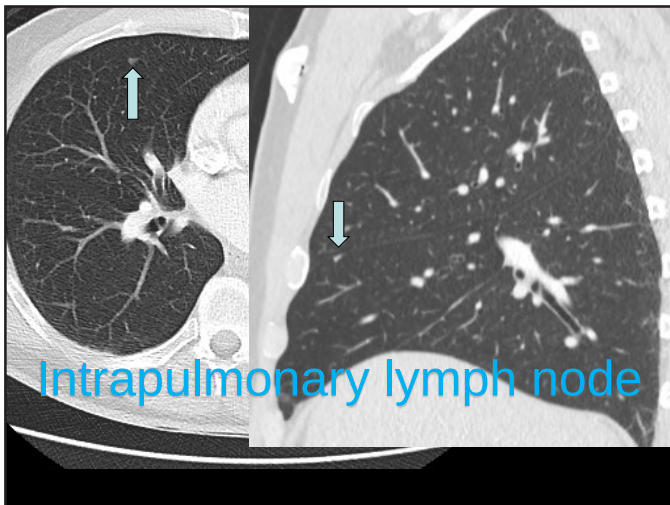
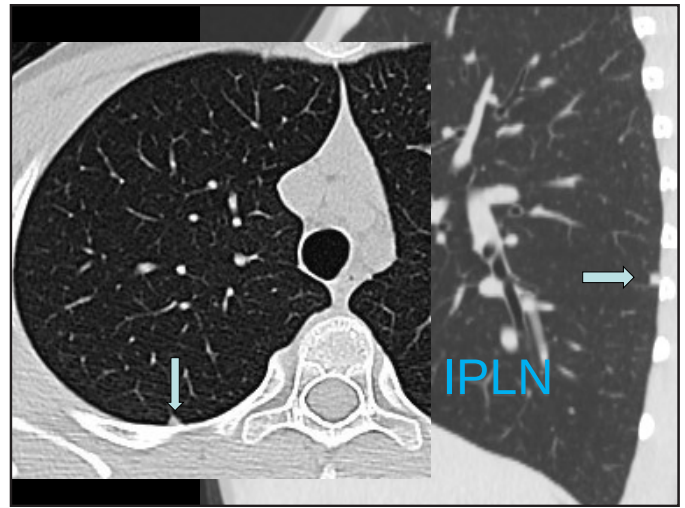
Fleischner Society Lung Nodules

Reminders:

1. Nodule diameter is the mean, not the maximum
e.g. 6 x 4 mm nodule = 5 mm nodule,
no follow up
2. Patients >35 years old

CT Vessel Suppression-Lung Nodules





US workup for incidental thyroid nodules on CT/MRI

Age ≥ 35 : Nodule > 1.5 cm

Age < 35 : Nodule > 1.0 cm

JACR 2015 Feb;12(2):143-50. doi: 10.1016/j.jacr.2014.09.038.
Managing incidental thyroid nodules detected on imaging: white paper of
the ACR Incidental Thyroid Findings Committee.

CT Colonoscopy (Virtual Colonoscopy)

Pros:

Essentially noninvasive
Faster, safer
Easier—if negative
No sedation
Similar sensitivity for
polyps > 5 mm
Sees outside the colon

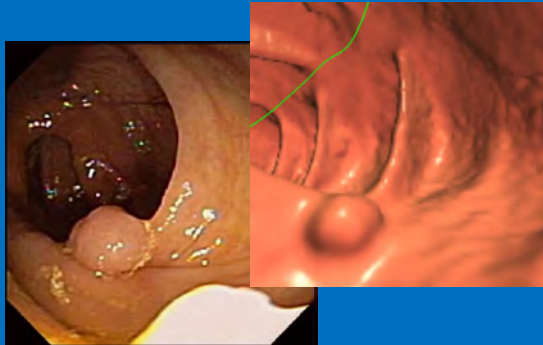
Neutral:

- Requires prep

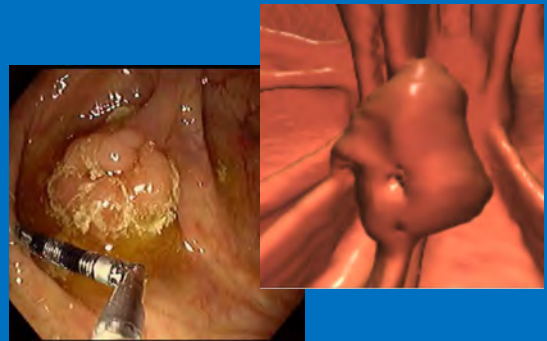
Cons:

- Less sensitive for polyps < 5 mm
- Coverage variable
- Dx only: + get scoped

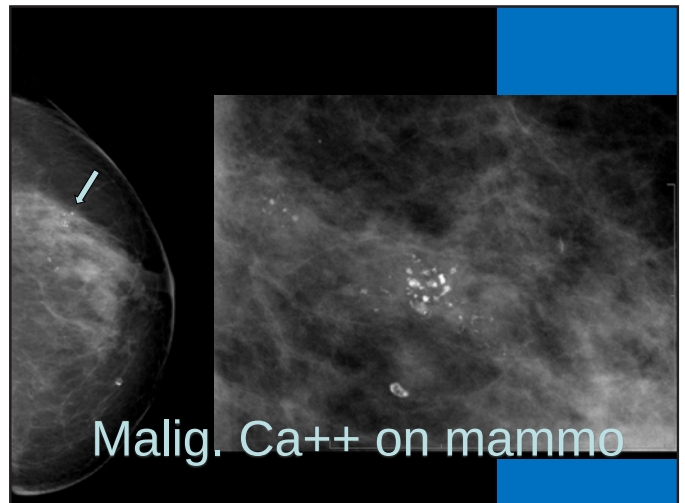
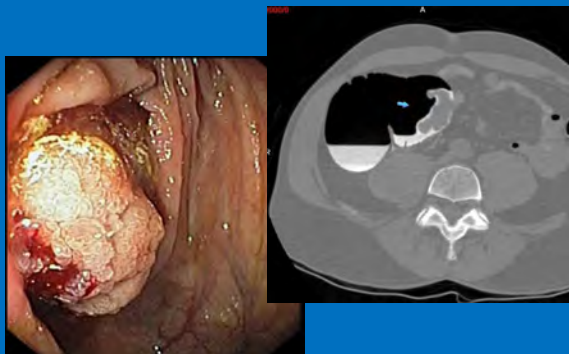
Sessile Polyp



Tubulovillous Adenoma



Adenocarcinoma

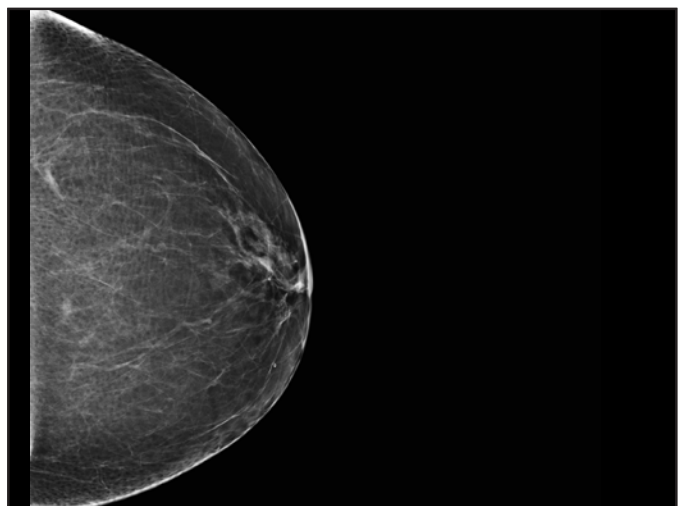


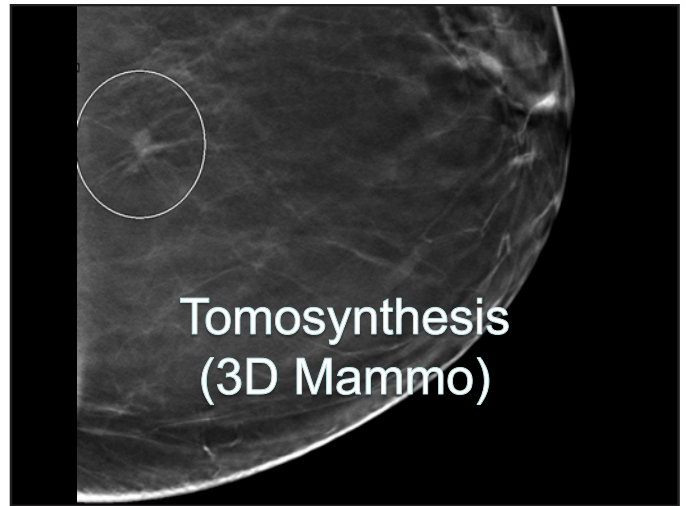
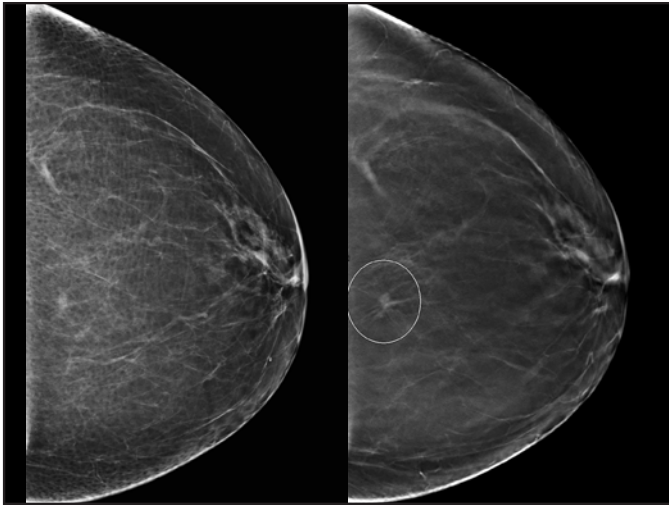
Breast Cancer Screening

USPSTF 2024: screening
mammogram age 40 (formerly 50)

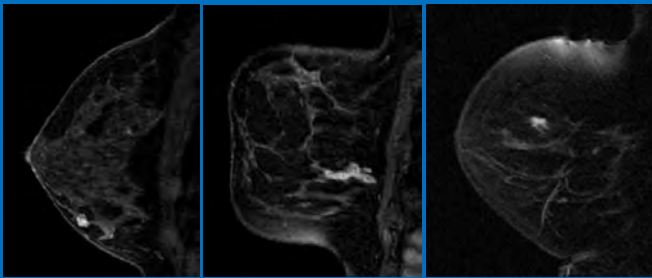
Frequency recommendations vary

American College of Radiology
and Society of Breast Imaging:
annual

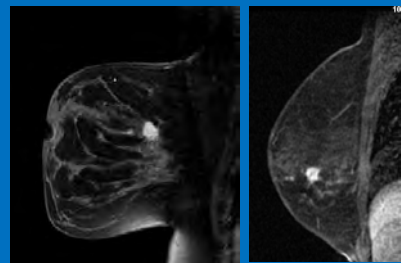




High risk screening



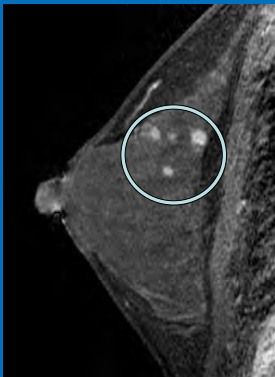
Breast MRI



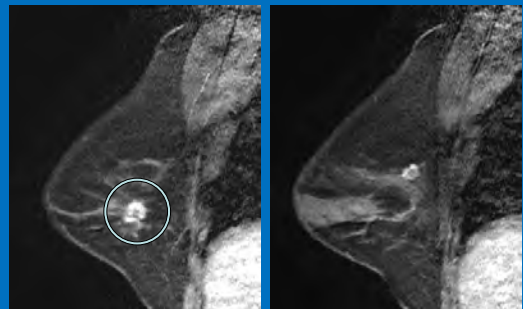
Distortion one view only
Normal US
Invasive lobular carcinoma

Asymmetry
Normal US
Invasive ductal carcinoma

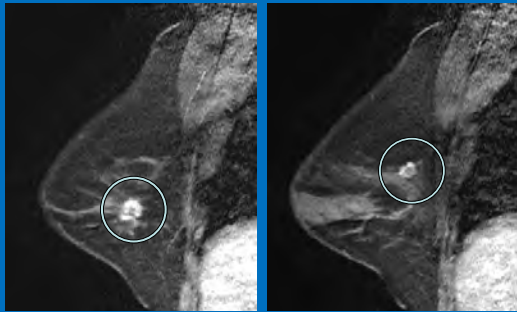
Pre-operative planning Tumor extent: Multifocal disease



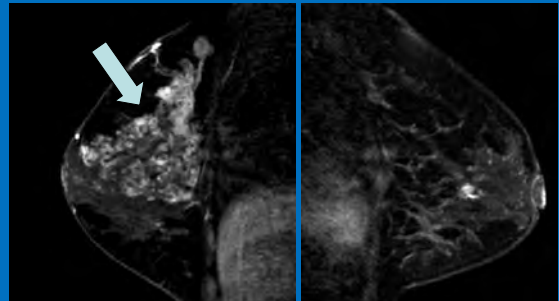
Pre-operative planning Tumor extent: Multicentric disease



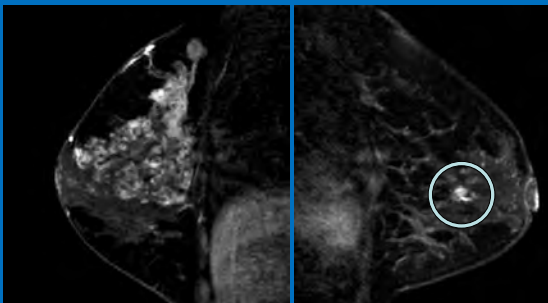
Pre-operative planning
Tumor extent: Multicentric disease



Pre-operative planning
Contralateral Breast



Pre-operative planning
Contralateral Breast



FINAL POINTS:

- No one best test for all pathology
- Multiple ways to perform CT, MRI
- Order efficiently
- Provide History & Goal
- Imaging constantly evolving

American College of Radiology www.acr.org

SELF EVALUATION

Radiology Update - What to Order and Why

1. The best study for visualizing acute intracranial hemorrhage is:
 - a. Head CT without contrast
 - b. Head CT with contrast
 - c. MRI (magnetic resonance imaging)
 - d. MRI with contrast
 - e. Cerebral angiogram
2. T/F - Patients may be allergic to elemental iodine.
3. 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
 - c. A & B
4. 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
 - d. All of the above
5. T/F - To prevent future intravenous contrast reactions in patients with previous allergic-like reaction, switching contrast agents is more important than steroid and antihistamine premedication.
6. The best study to evaluate most newly discovered liver masses is:
 - a. Ultrasound
 - b. MRI
 - c. CT
 - d. Nuclear medicine scan
7. The best test to detect appendicitis in a pregnant woman is:
 - a. ultrasound
 - b. MRI without contrast
 - c. CT
8. 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
9. 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
 - d. complications
 - e. there is negligible risk of colorectal perforation
 - f. detected significant lesions typically require subsequent conventional colonoscopy for biopsy or removal
10. 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

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

FACULTY

Deepak S. Patel, MD, FAAFP, FACSM

Deepak S. Patel, MD, FAAFP, FACSM, is a family and sports medicine physician and serves as Medical Director of Rush Copley Sports Medicine and Assistant Professor at Rush Medical College in Chicago. He maintains an active clinical practice and has held numerous leadership roles in medical education, including Director of Sports Medicine for the Rush Copley Family Medicine Residency. Dr. Patel is a nationally recognized expert in sports and musculoskeletal medicine, has authored and edited multiple publications and textbooks including *Concussion Management in Primary Care* and regularly presents at national and regional CME conferences. He serves as a subject matter expert and chair for multiple AAFP CME programs and is a member of the AAFP Education Advisory Panel for Emergency and Urgent Care.

You may contact Dr. Deepak with any questions or comments at Deepak_S_Patel@Rush.edu.

THE
2026-27

Medical-Dental-Legal
UPDATE

Subpoenas, Depositions, and the Role of the Medical Expert Witness Deepak S. Patel, MD, FAAFP, FACSM

Subpoenas, Depositions, and the Role of the Medical Expert Witness

Deepak S. Patel, MD, FAAFP, FACSM
Assistant Professor, Rush Medical College, Chicago, IL
Medical Director, Rush Copley Sports Medicine, Aurora
Family Medicine and Sports Medicine, Yorkville Primary
Care, Yorkville, IL
Chair/Subject Matter Expert for AAFP Sports Medicine,
Musculoskeletal Medicine & ER/Urgent Care CME

My experience

- Sports Medicine, Family Medicine practice,
- National Presenter/Chair/Subject Matter expert Sports , Musculoskeletal, ER/Urgent Care Medicine CME
- Concussion consultant: multiple area school districts
- Author/Editor
- Expert Witness/Deps
 - Defense & Plaintiff

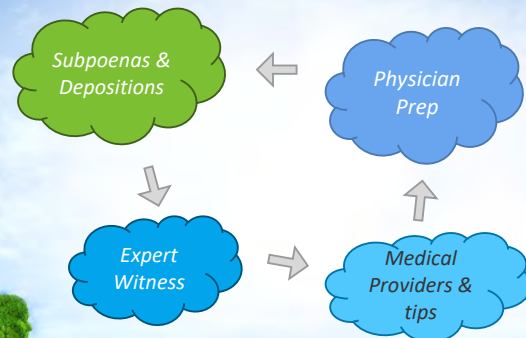


Objectives

By the end of this session, attendees will be able to:

- Differentiate types of subpoenas
- Identify expectations of medical expert witness
- Select appropriate medical experts in legal proceedings
- Prepare medical experts for deposition and cross examination

Overview

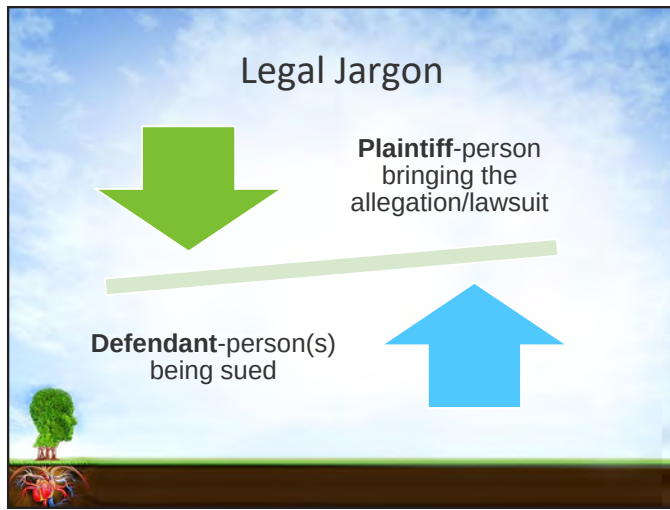


Injury Risks?



Injury Risks?

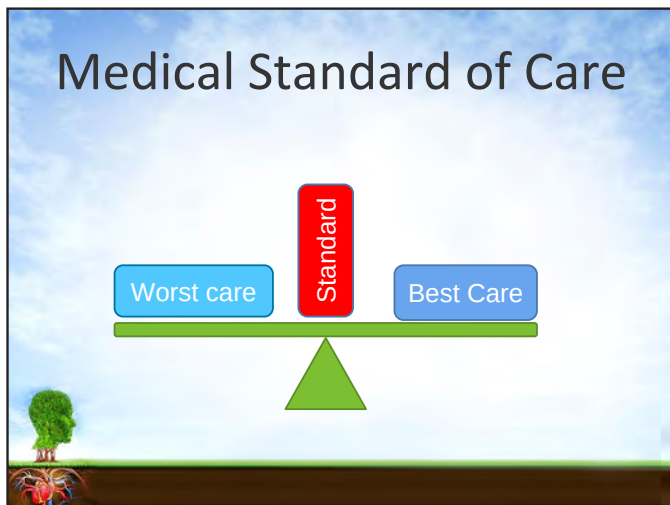




Medical Standard of Care

- NOT beyond a reasonable doubt!
- Most states adopt from Connecticut Code §52-184c: "...that level of care, skill and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar health care providers."

Vanderpool D. The Standard of Care. Innov Clin Neurosci. 2021 Jul-Sep;18(7-9):50-51. PMID: 34980995; PMCID: PMC8667701.



Medical Standard of Care (in order)

1. Statutes: federal and state, (prescribing laws)
2. Regulations: federal and state, (confidentiality rules)
3. Court opinions: such as duty to warn of dangerous patient case decisions
4. Other regulatory statements: federal and state, (Licensing board guidelines)
5. Authoritative clinical guidelines: guidelines are not the standard of care, but are a factor that. Following guidelines doesn't remove negligence, deviating also doesn't. Reason & clinical judgment to deviate from guidelines should be documented.
6. Professional organization policies & guidelines (APA or AACAP)
7. Journal/research articles
8. Accreditation standards
9. Facility policies and procedures

Vanderpool D. The Standard of Care. Innov Clin Neurosci. 2021 Jul-Sep;18(7-9):50-51. PMID: 34980995; PMCID: PMC8667701.



Deposition Subpoena

- Legal requirement, appear w attorneys & court reporter
- Certified letter, occasionally also a fax
- Under oath
- Facts & info finding
- Computer, Now over Zoom
- Plaintiff attorney, Defense attorney, court reporter, occasionally the patient

Deposition Tips

- Under oath
- Often recorded (Reshown at trial? Transcript?)
- Short answers-Avoid over-speaking, stick to facts
- Be polite and cooperate
- Understand the case/chart/charges
- Remain within specialty/expertise/own care & avoid presumptions for other providers
- May answer "I don't know"
- Request repeat/rephrase, or clarify
- Hypothetical questions, not always yes/no answer.

<https://test.phyins.com/magazine/art-good-deposition>

Tips for Medical Providers

- Stay calm, objective, honest
- Jury level (8th grade) explanations
- Stick to facts of case, avoid elaboration
- Define "a reasonable degree of medical certainty" (NOT BEYOND A REASONABLE DOUBT)
- Prepare for tough cross examination, even personal, financial motives, etc
- Literature search, if needed

<https://www.aafp.org/about/policies/all/physician-expert-witness.html>
Reyes, Carlo MD, JD. At Your Defense: Tips for Being an Effective Expert Witness. Emergency Medicine News 41(10):p 32, October 2019. | DOI: 10.1097/01.EEM.0000586488.57901.7e

Medical Expert Witness

Medical Experts, What?



Medical Expert Witness, WHO?

- Practicing medicine
- Physicians, APP (PA, NP), RN, PT, DC, DDS, etc.
- Same specialty in question (in-patient, surgical, ambulatory, etc)
- Ideally Experience with patient population and medical event

Medical Expert Witness, Why?

- Improve standard of care
- Use expertise/knowledge
 - Learn more?
- Educate attorneys on medical facts
- Defend colleagues
- Improve your own medical care & documentation
 - Chart audits
 - Exposure to serious complications

Medical Expert Witness, Time?

- Case review & prep when free
- Set your case load, just say NO
- Set your rate
- Consider a retainer, prepare invoices
- Schedule attorney meetings, depositions, trials etc: PTO
- Virtual depositions!!!
- Timeline: years



Medical Expert Witness, Process?

- Chart review-
- Patient records leading up to and after the "event"
- Bills, ambulance, police, coroners,
- Legal proceedings,
- Other Depositions,
- Provide objective opinions
 - research if needed



AMA Code of Ethics

Experts Must:

- Accurately represent their qualifications.
- Testify honestly
- Not allow their testimony to be influenced by financial compensation. Physicians must not accept compensation that is contingent on the outcome of litigation.



<https://code-medical-ethics.ama-assn.org/ethics-opinions/medical-testimony>

AMA Code of Ethics

- Testimony about own patients:they must hold the patient's medical interests paramount by:
- Protecting the confidentiality of the patient's health information, unless the physician is authorized or legally compelled to disclose the information.
- Delivering honest testimony. This requires that they engage in continuous self-examination to ensure that their testimony represents the facts of the case.
- Declining to testify if the matters could adversely affect their patients' medical interests unless the patient consents or unless ordered to do so by legally constituted authority.

Considering transferring the care of the patient to another physician if the legal proceedings result in placing the patient and the physician in adversarial positions.



<https://code-medical-ethics.ama-assn.org/ethics-opinions/medical-testimony>

AMA Code of Ethics

- Physicians who testify as expert witnesses must:
- Testify only in areas in which they have appropriate training and recent, substantive experience and knowledge.
- Evaluate cases objectively and provide an independent opinion.
- Ensure that their testimony:
 - reflects current scientific thought and standards of care that have gained acceptance among peers in the relevant field;
 - appropriately characterizes the theory on which testimony is based if the theory is not widely accepted in the profession;
 - considers standards that prevailed at the time the event under review occurred when testifying about a standard of care.



<https://code-medical-ethics.ama-assn.org/ethics-opinions/medical-testimony>

Medical Info For Attorneys



Question

Medical Doctors receive slightly more training to Physician Assistants/Associates & Nurse Practitioners?

- A. True
- B. False

Medical Providers

- MD, DO, MBBS (India): Bachelors, Medical school x4 yrs,
 - Residency > 3 yrs specialty, board certification
 - Clinical hrs: medical school: 6000 hrs
 - Family Medicine residency : 15000 hrs
- Physician Assistant (Associate): PA
 - Bachelors, PA school x2 yrs
 - Clinical hrs: 2000
 - few residencies, No specialty specific boards, can change fields
- Nurse Practitioner: NP
 - Bachelors Nursing (BSN), masters NP
 - Clinical Hrs: 500
 - New Doctorate in Nursing
 - Few specific specialty boards, can change fields
- Chiropractor: DC, Doctorate Chiropractic x 4yrs
- Physical Therapist: Masters, now Doctorate Physical therapy x 4 yrs
- Dentist (DDS), doctorate 4 yrs of dental school.

<https://www.patientsatrisk.com/differences>



My World of Questioning

Primary Care

- Family Medicine: Birth to Grave
- Internal Medicine: Adults
- Pediatrics: birth to ?22
- OB/Gyn: Women's health

Concussion specialists

- Sports Medicine
- PM&R
- Neurology
- Neurosurgery
- Neuropsychologist

Concussion Pearls

- Many signs and symptoms
- Loss of conscious: not accurate
- CT: not accurate
- MRI: limited value
- Proper Evaluation by experience clinician
 - Sports Med vs Neuro

Concussion: CT or MRI?

- Whenever suspicion of an intra-cerebral structural lesion exists
 - Prolonged disturbance of conscious state
 - Focal neurological deficit
 - Worsening symptoms
- AMSSM, Choosing wisely: "Avoid ordering a brain CT or brain MRI to evaluate an acute concussion unless there are progressive neurological symptoms, focal neurological findings on exam or there is concern for a skull fracture".²

1. McCrory P, Meeuwisse WH, Aubry M, et al. Consensus statement on concussion in sport: the 4th International Conference on Concussion in Sport held in Zurich, November 2012. *Br J Sports Med*. 2013;47:250-258.
2. American Medical Society for Sports Medicine; Five Things Physicians and Patients Should Question <http://www.choosingwisely.org/doctor-patient-lists/american-medical-society-for-sports-medicine/> accessed 6/1/2014

ORTHOPEDICS/MUSCULOSKELETAL

Orthopedics/Musculoskeletal Specialists

- Surgical: Orthopedic Surgeon
- Spine Surgeon: Orthopedic or Neurosurgery
- Nonsurgical: Sports medicine, PM& R, Rheumatology, Pain management, Chiropractor, Physical Therapist, Urgent Care, Family/Internal medicine
- Radiologist: experts in imaging reading

Orthopedic Caveats



Osteoarthritis common



Pain often subjective

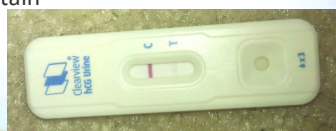


Imaging: x-rays, MRI, CT often not answer

Clinical correlation required

Fracture Diagnosis-Imaging

- X-ray preferred
- 3 views preferred (AP, LAT oblique)
- Fracture lucency seen on >1 view
- Repeat xray in 10-14 days may demonstrate findings
- CT/MRI an option if uncertain
 - \$\$\$



47 y/o Ankle pain

Initial

10 days after



MRI

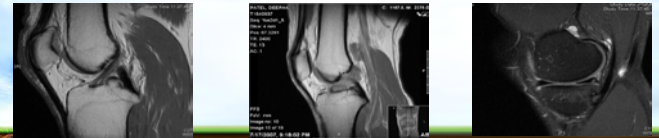
MRI

PROS:

- Excellent anatomic detail:
 - Muscle, Tendon, Ligament,
 - Meniscus, Cartilage,
 - Bone injury (contusion, stress fracture)

CONS:

- Cost (\$)
- Availability
- Requires clinical correlation
- PRIOR AUTHORIZATION?



Back Pain

Lumbar & Spinal Asymptomatic Abnormal MRI

- Lumbar: Asymptomatic Disk herniation's (22-60%).
 - MRI preferred, clinical correlation validity (SOR:C)
- Spinal cord abnormal in asymptomatic:
 - 19 Studies, 3786 pts
 - Asymptomatic Spinal Cord Compression 24.2%



Chou R, Qaseem A, Snow V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med.* 2007; 147: 478-491.
 Lawel, H, Patel, D., "What is the Role of Imaging in Acute Low Back Pain" *Current Reviews in Musculoskeletal Medicine*. Published online 4/28/09 (DOI: 10.1007/s12178-008-9037-0)
 Smith SS, Stewart ME, Davies BM, Kotter MRN. The Prevalence of Asymptomatic and Symptomatic Spinal Cord Compression on Magnetic Resonance Imaging: A Systematic Review and Meta-analysis. *Global Spine Journal.* 2021;11(4):597-607. doi:10.1177/1053426920941866

Degenerative Lumbar MRI

- 3369 patients
- Followed for 6 yrs, with and without back pain.
- 76.4% >1 abnormal MRI finding
- 8.3% > 5 MRI findings.
- Most MRI abnl ≠ further back pain severity
- >5 Mri abnl= mildly pain baseline, > incr. pain over 6 yrs
- **Conclusion.:** "Our study shows that the MRI degenerative findings we examined, individually or in combination, do not have clinically important associations with LBP, with almost all effects less than one unit on a 0 to 10 pain scale."

Kasch, Richard MD, Truttmann, Julia PhD*, Hancock, Mark J. PhD*, Maher, Christopher G. DMedSci*, Otto, Markus PhD*, Nell, Christopher MD*, Reichwein, Niklas*, Bülow, Robin MD, MSc*, Chenot, Jean-François MD, MPH*, Hofer, Andre MD*, Wassilew, Georgi MD*, Schmidt, Carsten Oliver PhD*, Association of Lumbar MRI Findings with Current and Future Back Pain in a Population-based Cohort Study. *SPINE* 47(3):p 201-211, February 01, 2022. | DOI: 10.1097/BRS.0000000000004198

Knee Pain

KNEE MRI Data

Test	Med. Meniscus	Lat. Meniscus	ACL	PCL	Art. Cartilage
Sensitivity	97.5	91.9	99	100	76.1
Specificity	92.9	93.6	95.9	99	94.9
PPV	93	92.7	91.9	80	94.7
NPV	97	92.9	99.5	100	76.9
+LR	13.7	14.3	21.5	100	14.9
-LR	.02	0.08	0.01	0.01	0.25
Accuracy	95.3%	93.6%	96.6%	99.6%	84.6%

Var CE, Camargo OP, Santana PJ, Valeri AC. Accuracy of magnetic resonance in identifying traumatic intraarticular knee lesions. *Clinics* 2005; 60:445-450.

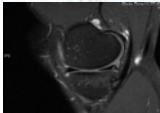
Question

What percent of asymptomatic patients over 50 y/o have a meniscus tear on MRI?

- A. 10 %
- B. 25 %
- C. 50 %
- D. 75 %

Meniscus Tear > 50 y/o?

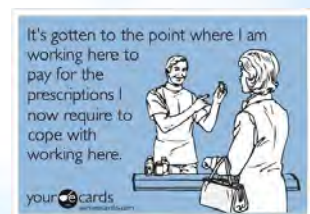
- Asymptomatic pts > 50 y/o had meniscus tears:
 - **61%**
- Common, maybe misleading on MRI. (SORT: B)
- Meniscus tear more common in patients w/ OA (**82% vs. 25%**) (SORT: A)



Englund M, Guermazi A, Gale D, et al. Incidental meniscal findings on knee MRI in middle-aged and elderly persons. *N Engl J Med*. 2008;359:1108-1115.

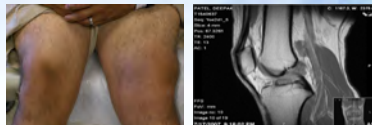
Knee MRI in >40 y/o Occ. Health?

- 57% of occ health with worse MRI findings on asymptomatic side



Knee Asymptomatic Abnormal MRI

- 230 knees
- Avg age 44 y/o
- 97% abnormal**
- 30% Meniscus tear: horizontal (23%), complex (3%), vertical (2%), radial (2%) and bucket handle (1%).
- Abnormal Cartilage 57 % (19% moderate, 31% severe)
- Abnormal bone marrow 48% knees (19% moderate, 31% severe)
- Tendon lesions: Moderate in 21% knees, high in 6%
- Ligament ruptures: 3% : ACL (2%)



1. Horga, L.M., Hirschmann, A.C., Henckel, J, et al. Prevalence of abnormal findings in 230 knees of asymptomatic adults using 3.0 T MRI. *Skeletal Radiol* 49, 1099–1107 (2020). <https://doi.org/10.1007/s00256-020-03394-z>

Shoulder

Question

What percent of asymptomatic patients have a rotator cuff tear on MRI?

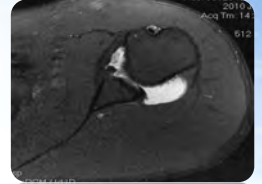
- A. 10 %
- B. 25 %
- C. 50 %
- D. 75 %



Asymptomatic Abnormal Shoulder MRI

- 35 studies,¹
- OA: 15-75%
- Labrum abnl: 30%
- Humeral head cyst 5%
- Long head biceps abnl: 30%

- Non athlete Labral abnl 9% (5/58)²
- Athlete labral abnl: 24 %²

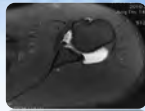


1. Ibbounig, Thomas, et al. "Systematic Review of Shoulder Imaging Abnormalities in Asymptomatic Adult Shoulders (SCRUTINY): Abnormalities of the Glenohumeral Joint." *Osteoarthritis and Cartilage* (2024).
2. Liu, Ruikang, et al. "Prevalence of shoulder labral abnormalities on MRI in a non-athletic asymptomatic young adult population." *Skeletal Radiology* 50 (2021): 921-925.

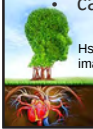


Asymptomatic Shoulder Abnormal MRI

- Both Ultrasound & MRI
- asymptomatic rotator cuff tears: high rates
- "rotator cuff tears may be considered an age-related, normal, degenerative change"
- AC joint arthritic changes common in older
- labral tears are common asymptomatic shoulders
- subacromial bursitis on imaging: not correlated to symptomatic & asymptomatic shoulders
- calcific tendinitis most stay asymptomatic.



Hsu, Connie, Toqa Afifi, and Zacharia Isaac. "Shoulder pathology on advanced imaging in asymptomatic non-athlete individuals: A narrative review." *PM&R* (2024).



Shoulder MRI, Orthopedic ID

- Orthopedic surgeons reviewed MRI of work comp patients to identify symptomatic shoulder.
- Sensitivity: 51%, Specificity: 67%
- **Conclusions**
- "Surgeons were only slightly better at indicating the symptomatic side than random chance. Shoulder pain in people aged 40 or older should probably be considered age-related unless there is good objective evidence of acute traumatic pathology."

Boersma, Emily Z., et al. "Accuracy and reliability of MRI-reports to determine which shoulder is symptomatic for workers compensation patients with unilateral symptoms." *Journal of Orthopaedics* 21 (2020): 199-202.

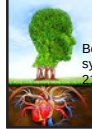


CHART REVIEW



Chart Review

- Standard of care
- Clinical reasoning
- Documentation
- Abbreviations
- Ask for help-Consulting expert/merit review



PHYSICIAN PREP

Physician bias

- Hippocratic oath (Modified¹):
 - “...I will practice the art only for the benefit of my patients. Whatever house I may visit, I will enter only to help the sick or to prevent illness, never to inflict harm, injustice or suffering.”
- AMA Code of ethics²: “
 - “A physician shall, while caring for a patient, regard responsibility to the patient as paramount.”
- Patient advocate
- Reluctant to engage with attorneys

1. <https://medschool.ucla.edu/blog-post/medical-school-graduation-and-the-hippocratic-oath>, accessed 4/23/24
2. <https://code-medical-ethics.ama-assn.org/principles>, accessed 4/23/24

Attorney tips

- Consult experts for merit review
- Verify Board certified
- Verify clinical practice
- Expert Ghosting ☹️
- Push for causation & permanence determination
 - Future care, limitations, etc?
- Verify Pre-existing conditions
- Ask the expert any & all questions

Ronquillo Y, Robinson KJ, Nouhan PP. Expert Witness. [Updated 2023 Jun 26]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK436001/>

Summary

- Medical Standard of Care
- Be prepared for deposition
- Consider expert witness roles
- Understand providers role & expertise
- Be aware of limitations in concussion & MSK injury evaluation & imaging
- Secure appropriate consulting & medical expert witness to bolster your case
- Prepare your witness if not experienced

Resources

- <https://www.healio.com/news/hematology-oncology/20241204/how-to-become-a-medical-expert-witness-and-other-side-hustles-for-physicians>
- <https://pmc.ncbi.nlm.nih.gov/articles/PMC1325285/>
- Giving depositions as a defendant or an expert. . 2006 Jan;19(1):60–62. doi: 10.1080/08998280.2006.11928128
- https://content-cdn.sessionboard.com/content/hvPbSnsGQCigaShON8OO_Become%20a%20Star%20at%20your%20Deposition-Any%20Insiders%20Workshop_Carr.pdf
- <https://www.aafp.org/pubs/fpm/issues/2001/0700/p34.html>
- https://journals.lww.com/pec-online/citation/1987/09000/the_physician_s_deposition_preparation_and.16.aspx
- <https://www.physiciansweekly.com/steps-great-deposition/>
- <https://www.thedoctors.com/articles/key-factors-in-a-deposition-what-healthcare-professionals-can-expect/>
- <https://www.thedoctors.com/articles/coping-with-litigation-tips-for-healthcare-professionals/>
- <https://seak.com/blog/uncategorized/10-biggest-legal-mistakes-physicians-make-preparing-testifying-deposition/>
- <https://ortholegalgroup.com/preparing-for-a-qme-deposition/>
- <https://www.svmc.com/resources/newsletters/200/the-deposition-why-when-and-how>
- <https://code-medical-ethics.ama-assn.org/ethics-opinions/medical-testimony>
- <https://www.aafp.org/pubs/fpm/issues/2021/0900/p25.html>

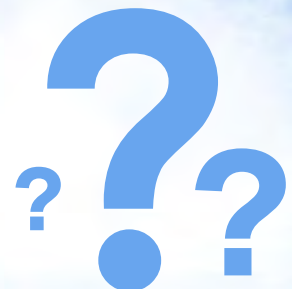
Do you have any questions?

THANKS!!

Patelsportsmed@gmail.com

www.rush.edu/dpatel

Peds or Chiropractor experts available?



SELF EVALUATION

Subpoenas, Depositions, and the Role of the Medical Expert Witness

True/False

1. Responding to a subpoena is optional if you are not the defendant?
2. The legal custom in medical cases is that you may be asked if your opinion is based on is beyond a reasonable doubt?
3. Medical standard of care in a medical legal case is not the best or ideal care you would provide a patient but what the majority of providers would?
4. An attorney, should contact an internal medicine physician who only sees adults, to review cases on adolescents and adults?
5. During a deposition, avoid jargon and speak to 8th grade level?
6. When a patient chart is extensive, wait until the deposition to review the pertinent pages and dates of service?
7. Expert witnesses may invoice hourly for the time spent on the case?
8. If an MRI indicates an injury or tear, it demonstrates causation?

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

FACULTY

Joshua R. Meyerson, MD, MPH

Joshua R. Meyerson, MD, MPH, of Charlevoix, Michigan, was a practicing pediatrician for 22 years and is now the medical director of 3 local health departments covering 10 northern Michigan counties. He is also medical director of two school-linked Child and Adolescent Health Centers. Dr. Meyerson is board certified in pediatrics and a diplomate of the American Board of Pediatrics. He also serves on the Michigan Advisory Committee on Immunizations, is a clinical assistant professor in Michigan State University College of Human Medicine's Departments of Family medicine and Pediatrics, and is an educator with the Physician Peer Education Project on Immunization.

You may contact Dr. Meyerson with your questions and comments at (231) 330-1410, or by email at jmeyerson43@gmail.com.

THE
2026-27

Medical-Dental-Legal
UPDATE

Communicable Diseases – The Public Health Perspective

Communicable Diseases The Public Health Perspective

Joshua Meyerson, MD, MPH

Public Health

Control and Prevention of Communicable Diseases was a primary role of Public Health and Local Health Departments in the 20th century:

- PH responsible for largest increase in longevity – nearly 20 years
- Sanitation and Clean Drinking Water
- Immunizations and Antibiotics
- Outbreak Control: Case finding, contact tracing, isolation, quarantine

Leading Causes of Death, US

<u>1917</u>	<u>2019</u>
1. Heart Disease	1. Heart Disease
2. Pneumonia and Influenza	2. Cancer
3. Tuberculosis	3. Unintentional Injuries
4. Nephritis	4. Chronic Lower Resp Diseases
5. Stroke	5. Stroke
6. Cancer	6. Alzheimer Disease
7. Accidents/Injuries	7. Diabetes
8. Diarrhea, enteritis, GI disease	8. Nephritis/Kidney Disease
9. Prematurity	9. Influenza and Pneumonia
10. Syphilis	10. Suicide

CDC National Center for Health Statistics, Vital Statistics System

Infectious Diseases no longer a leading cause of death in US
Until 2021...

1. Heart disease: 695,547
2. Cancer: 605,213
3. COVID-19: 416,893
4. Accidents (unintentional injuries): 224,935
5. Stroke (cerebrovascular diseases): 162,890
6. Chronic lower respiratory diseases: 142,342
7. Alzheimer's disease: 119,399
8. Diabetes: 103,294
9. Chronic liver disease and cirrhosis : 56,585
10. Nephritis, nephrotic syndrome, and nephrosis: 54,358

<https://www.cdc.gov/nchs/products/databriefs/db456.htm>

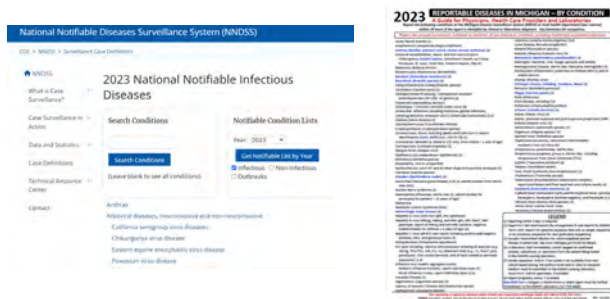
Local Health Departments

- Most all states have “Local Health Departments” ~3489 in US
- May be regional, county, district, city
- Generally, the “boots on the ground”
- States and CDC provide legal framework, guidance, support, and surveillance networks
- Most public health actions are taken at a local level

LHD Roles in Control of Communicable Disease

- LHD still is obligated to investigate cases of reportable disease as well as “unusual occurrences or outbreaks”
- The LHD has primary responsibility to take action when there is a health threat to the public (only entity that does)
- Has Legal authority to investigate (i.e. Michigan PH Code 1978)
- Provides guidance to area schools, congregate care facilities, communities during outbreaks

Reportable Diseases and Conditions



Not Reportable But Common

- Lice
 - Infestation, not infection
- Scabies in LTCF
- Strep Throat
- Hand Foot and Mouth Disease, Fifth's Disease, RSV

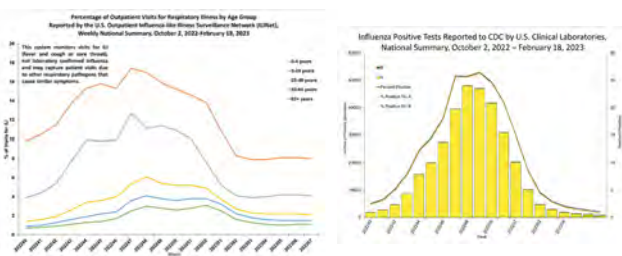
Reporting- Why?

- Important to gather epi data, enter into statewide databases and linked to CDC for surveillance and better understanding
- Investigation to look for preventable causes, risk factors, and any ongoing threat to public that can be mitigated
- Can help generate control efforts from outreach, vaccination, testing and treatment, communication with providers and public
- All starts with reports from labs and providers
- Outbreaks often first realized by astute provider
 - 2 persons not living in same household

Influenza Surveillance

- U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet)
- outpatient healthcare providers in all 50 states, Puerto Rico, the District of Columbia, and the U.S. Virgin Islands. Approximately 85 million patient visits were reported during the 2020-21 season. Each week, more than 3,000 outpatient health care providers around the country report to CDC the number of patient visits for ILI by age group (0-4 years, 5-24 years, 25-49 years, 50-64 years, and ≥65 years) and the total number of visits for any reason.

Combined with sentinel laboratory network weekly
“Flu View”



STI's

- Chlamydia very common, Gonorrhea and Syphilis increasing
- LHD can conduct contact tracing and assure treatment of sexual contacts/partners
- Also provide education and often f/u for repeat testing, prevention of reinfection, treatment



<https://www.cdc.gov/std/treatment-guidelines>

Chlamydia and Gonorrhea

All Sexually Active women through age 25
Males with risk factors
Testing by Urine or Swab by NAAT

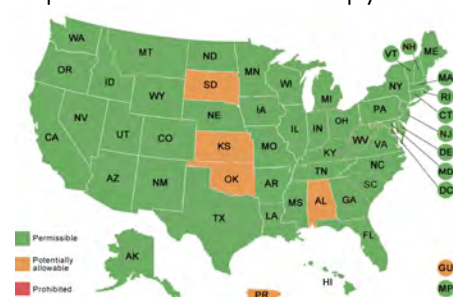
CT:

- Doxycycline 100mg BID X 7d
 - AZ 1G or Levo 500 X 7d
- Retest at 3 months
- Treat partners

GC:

- Ceftriaxone 500mg IM
- Retest at 3 months
- Treat partners

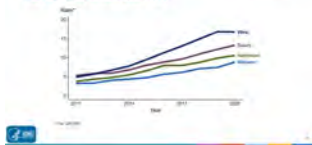
Expedited Partner Therapy - EPT



Syphilis

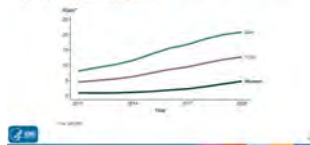
Increasing Nationwide

Primary and Secondary Syphilis – Rates of Reported Cases by Region, United States, 2011–2020



MSM, but rates on rise in Women too

Primary and Secondary Syphilis – Rates of Reported Cases by Sex, United States, 2011–2020



Hepatitis C

- Common cause of chronic hepatitis, cirrhosis, Liver CA
- Most new cases associated with Injectable Drug Use
- Testing at risk individuals important – Antibody screen & PCR confirm
- All adults can be screened for Hep C and Hep B at least once
- Prevention – harm reduction programs work
- Treatment curative but can be reinfected - <https://www.hcvguidelines.org/>
 - Can be incorporated into primary care
 - Persons with HCV should receive both Hep A and Hep B Vaccine
- Can be perinatally acquired – routine prenatal testing

“Food Borne Illness”

- Bacterial – Salmonella, Campylobacter, E Coli/Shigella
- Norovirus
- Hepatitis A
- Food Poisoning – *S aureus*, *B Cereus* toxin mediated
- Waterborne – Giardia, Cyclospora
- Sporadic, local, or national outbreak

Epi and Lab Helpful Guides

- Last meal bias
- Important to know Incubation Period for different etiologies
- “One or two buckets”, systemic symptoms, dysentery
- Use of stool cultures other tests when clinically indicated
- Incorrectly prepared, stored, or contaminated foods
- Sporadic cases vs outbreak related

Foodborne Illness - Norovirus

- Norovirus most common cause of outbreaks – 20 million/year
- Person to person or fomites/ready to eat food
- Viral with short incubation period (12–48hrs)
- Generally self-limited disease
- Acute onset V/D along with low grade fever, cramps, malaise
- Interviews of cases and stool sample testing can confirm
- Highly infectious, important to keep food handlers off work until sx’s resolved
- Hand Hygiene, Exclusion/Isolation
- No long-term immunity

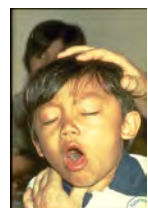
Vaccine Preventable Diseases



- Surveillance
- Diagnosis and Reporting important for timely action to prevent spread
- Treatment and potential PEP and prevention of secondary cases
- Outbreaks continue to occur – Measles, Varicella, Hepatitis A

Pertussis

- Paroxysmal, post tussive emesis
- Treatment with Abx (Azithromycin) to reduce spread
- Treatment of close contacts to prevent secondary cases
- Immunization important but treat close contacts regardless of vaccination status
- Highest risk are newborns so contact investigation more aggressive if infants and/or pregnant women involved



Measles

- Recent outbreaks in areas of US highlight continued risk
- Outbreaks more likely in areas with lower immunization rates
- Herd Immunity >90% reduces risk of continued spread
- Isolation 4 days after rash onset/Quarantine 14
- PEP with MMR vaccine (within 3 days of exposure) to contacts that have not had 2 doses of vaccine or other proof of immunity
- Community vaccination efforts during outbreaks



Chickenpox

- Often a clinical diagnosis but lab confirmation helpful as many clinicians are not experienced dx of varicella disease
- Incubation 10-21 days
- Isolation until rash has crusted over
- PEP of all contacts that are nonimmune – varicella vaccine given within 3-5 days effective at reducing spread
- Outbreak control: Quarantine of contacts that are nonimmune until 21 days after exposure to prevent secondary spread



Hepatitis A

- Hep A Virus spread person to person or through contaminated food
- Incubation period 15-50 days
- Generally self-limited hepatitis with N/V, Jaundice
- Large Outbreaks in US 2017-2019 associated with high hospitalization rates and some mortality
- Vaccine highly effective and can also be used for PEP within 14 days of exposure
- Universal recommendation for HAV in childhood schedule could greatly reduce incidence

Meningococcal Disease

- Neisseria Meningitidis* gram - diplococci
- Fairly rare in US, but continued high morbidity in cases even with prompt tx
- Diagnosis requires prompt PEP due to short incubation period
- Regardless of vaccine status, close contacts should receive Abx
 - Ceftriaxone IM, Rifampin, Cipro

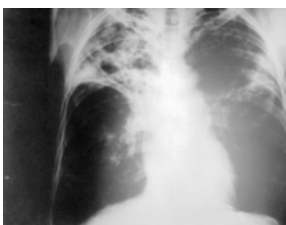
Hib very rare – would also require Abx PEP

Other causes of Meningitis do not require PEP

- Pneumococcal, other bacterial, "aseptic"



Tuberculosis



- Was a leading cause of death at turn of 20th century
- Pasteurization and Medication
- Risk based screening
- Isolation and Evaluation of Contacts – contact tracing
- Treatment of LTBI to reduce new cases and spread

Tuberculosis

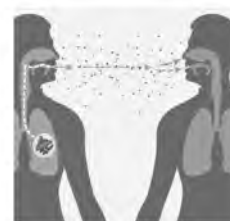
- Mycobacteria tuberculosis* complex (*M. Bovis* + *M. Africanum*)
- Still leading cause of M/M globally
- Human to human transmission
 - M Bovis* - zoonotic infection
- Pulmonary TB most common presentation
- Extrapulmonary – more common children and Immunodeficient
 - Can affect any organ or tissue
 - TB Meningitis, Osteo, GI, Lymph Nodes

2022 Reported TB in the US - CDC

- TB incidence is returning to pre-pandemic levels. 8300 cases in US in 2022
- As in past years, cases of TB disease were not evenly distributed across the United States. Four states account for half of all reported U.S. TB cases: California, Texas, New York, and Florida.
- People from racial and ethnic minority groups and non-U.S.-born persons continued to be disproportionately affected by TB disease in the United States
- TB diagnosis and treatment to interrupt transmission and prevention of TB through treatment of latent TB infection are critical to U.S. TB elimination efforts.

CDC MMWR Weekly Vol 72 No. 12 March 24, 2023

Transmission



How is TB Transmitted?

- TB is passed (transmitted) through the air when someone who is infected **coughs, sneezes, shouts, or sings**
- Droplets of saliva contain thousands of **TB bacilli**
- Once inhaled, the droplets push their way into the lungs, settling in tiny air sacs (alveoli)
- TB is **NOT** spread through touch, blood, sperm, vaginal fluids, food or liquids, sharing utensils, dust, dirt, or vehicle fumes

Latent TB Infection (LTBI) vs TB Disease

LTBI is the presence of *M. tuberculosis* organisms (tubercle bacilli) without signs and symptoms or radiographic or bacteriologic evidence of TB disease.



LTBI vs. Pulmonary TB Disease

Latent TB Infection

- Positive TST* or IGRA[†] result
- Chest radiograph normal
- No symptoms or physical findings suggestive of TB

*tuberculin skin test

[†]Interferon-Gamma Release Assay (QFT or T-Spot)

Pulmonary TB Disease

- TST or IGRA is usually positive unless anergic
- Chest radiograph is usually abnormal
- Symptomatic - fever, cough, night sweats, weight loss, fatigue, hemoptysis, decreased appetite
- Sputum usually smear or culture positive

Evaluation for TB Infection

- Immigrant/Refugee
- Health Care Personnel – most do not need annually – based on local incidence
- Recent Exposure or live or work in high-risk setting – homeless shelters, prisons
- International Work/Travel
- Those starting medications that increase risk of TB disease/reactivation
 - TNF Blockers, ? mAb interleukin inhibitors

Evaluation for TB Infection – Pick One

TST

- Traditional Skin test
- Cheap
- Requires 2 visits
- Read Induration not Erythema
- Not as specific
- Boosting phenomena

IGRA

- Blood test - measures and compares amount of interferon-gamma released by blood cells in response to antigens and controls
- More Expensive
- One visit
- Less interpretation error
- 2 years and older

Factors That May Cause False-Positive TST Reactions

- Nontuberculous mycobacteria
 - Reactions caused by nontuberculous mycobacteria are usually ≤ 10 mm of induration
- BCG vaccination
 - Reactivity in BCG vaccine recipients generally wanes over time; positive TST result is likely due to TB infection if risk factors are present
- IGRA less likely to be affected

Factors That May Cause False-Negative TST Reactions

Anergy

- Inability to react to a TST because of a weakened immune system
- Can see in active TB cases
- If TB suspected clinically in ill individual would not rely on negative test for TB infection

Evaluation of Persons with LTBI

- TB Disease Ruled Out – asymptomatic, negative CXR
- Consider for LTBI Tx: Recent infection (12 months), medical risk factor increases risk of progression to active TB disease. Treatment greatly reduces risk of later Disease.
- Completion based on number of doses taken, not on duration: 3 months Tx=90 doses taken

Excellent CDC Guide:

[Latent Tuberculosis Infection: A Guide for Primary Health Care Providers](#)



Treatment Regimens for Latent TB Infection

Priority rank*	Regimen	Recommendation (strong or conditional)	Evidence (high, moderate, low, very low)
Preferred	3 mos isoniazid plus Pyridoxine (rifapentine) given once weekly (12 doses total)	Strong	Moderate
Preferred	4 mos rifampin given daily	Strong	Moderate (HIV negative)
Preferred	3 mos isoniazid plus rifampin given daily	Conditional	Very low (HIV negative)
Alternative	6 mos isoniazid given daily	Conditional	Moderate (HIV negative)
Alternative	9 mos isoniazid given daily	Conditional	Moderate (HIV positive)

Note: Rifampin (RIF) and Pyrazinamide (PZA) should not be offered to persons with LTBI. RIF and PZA should continue to be administered in multidrug regimens for the treatment of persons with TB disease.

CDC Guidelines for the treatment of LTBI, 2020

Tuberculosis – LHD role

- TB case management
- Some LHD provide treatment
- Address isolation requirements and determination of contagiousness
- Contact tracing and evaluation for LTBI
- DOT
- Address ability and barriers to compliance and completion of therapy
- Assist with medication, f/u, costs related to treatment
- Goal is to reduce spread in community

Rabies

- Viral Disease transmitted through bite of a rabid animal
- In US predominantly wild animals – bats, racoons, skunks, fox
- Can occur in most mammals including cats and dogs, horses
- NOT squirrels, rabbits, chipmunks, rodents
- Incubation period 3-8 weeks or longer
- Infectious only once ill and virus present in salivary glands
- In humans almost uniformly fatal once symptoms begin

Animal Bites – Assessment of Risk

- Cats and Dogs: bite provoked??
- Rare in pets but possible
 - Observation of animal highly preferable vs euthanize and testing
 - If pet alive 10 days after bite there is no risk of rabies transmission
- Wild Animals
 - No protocol for observation
 - Ideally capture and test
 - Rabies PEP only if positive



Bats

- Most common rabies + animal reported to our LHD, leading cause of rabies in humans. Found in all states except Hawaii
- Most often related to a bat found in a house
- Sleeping or unattended nonverbal person at risk
- Always best to capture and test bat IF exposure occurred
- PEP if and only if exposure, bat +, or bat not tested



Rabies Postexposure Prophylaxis (PEP)

- Rabies Immunoglobulin + Rabies Vaccine Day 0,3,7,14
- RIG can be multiple injections as weight based 20 IU/Kg
- Generally, well tolerated
- Main Issue with PEP is COST
- Cost of RIG and Vaccine alone can be over \$20,000 + ED visit, OV
- BUT Rabies is uniformly fatal once symptoms begin
- PEP is lifesaving if true risk exists

What's Next?

- At end of 20th century CD felt to be "in the past", very little attention or funding
- Clearly Control of Communicable Disease still of primary importance for the general health and welfare of our citizens
- Always a new outbreak, changing epi of zoonotic and tropical diseases (Mpox)
- Next Epidemic just a plane ride away
- Primary responsibility remains at the LHD level
- When Providers and Public Health maintain good communication, better outcomes for individuals and communities
- Know your LHD and local resources

Zoonotic Diseases

Tick Borne

- Lyme, Babesiosis, Anaplasmosis, RMSF

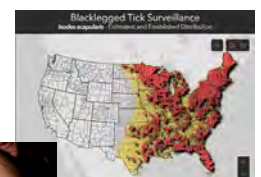
Mosquito Borne

- WNV, EEE
- Chikungunya/Dengue/Zika
- Malaria



Lyme Disease

- 35,000 cases reported with estimate that actual 10X higher
- Blacklegged Tick *Ixodes scapularis* vector
- *Borrelia Burgdorferi* etiology
- Acute illness with EM rash in >80%, fever HA fatigue
- Secondary Arthritis, Heart Block, Neurological



Lyme Disease

Prevention

- Tick checks and removal
- Know your seasons
- Other prevention methods – clothing, DEET, stay on trails
- Testing – two tier from reputable lab
- Diagnosis can be clinical
- Doxycycline
- [Preventive Rx after bite](#) based on local incidence



Thank You

SELF EVALUATION

Communicable Diseases – The Public Health Perspective

1. T/F - Communicable diseases only need to be reported to the LHD by positive laboratory reports.
2. Important reasons for providers to report communicable diseases include:
 - a. Reporting helps provide overall epidemiological data that will help improve surveillance and understanding of disease prevalence.
 - b. May help identify outbreaks in a population that necessitate public health interventions
 - c. May require contact tracing and post exposure prophylaxis of contacts that will reduce the spread of disease in the community.
 - d. All of the above.
3. T/F - Most cases of acute gastrointestinal complaints are the result of the most recently ingested food.
4. T/F - Household members of a pertussis case that are up to date on pertussis vaccines do not require post exposure chemoprophylaxis.
5. T/F - Nonimmune contacts of a case of chickenpox should be offered varicella vaccine.
6. A client receives a Tuberculin skin test prior to starting nursing school and it is read at 48 hours as 16mm of induration (positive). Which of the following is NOT true:
 - a. They should be screened for symptoms of TB disease (fever, productive cough, weight loss)
 - b. If not done recently, a chest radiograph should be considered to evaluate for active pulmonary TB.
 - c. They should remain in isolation and not work or attend school until further evaluation at a TB clinic.
 - d. A past history of BCG vaccine as a child is not likely to be the cause of this positive test.
7. Which of the following is not an indication for Rabies Post exposure prophylaxis:
 - a. A person bit by a racoon in a campground and the animal was not able to be captured and tested.
 - b. A person woke up in bed with a bat on their bare skin. They brushed the bat off and quickly released it to the outdoors where it flew off.
 - c. A person bit by a squirrel in a park, and they cannot identify the specific animal that bit them.
 - d. A family cat that was acting ill and bit several household members. The veterinarian had the animal euthanized and tested and it is positive for rabies.

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

Research Design and Execution in Medicine

Michael W. Donnino, MD



Research Design and Execution in Medicine

Michael Donnino, MD
Professor of Emergency Medicine, Harvard Medical School
Director for Resuscitation Science, Beth Israel Deaconess Medical Center
Email: michael.donnino@gmail.com / Twitter: @mdonnino

DISCLOSURES

- ① research grants: NIH, Day zero diagnostics, foundations, philanthropy

OBJECTIVES



- To provide a methodology for taking an clinical idea and transforming into research
- To explore the challenges of clinical study design and execution

WHERE TO START? YOU HAVE A GREAT IDEA!

•

A CASE OF SEVERE ACIDOSIS



- 42 year old male with no known past medical history presented with confusion and severe abdominal pain
- Temp: 99.3, HR: 108 BP: 98/50 RR: 30 Sat: 98%
- Exam: Dry mucous membranes and diffuse abdominal tenderness
- Key Labs: pH = 6.8 pCO₂=5 bicarb=3 Lactate = 27 mmol/dl

A CASE OF ACIDOSIS -> TO THE OR!



- Pre-op Diagnosis: Presumed ischemic bowel
- Post-op Diagnosis: NORMAL bowel
- whoops- lactate was 27 mmol/dl !
- Now what?

POST-OPERATIVE COURSE



- Lactate rapidly normalized
- Patient extubated within hours
- Asking for a food try and when he can go home!
- Review of case reveals he only received 500 cc of fluid and one intravenous medication in the ED but no other therapies???

WHAT JUST HAPPENED?

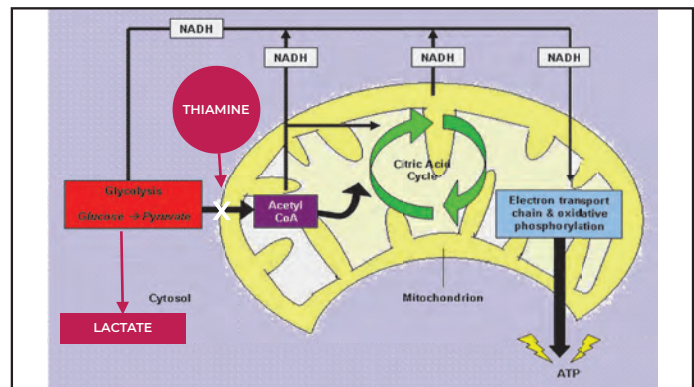


- 1 Reviewed chart for ANY interventions that could have impacted the course
- 2 Only intervention (besides surgery) that the patient received was a thiamine 200 mg IV
- 3 Literature search revealed a study showing an association between thiamine deficiency and lactate acidosis

WHAT JUST HAPPENED?



- 1 Reviewed chart for ANY interventions that could have impacted the course
- 2 Only intervention (besides surgery) that the patient received was a thiamine 200 mg IV
- 3 Literature search revealed a study showing an association between thiamine deficiency and lactate acidosis
- 4 Pulled out my old biochem book!



SHOULD I MOVE FORWARD WITH THIS OBSERVATION OR IDEA?



- Is this interesting to **YOU**?
- Do you think it will be interesting to **OTHERS**?
- Is the concept **SIGNIFICANT**?

WOW, INTERESTING AND SIGNIFICANT - WHAT NEXT?"



- What is known about your idea (ie., complete **literature search**)?
- Is this something you/others just need to know or are there some questions that need to be answered (ie., research)?
- Is there a good research question? Might there be a line of research?

WOW, INTERESTING AND SIGNIFICANT - WHAT NEXT?"



- What is known about your idea (ie., solid **literature search**)?
- Is this something I/others just need to know or are there some questions that need to be answered (ie., research)?
- Is there a good research question? Might there be a line of research?

WHAT IMPORTANT QUESTIONS MIGHT BE RAISED FROM THIS CLINICAL OBSERVATION?



- Is this happening more than we realize?
- What if someone with septic shock were thiamine deficient?
- What happens to thiamine during critical illness?
- Might thiamine be helpful for acidosis even if there is not deficiency?

GASTROINTESTINAL BERIBERI: A PREVIOUSLY UNRECOGNIZED SYNDROME

Patient	Date	pH	Bicarbonate	Lactate
LU	03/2002	6.82	4	27.2
LU	08/2002	6.83	4	30.0
LU	03/2003	6.73	5	23.8
MS	03/2004	7.06	5	18.6

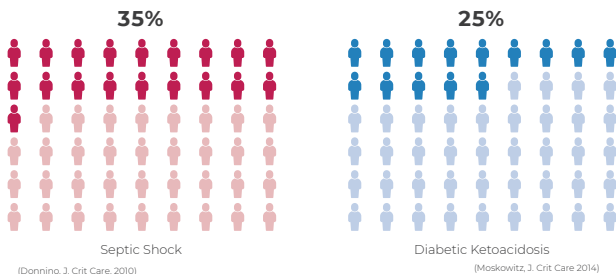
Donnino M. Gastrointestinal Beriberi: A Previously Unrecognized Syndrome. *Annals of Internal Medicine*. (2004) 141 (1): 898-99

WHAT IMPORTANT QUESTIONS MIGHT BE RAISED FROM THIS CLINICAL OBSERVATION?



- Is this happening more than we realize? --> PREVALENCE STUDY
- Could lactic acidosis in septic shock be related to thiamine?
- What happens to thiamine during critical illness? --> CABG study
- Might thiamine be helpful for acidosis even if there is not deficiency?

THIAMINE DEFICIENCY IN THE CRITICALLY ILL



FURTHERING YOUR IDEA/PROGRESS



- Other angles: Change in thiamine during critical illness (CABG model)
- Observational studies (acid-base patterns in Wernicke's)
- Review article (s): Wernicke's Encephalopathy
 - Narrative reviews harder to publish recently
 - Consider narrative vs. scoping, vs. systematic review

Late Breaker Articles

Randomized, Double-Blind, Placebo-Controlled Trial of Thiamine as a Metabolic Resuscitator in Septic Shock: A Pilot Study

Michael W. Donnino, M.D.,^{1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38,39,40,41,42,43,44,45,46,47,48,49,50,51,52,53,54,55,56,57,58,59,60,61,62,63,64,65,66,67,68,69,70,71,72,73,74,75,76,77,78,79,80,81,82,83,84,85,86,87,88,89,90,91,92,93,94,95,96,97,98,99,100}
Katherine M. Berg, M.D.,^{1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38,39,40,41,42,43,44,45,46,47,48,49,50,51,52,53,54,55,56,57,58,59,60,61,62,63,64,65,66,67,68,69,70,71,72,73,74,75,76,77,78,79,80,81,82,83,84,85,86,87,88,89,90,91,92,93,94,95,96,97,98,99,100}
Amy Moskowitz, M.D.,^{1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38,39,40,41,42,43,44,45,46,47,48,49,50,51,52,53,54,55,56,57,58,59,60,61,62,63,64,65,66,67,68,69,70,71,72,73,74,75,76,77,78,79,80,81,82,83,84,85,86,87,88,89,90,91,92,93,94,95,96,97,98,99,100}
for the Centers of Resuscitation Science Research Group

Objective: To determine if intravenous thiamine would reduce lactate in patients with septic shock.

Design: Randomized, double-blind, placebo-controlled trial.

Setting: Two US hospitals.

Patients: Adult patients with septic shock and elevated (>3 mmol/L) lactate between 2010 and 2014.

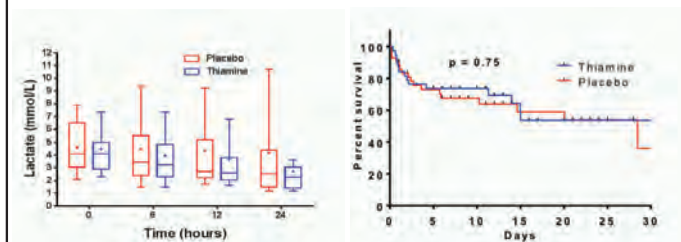
Intervention: Thiamine 200 mg or matching placebo twice daily for 7 days or until hospital discharge.

Measurements and Main Results: The primary outcome was lactate levels 24 hours after the first study dose. Of 715 patients meeting the inclusion criteria, 88 patients were enrolled and received study drug. There was no difference in the primary outcome of lactate levels at 24 hours after study start between the thiamine and placebo groups (median: 3.8 mmol/L [IQR: 3.4 to 4.4 mmol/L] vs. 4.1 mmol/L [IQR: 3.6 to 4.7 mmol/L], $p = 0.45$). There was no difference in secondary outcomes including time to shock reversal, severity of illness and mortality. 39% of the patients were thiamine deficient at baseline. In the prespecified subgroup, those in the thiamine treatment group had statistically significantly lower lactate levels at 24 hours (median 3.1 mmol/L [IQR: 2.6 to 3.6 mmol/L] vs. 4.1 mmol/L [IQR: 3.6 to 4.7 mmol/L], $p = 0.03$). There was a statistically significant decrease in mortality over time in those receiving thiamine vs. first subgroup ($p = 0.047$).

Conclusion: Administration of thiamine did not improve lactate levels or other outcomes in the overall group of patients with septic shock and elevated lactate. A subgroup with baseline thiamine deficiency patients in the thiamine group had significantly lower lactate levels at 24 hours and significant decrease in mortality over time. (CMAJ 2016; 188:260-267)

Key Words: lactate; metabolism; sepsis; septic shock; thiamine.

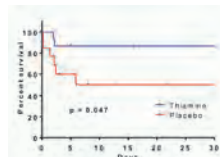
THIAMINE IN SEPTIC SHOCK



THIAMINE DEFICIENT SUBGROUP (N=35)

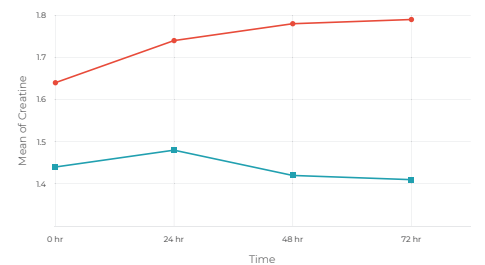
43% PLACEBO

13% THIAMINE

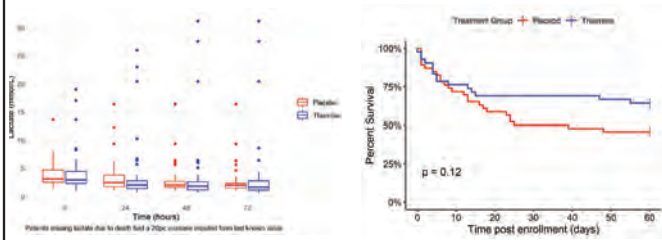


FOLLOW-UP RCT WITH FOCUS ON RENAL PROTECTION

PRIMARY ENDPOINT - CREATININE



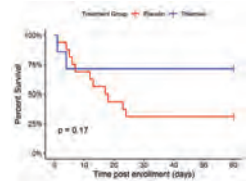
THIAMINE IN SEPTIC SHOCK



THIAMINE DEFICIENT SUBGROUP (N=23)

69% 
PLACEBO

29% 
THIAMINE



ALIVE AND RENAL REPLACEMENT FREE

TRIAL #1

68% VS 51%
(THIAMINE) (PLACEBO)

TRIAL #2

60% VS 41%
(THIAMINE) (PLACEBO)



INTUBATION
DURING CARDIAC
ARREST
(Andersen, JAMA 2016;
Andersen JAMA 2017)

CANNABINOID
HYPEREMESIS
(Donnino, JEM, 2009)

CURB-65 AND
SOFA
(Ilg, Annals of EM 2019;
Moskowitz, AJRCCM,
2016)

HYPEROXIA IN
CENTRAL
VENOUS
GASES?

LACTATE IS
HELPFUL!
(Donnino,
Resuscitation,
2007; Howell,
Intensive Care
Medicine, 2007)

LACTATE HAS
LIMITATIONS!
(Dugas, Journal of Crit Care
2012; Andersen Mayo Clinic
Proceedings, 2013)

CONCEPT OF PARALLEL WORK



- Lots of research in septic shock
- Not much research in post-cardiac arrest
- Sepsis and post-cardiac arrest are similar
- Take work from field of sepsis and replicate in the post-cardiac arrest patients...
- Other examples – if you are in pediatrics – lots of work done in adults has not been examined in children...

WHERE ELSE CAN YOU GET IDEAS?



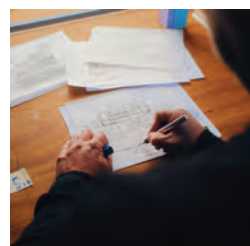
- Conferences, abstracts
- Discussions with friends/colleagues
- Trial (s) that a senior investigator is working on
- Twitter and social media - really???

THEMES



- Curiosity!
- Challenging the status quo
- Literature search looking for the holes
- Start with the low-hanging fruit of case reports, observational studies, and review articles. Then, can move to prospective observational and perhaps a clinical trial

NOW, TIME TO THINK ABOUT DESIGNING A CLINICAL TRIAL



- Sample size
- Determinants of Sample Size:
 - Treatment Effect
 - Variability
- Primary endpoint

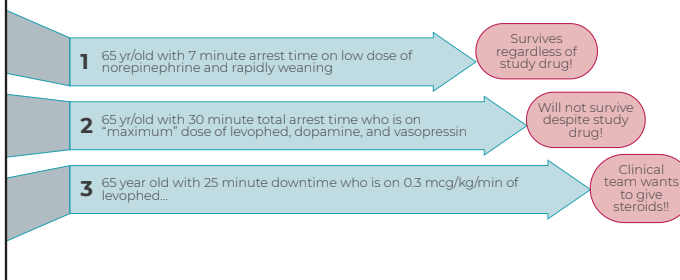
LET'S DESIGN A TRIAL



- 65 year old patient suffered cardiac arrest with approximately 25 minutes of arrest time...
- Patient is now post-arrest on a 0.3 mcg/kg/min of norepinephrine



WHO DID WE GET?



SO WHAT ARE THE LESSONS?



- Exclude "too sick" (going to die or not reach endpoint regardless)
- Exclude "not sick enough" (will live or reach endpoint regardless)
- Look at the "just right" population (true at-risk population)

BASICS OF TRIAL DESIGN



- Choose the optimal population to begin
- Optimize power through focusing on homogeneity of the population and typically continuous variables
- Minimize variability - can control this through setting baseline "not to sick" AND "too sick" criteria
- If successful, then move to generalizing to other populations and/or tailoring your dose or duration

APRIL 2021 - STATISTICAL EMERGENCY!



- TTS → thrombosis and death in small number of Johnson and Johnson vaccinated
- Did the benefits of vaccine outweigh the risk?

APRIL 2021 - STATISTICAL EMERGENCY!



- TTS → thrombosis and death in small number of Johnson and Johnson vaccinated
- Did the benefits of vaccine outweigh the risk?
- Analysis: Risk of death from COVID over next 6 months slightly outweighed the risk of death from vaccine (when compared to no vaccine)

IMPORTANCE OF THE CONTROL GROUP



- Most important: DO NOT harm the controls (accidentally of course)
- What is the standard of care?
 - Will I have a control group that represents true standard of care
 - When in doubt, make "usual care" the control group (my opinion)

FIXED TREATMENT GROUPS FOR THERAPIES WITH TITRATED CARE: RISK FOR PATIENTS?



- What are fixed-treatment groups?
- When/why is this a problem?

TYPES OF CONTROL GROUPS AND THE "PLACEBO" EFFECT



- Active comparators
- Placebo (intended to be inactive)

PROTOCOL DEVIATIONS (PD)



- Examples of PDs
 - Missed study drug administration
 - Error in study drug administration
 - Error in specimen collection
 - Error in data handling
 - Unblinding
 - Missing lab values
- Major PDs -- report
 - Failure to draw safety labs, enrollment of ineligible subject

PITFALL #5



- No power calculation

PITFALL #4



- Overestimating your capacity for enrollment
- Happens for both inexperienced and experienced investigators
- "Best way to cure a disease is to study it"

PITFALL #3



- Falling into a regulatory trap
- Look at the IRB as a partner not an adversary
- Good organization - watch "over enrollments", report all AEs/PDs

PITFALL #2



- Failing to consider missing data until the end of the study period
- Ways to mitigate missing data
- Creating systems

PITFALL #1



- Project paralysis by perfectionism
- You will be not get 100% of the grants that you do not apply for
- Enemy of good is perfect!

CONCLUSIONS



- Curiosity with step-wise exploration is optimal way to advance idea from clinical space to research
- Successful clinical studies require careful attention to study design and the execution challenges

PITFALL #4



- Over-reliance of retrospective data and assumptions of causality
- Correlation is not causation!

TWO FIXED TREATMENT GROUPS WHERE NEITHER REPRESENT "STANDARD OF CARE"



- Titration of care often the actual standard of care
- Fixed-treatments remove capacity for titration of care
- Similar situation: attempts to "create" a control group that has minimum standard of care

SOLUTIONS FOR FIXED-TREATMENT GROUP TRIALS



- Avoid if possible
- Create usual care control groups
- Carefully assess standard of care to determine if titration of care is utilized -> key determinant is not necessarily are the two groups reasonable BUT whether the "usual care" involves titration

LOW TIDAL VOLUME VENTILATION: A CLASSIC FIXED TREATMENT ISSUE



- Question: should we use LOW tidal volume ventilation in Acute Lung Injury?
- Created TWO groups
 - 6 CC/KG (LOW)
 - 12 CC/KG (HIGH)
- What was the standard of care? IT DEPENDS!!!

BASICS OF TRIAL DESIGN



- Choose the optimal population to begin
- Choose the optimal "dose" and/or exposure to begin
- Optimize power through focusing on homogeneity of the population and typically continuous variables
- Minimize variability - can control this through setting baseline "not to sick" AND "too sick" criteria
- If successful, then move to generalizing to other populations and/or tailoring your dose or duration

Specific Aims

Specific Aim 1: To determine if the administration of thiamine to critically ill patients with septic shock will improve lactate clearance

Specific Aim 2: To determine whether the administration of thiamine to patients with septic shock improves lactate clearance in those with thiamine deficiency

Randomized, Double-Blind, Placebo-Controlled Trial of Thiamine as a Metabolic Resuscitator in Septic Shock: A Pilot Study

Michael W. Dunne, M.D.^{1,2}, Lars V. Andersen, M.D.^{3,4}, Margaret Chase, M.D., M.P.H.⁵, Katherine M. Berg, M.D.⁶, Mark Tidwell, M.D.⁷, Tyler Giberson, B.S.⁸, Richard Wolfe, M.D.⁹, Art Moskowitz, M.D.¹⁰, Howard Steinhaue, M.D.¹¹, Long Ngu, Ph.D.¹², Michael N. Cocchi, M.D.¹³ for the Center for Resuscitation Science Research Group

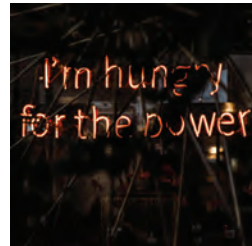
Objectives: To determine if intravenous thiamine would reduce lactate in patients with septic shock.
Design: Randomized, double-blind, placebo-controlled trial.
Setting: Two US hospitals.
Patients: Adult patients with septic shock and elevated (>3 mmol/L) lactate between 2010 and 2014.
Interventions: Thiamine 200mg or matching placebo once daily for 7 days or until hospital discharge.
Measurements and Main Results: The primary outcome was lactate levels 24 hours after the first study drug. Of 175 patients meeting the inclusion criteria, 88 patients were enrolled and received study drug. There was no difference in the primary outcome of lactate levels at 24 hours after study start between the thiamine and placebo groups (median: 3.3 mmol/L, IQR: 2.4-4.4 vs 2.6 mmol/L, IQR: 1.8-3.1, $p=0.45$). There was no difference in secondary outcomes including time to shock reversal, severity of illness and mortality. 30% of the patients were thiamine deficient at baseline. In this preselected subgroup, those in the thiamine treatment group had statistically significantly lower lactate levels at 24 hours (median 2.1 mmol/L, IQR: 1.4-2.5 vs 3.1 IQR: 2.3-4.3, $p=0.05$). There was a statistically significant decrease in mortality over time in those receiving thiamine in the subgroup ($p=0.047$).
Conclusions: Administration of thiamine did not improve lactate levels or other outcomes in the overall group of patients with septic shock and elevated lactate. In those with baseline thiamine deficiency, patients in the thiamine group had significantly lower lactate levels at 24 hours and a possible decrease in mortality over time. (CMAJ March 2016; 188:360-367)
Key Words: lactate; metabolism; sepsis; septic shock; thiamine; thiamine deficiency.

GASTROINTESTINAL BERIBERI: A PREVIOUSLY UNRECOGNIZED SYNDROME

Patient	Date	pH	Bicarbonate	Lactate
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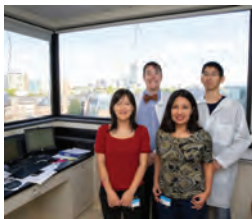
Donnino M. Gastrointestinal Beriberi: A Previously Unrecognized Syndrome. *Annals of Internal Medicine*. (2004) 141 (11): 898-99

WHERE TO START? YOU HAVE A GREAT IDEA!



- What is the power and can I do this?
- What is your primary endpoint?
- Is the endpoint RELEVANT to your trial/goals?
- How can I OPTIMIZE for power?

SERIES OF LAB-BASED DEVELOPMENTS



- Optimized/developed assay for pyruvate dehydrogenase
- Established a metabolic and biomarker core laboratory
- Developed methodology for measuring oxygen consumption (mitochondrial function) from blood

Donnino et al. *Critical Care*. 2010;14(1):R102.

Critical Care

RESEARCH

Open Access

Corticosteroid therapy in refractory shock following cardiac arrest: a randomized, double-blind, placebo-controlled, trial

Michael W. Donnino^{1,2*}, Lars W. Andersen^{3,4,5}, Katherine M. Berg⁶, Maureen Chase⁷, Robert Shewlin⁸, Howard Smithline⁹, Erin Caney¹⁰, Long Ngo¹¹, Parth V. Patel¹², Xiaowen Lu¹³, Donald Cutlip¹⁴, Peter Zimetbaum¹⁵, Michael N. Cocchi¹⁶ and the collaborating authors from the Beth Israel Deaconess Medical Center's Center for Resuscitation Science Research Group

Abstract

Background: The purpose of this study was to determine whether the provision of corticosteroids improves time to shock reversal and outcomes in patients with post-cardiac arrest shock.

Methods: We conducted a randomized, double-blind trial of post-cardiac arrest patients in shock, defined as vasopressor support for a minimum of 1 hour. Patients were randomized to intravenous hydrocortisone 100 mg of placebo every 8 hours for 7 days or until shock reversal. The primary endpoint was time to shock reversal.

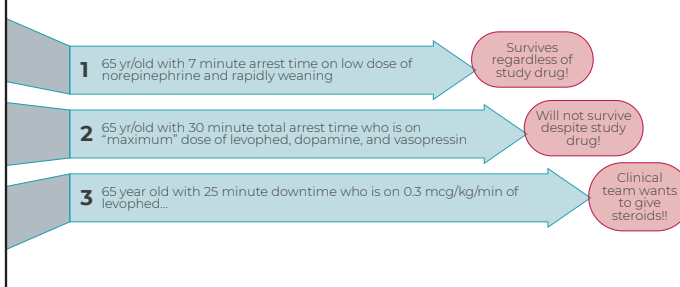
Results: Fifty patients were included with 25 in each group. There was no difference in time to shock reversal between groups (median 0.83 [95% CI 0.40-1.73], $p = 0.63$). We found no difference in secondary outcomes including shock reversal (52% vs. 46%, $p = 0.57$), good neurological outcome (24% vs. 32%, $p = 0.33$) or survival to discharge (28% vs. 36%, $p = 0.54$) between the hydrocortisone and placebo groups. Of the patients with a baseline cortisol $< 15 \mu\text{g/dL}$, 100% (6/6) in the hydrocortisone group achieved shock reversal compared to 33% (1/3) in the placebo group ($p = 0.08$). All patients in the placebo group died (100% 3/3) whereas 50% (3/6) died in the hydrocortisone group ($p = 0.43$).

Conclusions: In a population of cardiac arrest patients with vasopressor-dependent shock, treatment with hydrocortisone did not improve time to shock reversal, rate of shock reversal, or clinical outcomes when compared to placebo.

Clinical trial registration: Clinicaltrials.gov NCT00076585; registration date: May 9, 2008.

Keywords: Cardiac arrest, Steroids, Hydrocortisone, Shock, Vasopressors, Adrenal

WHO DID WE GET?



WHERE TO START/SUBMIT?



HOW IS MY ARTICLE REVIEWED/JUDGED?

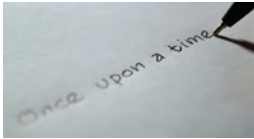
- 1 Combination of quality/significance of your paper plus editorial goals/target audience of the journal
- 2 Editorial review versus peer review

MANUSCRIPT OVERVIEW

Telling Your Story Effectively



INTRODUCTION



- Paragraph #1: Disease/problem background
- Paragraph #2: Your idea/intervention/observation
- Paragraph #3: Your hypothesis and plan to **test**

METHODS - GET TARGET JOURNAL FORMAT



- 1 Design/Setting (include IRB and regulatory information)
- 2 Study Population
- 3 Intervention (if any)
- 4 Data Collection
- 5 Outcome Measures
- 6 Power Calculation
- 7 Statistical Methods

RESULTS - TABLES/FIGURES



- "Table 1"
 - Baseline Characteristics of the study **population**
 - Typically, no need for p value comparison in RCTs
- Other tips
 - Consider using Graphpad for figures/tables
 - Make sure to include all units
 - Create a legend for all
- Figure 1 - **CONSORT** diagram
 - Accounting for all patients and/or group allocations

RESULTS - WRITTEN PORTION



- Paragraph #1: Describe key population and refer to Table 1 (can repeat but keep to a minimum)
- Paragraph #2: Describe key findings
- Paragraph #3: Describe any sensitivity or secondary analyses
- Tip: Avoid discussion in the results!

DISCUSSION



- Paragraph #1: SUMMARIZE the results in simplistic language
- Paragraph #2- #4:
 - Put study in context of literature
 - Point out what your study adds
 - If you study contrasts with previous, provide brief speculation of why
 - Can discuss potential mechanisms
 - Can discuss potential reasons why your study/intervention did not work
 - Can discuss potential clinical applications/importance of the findings

DISCUSSION



- Paragraph #5: Depending on size of the paper can briefly summarize findings and introduce "new directions" concept

LIMITATIONS



- Some journals have specific limitations section whereas others just expect you to include in the end portion of the discussion
- State common limitations and some specific if known

CONCLUSIONS



- Brief statement of principal findings
- I personally don't like the "future studies" ending to papers and only do if peer review forces me. Mixed opinions on this

CONCLUSIONS

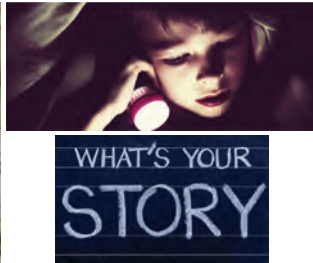


- "If you want to increase your success rate, double your failure rate"

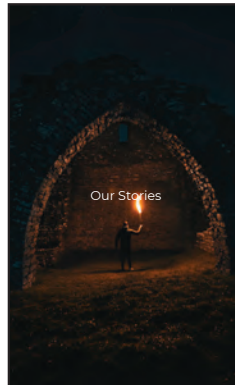
GETTING YOUR STUDY FUNDED!



TELLING YOUR STORY



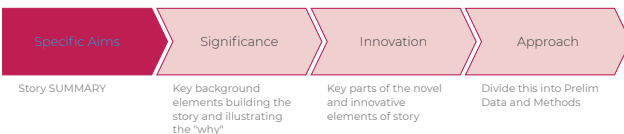
WHAT STORIES NEED TO BE TOLD??



- 1 Science Story
- 2 Your Story
- 3 Your Team's Story

GRANT SECTIONS OVERVIEW

Telling Your Story One Step at a Time



STATE AND TEST HYPOTHESIS



- Seems obvious, right?
- Corollary: Do NOT overstate the hypothesis!

STORY FLOW AND STRUCTURE



- Generally, declarative, descriptive sentences to open each paragraph (summarize message) - [example](#)
- Transition from paragraph to paragraph and section to section

STYLE COUNTS



- 1 Bold strategically (my preference)
- 2 Italics strategically
- 3 Spaces - less is often more!!!
- 4 [Pictures, Tables, Figures!!](#)
- 5 Adequate sizes of tables and figures

PRELIMINARY DATA TO SUPPORT YOUR STORY



- Many grants say you do not need BUT often you do especially if being compared to your competition
- **Ideas**
 - Support for your hypothesis (optimal)
 - Defining the population
 - Illustrating your expertise
 - Proof of enrollments
- Do not need to be published but bonus if you have a publication story

KNOW THE AUDIENCE!



- Who is reviewing the grant?
- What is their expertise in this area?
- Do you have any control?

ENVIRONMENT: IF YOU BUILD IT THEY WILL COME



BUILD YOUR TEAM



- Ensure adequate expertise
- Key stakeholders (letters at least)
- Innovative collaborators

SUPPORTING DOCUMENTS

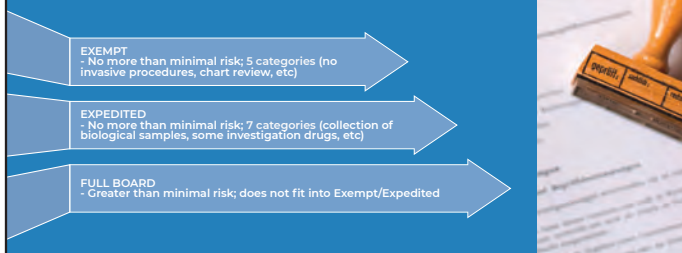
- 1 YOU need to take control of all of your collaborator's documents!
- 2 Draft letters of support
- 3 Review all Biosketches
- 4 **Make** check list of all items early on!
- 5 Tell your team's story!!

CLOSING ARGUMENTS



- Consider an ending **summary**
- Consider a "study considerations" or troubleshooting section
-

ENTERING THE REGULATORY WORLD STARTING WITH IRB APPROVAL



5 CATEGORIES FOR EXEMPT REVIEW

- 1 Research in educational settings involving normal educational practices -- no adverse impacts
- 2 Research only involving educational tests, surveys, interviews, or public behaviors
- 3 Benign behavioral interventions coupled with data collection
- 4 Secondary research such as chart review
- 5 Research to study/evaluate/improve public benefit or service programs





7 CATEGORIES FOR EXPEDITED REVIEW

- 1 Some studies with drugs and devices
- 2 Phlebotomy
- 3 Noninvasive biological specimen collection (ex. hair or nail clippings)
- 4 Data collection via noninvasive procedures (ex. MRI, EKG, US)
- 5 Research with materials collected solely for non-research purposes
- 6 Use of video/voice recordings made for research
- 7 Research on individual/group behavior or using surveys/focus groups



IRB FORMS

Part B: Study Description

ADVERSE EVENTS



- Serious
- Expected versus Unexpected
- Related versus Unrelated

CONSENT: REMEMBER THE POWER OF REDCAP AND REMOTE CONSENT



- In-person versus remote
- Remember the consent note

READY TO ROLL - GET THE STANDARD OPERATING PROCEDURES!



- Set standard operating procedures (SOPs) for all team-related activities and data abstraction
- Create mechanisms to avoid mistakes (check box lists)

Patient Label	Thiamine as a Metabolic Resuscitator in Cardiac Arrest (EFIC Trial)
	Patient Number: _____
	RA: _____
Standard Operating Procedure	
Inclusion ☐ Adult (age ≥ 18 years) ☐ Cardiac arrest with sustained (> 20 minutes) return of spontaneous circulation (ROSC) ☐ Within 4.5 hours of cardiac arrest event ☐ Comatose (i.e. not following commands) ☐ Lactate ≥ 3	No exclusion ☐ Known indication for thiamine administration (alcoholism, known or highly suspected deficiency) or treatment with thiamine beyond the amount found in a standard multivitamin within the last 10 days ☐ Traumatic etiology of arrest ☐ Comfort measures only or anticipated withdrawal of support within 24 hours ☐ Protected populations (pregnant women, prisoners) ☐ Known allergy to thiamine

☐ Ask the research MD and clinical team resident/attending about 30-day survival likelihood. "How likely do you think it is that this patient will be alive at 30 days?"

Research MD: _____ Very Likely Uncertain Very Unlikely RA Initials: _____

Clinical Team MD: _____ Very Likely Uncertain Very Unlikely RA Initials: _____

☐ Send out email enrollment notification to Ed-Critical Core Research Team

☐ Notify on call Lab RA by phone/pager in the event patient does not survive to a specified time point

0-hour:

- Bring: Study drug, 2 EDTA, 1 Corvac, 1 AB
- Blood draw (immediately prior to administration of study drug)
 - One 10mL EDTA kept in room temp and placed on table in Xiaowen lab (Seahorse)
 - One 10mL EDTA left in fridge in research lab (PDH/Thiamine)
 - Pipette 4 – 0.5mL of whole-blood into cryovials to be frozen
 - PI added if sitting longer than 30 min
 - One 10mL Corvac for processing and store in freezer
 - One Lactate to clinical lab (in blood gas tube, arterial if possible, and record whether arterial or venous used) and clinical labs (HCO₃, Bili, PK, Creat).
 - 0hr blood draw date/time: _____ RA Initials: _____
- Study drug
 - 0hr study drug date/time: _____ RA Initials: _____

MAKE A DATA DICTIONARY



- Sets standard for the entire team
- What you say today, you might forget tomorrow

DATA COLLECTION

```

it("onreadystatechange",H),
Number String Function Array
ction F(e){var t=[e];re
l&&e.stopOnFalse){r=!1;bre
th:r&&(s=t,c(r))return thi
return u=[],this,disable:f
on(){return p.fireWith(this
={state:function(){return n
.promise().done(n.resolve).
on(){n=s,t[1^e][2].disabl
ll(arguments),r=n.length,i=
ay(r);r>t;t++n[t]&&b.isFun
c/table>a href='/a'>a</a><
"input")][0],r.style.cssText
tAttribute("style"),hrefNo
    
```

- Use quality method such as RedCap - what is the issue with excel?
- Maintain consistency across team (importance of data dictionary)
- Consider "double data entry" for key variables such as the primary endpoint

SCREENING LOGS AND CONSORT DIAGRAM



- Importance of keeping a SCREENING LOG
- Prospectively indicate why excluded (can be overlapping)
- The denominator can be subjective so "choose wisely"

SO, REMEMBER...



- Prior to executing your research, set up all key elements (SOPs, data dictionary, database, etc..)
- When in doubt, write it down and keep in a safe place!

TRIAL MONITORING



- You are responsible for a trial monitoring plan
 - Adverse events and protocol deviations -- definitions/examples to follow
- Can vary widely depending on the risk-level of the trial and structure
- Data and Safety Monitoring Board (DSMB)
 - Charter needs to consider safety, feasibility, and efficacy
 - Odd number of members, different structures and blinding/unblinding options

DATA MONITORING PLAN



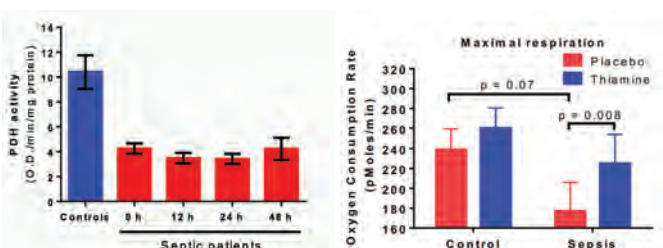
- Every study needs a data monitoring plan - what is this?
- May or may not need a Data Safety Monitoring Board (DSMB)

STATISTICAL ANALYSIS PLAN



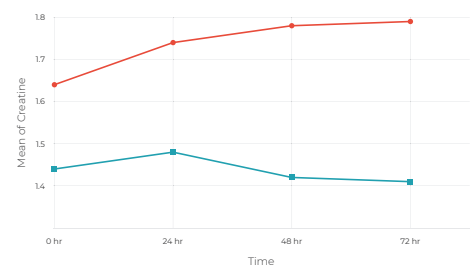
- Publish prior to unblinding and as early possible
- Be thoughtful as what you put in the plan will impact your results/paper
- Seek out statistical expertise in BOTH the planning and execution portions of the trial

PYRUVATE DEHYDROGENASE AND OXYGEN CONSUMPTION DEPRESSED IN SEPSIS



PRIMARY ENDPOINT - CREATININE

FOLLOW-UP RCT WITH FOCUS ON RENAL PROTECTION



p=0.07

CLOSING THE DATABASE



- Ensure all queries are answered
- “Lock” database prior to unblinding

CLOSING THE DEAL: BUDGETS, CONTRACTS, AND ALL THAT STUFF

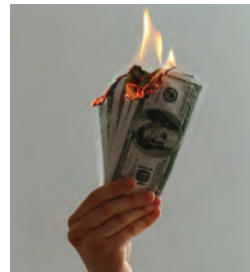
Michael Donnino, MD
Professor of Emergency Medicine and Medicine, Harvard Medical School
Director for Resuscitation Science, Beth Israel Deaconess Medical Center
Email: michael.donnino@gmail.com / Twitter: @mrdonnino

BASICS OF CLINICAL TRIAL BUDGETS



- Direct costs versus indirect costs
- How are indirects determined?

WHAT ARE KEY BUDGETARY ITEMS



- Personnel
 - Effort (Percent Effort versus Calendar Months)
 - Key versus other
 - What about mentors?
 - Statistical Personnel
- Data Management (RedCap is free though RedCloud and others are not)
- Materials (biomarkers, intervention, etc...)
 - Do your homework!
 - Be prepared for cuts

FUNDING SOURCES- IS THERE A DIFFERENCE AND HOW TO STRATEGIZE YOUR INFRASTRUCTURE



- NIH and/or equivalent (eg., AHA)
- Philanthropic (Gift versus Research)
- Foundation
- Industry
 - Investigator-initiated versus primary industry
- Networks

POOLING RESOURCES



- Clinical trials is a team sport
- Hard to enroll with 1 research assistant but can pool to gain 2+
- Hot off the press data on 9a-5p enrollment strategies

CONTRACTS



- Clinical Trials Office (CTO)
- Office of Sponsored Studies

OUTSIDE COLLABORATIONS



- Consultants
- Collaborator
- Billing Agreement versus Subcontract

LEGAL ELEMENTS



- What is your responsibility?
- Does the fine print matter?
 - Data control
 - Equipment Damage
 - Liability
- Wait, does our malpractice cover for research activities?

REPORTING



- NIH: Annual Reports
 - What to include?
 - Metrics and attributions
 - Pitfalls!
- FDA: Annual Reports
 - What to include?
 - When to report?
- IRB: Continuing Review

TRIAL CHALLENGES



- Budget Shortfall
 - Surprise fees
 - Who is responsible?
- Enrollment Difficulties
 - Common problem - have a plan B prior to starting
 - What are some ways to overcome?
- Personnel Issues

PITFALL #5



- No power calculation

PITFALL #4



- Overestimating your capacity for enrollment
- Happens for both inexperienced and experienced investigators
- "Best way to cure a disease is to study it"

PITFALL #3



- Falling into a regulatory trap
- Look at the IRB as a partner not an adversary
- Good organization - watch "over enrollments", report all AEs/PDs

PITFALL #2



- Failing to consider missing data until the end of the study period
- Ways to mitigate missing data
- Creating systems

PITFALL #4



- Over-reliance of retrospective data and assumptions of causality
- Correlation is not causation!

PITFALL #1



- Project paralysis by perfectionism
- You will be not get 100% of the grants that you do not apply for
- Enemy of good is perfect!

QUESTIONS AND FEEDBACK



•

POWER TROUBLE



- You would like to do a study evaluating thiamine in septic shock. The primary endpoint is change in lactate levels from time 0 to 24 hours.
- You have the statistician run a power calculation and the result is a need for 300 patients based on the dataset you provided to them
- What, if anything, could be done to improve the power without changing the primary endpoint or the dataset that you provided them.

REPORTING CHALLENGES



- You submit your annual report for to the IRB for a small case series testing a new therapy with a goal of 20 participants
- The IRB raises a concern that you indicated there have been 22 people consented even though 5 of them turned out not to be eligible for your study and did not enter the study protocol
- How should you respond to the IRB and handle this situation?

DRUG DELIVERY CHALLENGES



- You finally enroll a patient for your study of hydrocortisone for pancreatitis - congratulations!
- The participant receives a dose of hydrocortisone (or placebo) at 4PM however when you review the case in the morning, it appears that there was no drug delivered at 4AM.
- How should this be handled immediately and going forward?

REPORTING CHALLENGES



- You submit your annual report for to the IRB for a small case series testing a new therapy with a goal of 20 participants
- The IRB raises a concern that you indicated there have been 22 people consented even though 5 of them turned out not to be eligible for your study and did not enter the study protocol
- How should you respond to the IRB and handle this situation?

REPORTING CHALLENGES



- You enroll an 84 year old patient in your protocol testing giving acetaminophen to control fever during sepsis
- On the second night of the study protocol, the patient develops worsening sepsis, is transferred to the ICU, and ultimately dies
- Does this event need to be reported to the IRB? How would you classify this event?

RESULTS CHALLENGES



- You finally finished your trial of 100 patients randomized to ketamine versus placebo for an adjunctive therapy for sedation - congratulations!
- You now need to unblind the study. How would you go about doing this? Who controlled your randomization list?

REPORTING CHALLENGES



- You are creating a biobank of blood for patients with septic shock and ARDS with timepoints of 0, 24, 48, and 72 hours
- Finally, you have enrolled 25 patients!
- You go to analyze your samples but realize that the timeframes are different for each patient as each person on your team considered a different "time zero". Also, you noticed that there are missing samples for 15 patients at multiple time points that you were not aware of. What happened and what should be done to avoid this?

THE AUDIT



- You are conducting a 50 patient randomized trial of niacin compared to placebo. You are audited by the IRB.
- The IRB would like to see source documentation of inclusion/exclusion criteria - what is this?
- The IRB asks to see your consent notes - what is this and where have you stored them?

PUBLICATION CHALLENGES



- You submit your RCT results to a journal, finally - congratulations!
- The journal asks for your SAP.
- What is your reply?

FDA-REGULATED STUDIES



- Do you need an IND (Investigational New Drug) from the FDA?
- Challenges with the FDA and the study that changed procedure

IND EXEMPT CRITERIA

- The drug must be marketed in the United States
- The study cannot be intended to support a new indication or significant change to product labeling
- Study cannot be used to support significant change in advertising or new advertising of a product
- The study does not significantly increase risk (route, dose, patient population, other factor)
- Must be approved by and adhere to IRB

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SO YOU NEED AN IND - WHAT NOW?

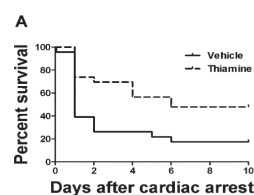


- Application to the FDA - similar to the IRB in some sense but vague
- 30-day turnaround or you can start your trial
- Ongoing reporting obligations including annual report - similar to IRB but again structure is vague
- Most surprising element - lack of communication

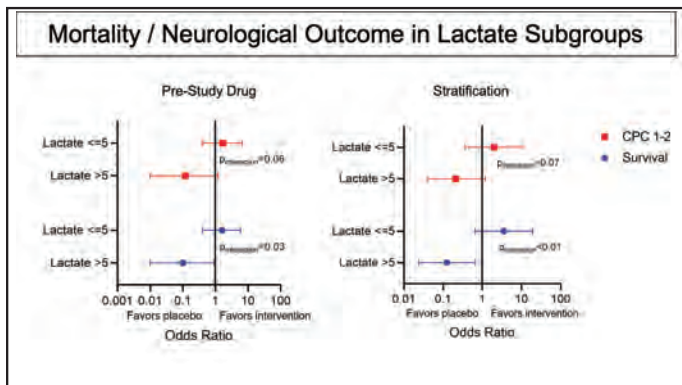
RENAL BIOMARKERS - 24 HOURS

	Thiamine (n=32)	Placebo (n=37)	p-value
KIM-1 (pg/mL)	10.65x10 ^{±2}	14.09x10 ^{±2}	0.03
NGAL (pg/mL)	13.59x 10 ^{±5}	23.51x10 ^{±5}	0.004
Cystatin (pg/mL)	20.50x10 ^{±5}	24.57x10 ^{±5}	0.06

WHAT ABOUT CARDIAC ARREST?



(Ikeda, Resuscitation, 2016)



SELF EVALUATION

Research Design and Execution in Medicine

1. What was the only intervention (aside from surgery) identified in the case of severe lactic acidosis?
 - a. Intravenous fluids
 - b. Broad-spectrum antibiotics
 - c. Thiamine 200 mg IV
 - d. Sodium bicarbonate
2. T/F - An initial step after identifying an interesting clinical observation is performing a complete literature search.
3. Which of the following is a key determinant of sample size in clinical trial design?
 - a. Number of investigators
 - b. Primary endpoint
 - c. Journal impact factor
 - d. Patient satisfaction scores
4. Which patient population should be targeted when designing a clinical trial?
 - a. Only the sickest patients
 - b. Only the healthiest patients
 - c. A "just right" at-risk population
 - d. All patients regardless of severity
5. T/F - Correlation between two variables proves a causal relationship.

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

FACULTY

Michael J. Howell, MD, MPH

Michael J. Howell, MD, MPH, of Minneapolis, Minnesota, is a Professor of Neurology at University of Minnesota where he is Vice-Chair for Education and Faculty Affairs. He is board certified in both neurology and sleep medicine, and is a fellow of the American Academies of both specialties. Dr. Howell is a frequent international speaker, a co-investigator of numerous research projects, widely published, and Chief Medical Officer of GEM Health.

You may contact Dr. Howell with your questions and comments at remwalkers@gmail.com.

THE
2026-27

Medical-Dental-Legal
UPDATE

Sleep and Circadian Wellbeing

Michael J. Howell, MD, MPH

Sleep and Circadian Wellbeing

Michael Howell MD
Professor of Neurology
University of Minnesota

Contents

- Find a new motivation for healthy sleep
- Understanding and identifying your circadian rhythm
 - Adjusting your circadian rhythm
- What to do when you can't fall asleep
- Evidence based review on supplements for sleep and wakefulness
- Screening for sleep disorders across the day
- Become a good napper

Finding a new motivation for healthy sleep

Finding motivation that resonates

- Improving sleep often takes behavioral change.
- Benefits of sleep on:
 - The Brain
 - Cardiovascular health
 - Weight Management
 - Immune Health
 - Athletic, Professional and Artistic Performance

Better sleep and the brain

- Vigilance and alertness
 - Improve safety
 - Fewer accidents
- Mood and temper
 - Decrease depression
 - Decreased suicidal ideation
- Anxiety
 - Decreased anxiety and more manageable phobias



(Olaithe et al 2018, de Zambotti et al 2018, Steel et al 2018)

Better sleep and the brain

- Substance abuse
 - Helps those trying to modify substance use and abuse
- Glymphatic clearance
 - Removes toxic metabolic by products.
 - Relationship to Alzheimer's disease and concussion pathology
- Chronic pain
 - Decreases the likelihood of developing chronic pain
 - Lessens pain burden for those already in chronic pain



(Finan et al 2013, Sun et al 2019, Cordone et al 2019)

Better sleep and cardiovascular health

- Coronary artery disease
 - Fewer heart attacks
- Heart function
 - Improved cardiac performance
- Heart rhythm
 - Decreased cardiac arrhythmia's
- Cerebral artery disease
 - Fewer Strokes



(McDermott et al 2018, Kwon et al 2018)

Better sleep and weight management

- Appetite
 - Decreased hunger
 - Increased satiety
- Thermogenesis
 - Increased capacity and motivation for exercise
 - Increased NEAT: Non-Exercise Activity Thermogenesis
- Nutrition choices
 - Improved selection of healthy foods



(Sun et al 2019, Zhu et al 2019)

Better sleep and the immune system

- Pathogens
 - Decreases infections
 - Shortens response time
- Malignancy
 - Improve immune surveillance
- Vaccination Response
 - Promotes stronger immune response



(Faraut et al 2012)

Better sleep and performance

- Professional
 - Decreased burnout for health care providers
 - Better interpersonal interactions
 - More creativity and better problem solving

(Mah et al 2011, Benton et al 2013, Stewart et al 2019)

Better sleep and performance

- Professional
 - Decreased burnout for health care providers
 - Better interpersonal interactions
 - More creativity and better problem solving
- Athletic
 - Faster reaction times
 - Fewer errors
 - Greater accuracy



(Mah et al 2011, Benton et al 2013, Stewart et al 2019)

Understanding, identifying and adjusting your circadian rhythm.

Circadian Rhythm

- Your bodies 24-hour biological clock.
- Ubiquitous through out nature
- Cellular genetic machinery operates in 24-hour DNA-RNA-Protein feedback loop.
- Controlled by the suprachiasmatic nucleus in the hypothalamus
- A primary determinant of the wake-sleep cycle



Circadian Rhythm diversity

- Circadian rhythms exist upon a diverse range.
 - Early Birds-Circadian Advance
 - Night Owls-Circadian Delay
- Circadian diversity can be clearly advantageous for a population.
- Conversely, circadian diversity can be a challenge when work, school and social life misaligns with inherited trait.

Circadian Rhythm disorders

- When environment and lifestyle are misaligned with intrinsic biological clock.
 - Jet Lag
 - Social Jet Lag
- Circadian Rhythm disorders commonly present as sleep problems.
 - Circadian Rhythm Delay
 - Circadian Rhythm Advance

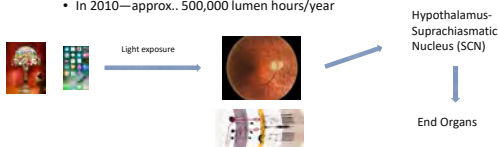
Circadian Rhythm Delay

- Difficulty initiating sleep.
 - Often misdiagnosed as an Insomniac
- Difficulty waking up the AM.
 - Often misdiagnosed as a narcoleptic or related disorder of hypersomnia.

(Culnan et al 2019)

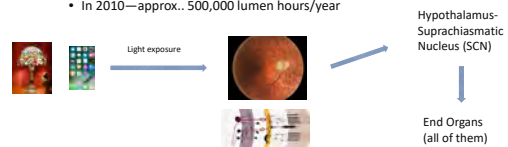
Circadian Rhythm Delay

- Common especially among adolescents and young adults.
- Related to the brain's response to evening light exposure.
 - In large part a modern disorder.
 - In 1700—approx. 500 lumen hours/year
 - In 2010—approx. 500,000 lumen hours/year



Circadian Rhythm Delay

- Common especially among adolescents and young adults.
- Related to the brain's response to evening light exposure.
 - In large part a modern disorder.
 - In 1700—approx. 500 lumen hours/year
 - In 2010—approx. 500,000 lumen hours/year



Treatment-Circadian Rhythm Delay

- Avoid sleeping pills and avoid daytime stimulants
- Morning
 - Sunlight or a 10,000-lux light box
 - Use at a consistent time (7 days a week) for 30—120 minutes
- Evening
 - Melatonin 0.5-1.0mg po 3-4 hours before bedtime.
 - Dim screens and use blue light blocking software

(Culnan et al 2019)

Circadian Rhythm Advance

- Difficulty staying awake in the evening.
 - Falling asleep socially.
 - Troubles at movies, plays, dinner parties
- Difficulty waking up early and not being able to fall back asleep.
 - May lay in bed for several hours before getting up for the day.

(Culnan et al 2019)

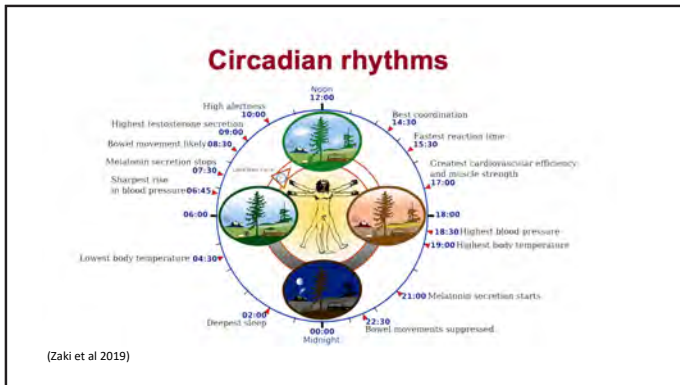
Treatment-Circadian Rhythm Advance

- Avoid evening stimulants and middle of the night sleeping pills
- Evening
 - Sunlight or a 10,000-lux light box
 - Use at a consistent time (7 days a week) for 30—120 minutes
- Morning
 - Melatonin 0.5-1.0mg po during an early morning (for example 2AM) wakeup.
- Be mindful of meal timing

(Culnan et al 2019)

Circadian Rhythm Disorders-Challenging

- Persistent sleep wake disorders resistant to conventional sleeping medications.
- More than just sleep and wake problems.
 - Appetite and weight management problems
 - Gut Motility issues
 - Difficulty concentrating for work/school
 - Hormonal disruption



What to do when you can't fall asleep

Insomnia-The experience

- Laying awake in a dark room trying to sleep
 - Frustrating
 - Ruminating thoughts
 - Non-stressful upcoming events become anxiety provoking
- The harder you try to sleep the more elusive sleep becomes.

Insomnia Etiology-a conditioned response

- Trying to sleep becomes an insomnia trap
 - Despite feeling tired the act of climbing into bed is an alerting not sedating response. Psychophysiological Insomnia develops as a conditioned response.
- Feel tired and sleepy outside of the bedroom
 - Alert once an insomniac climb into bed.
 - May sleep better in hotel's and out of the typical sleeping environment.
- Daytime consequences
 - Hypervigilance
 - CNS hypermetabolism

(Mitchel et al 2019)

First step in insomnia treatment:

- **Primum non nocere** – First do no harm
- Stop promoting the adverse conditioned response
 - Stop lying in bed when not sleeping
 - The bedroom should be reserved for sleeping and sexual activity.
- Often requires difficult behavioral change
 - Patient often see recommendations as paradoxical

(Mitchel et al 2019)

Insomnia Treatment-Cognitive Behavioral Therapy

- Cognitive Behavioral Therapy for Insomnia
 - Using Stimulus control, bedroom restriction and mindfulness you gradually decrease the adverse (wakeful) conditioning and promote positive (soporific) conditioning to the bedroom environment.
- Usually administered by a licensed psychologist
 - Unique skill set from practitioners in other forms of CBT
 - Also available with evidence-based online programs.
- Very compelling evidence
 - Most effective strategy to cure insomnia.

(Mitchel et al 2019)

Treatment-Cognitive Behavioral Therapy-Insomnia

- The two rules:
 - Get out of bed if you are not sleeping
 - Don't fall asleep outside of the bedroom.

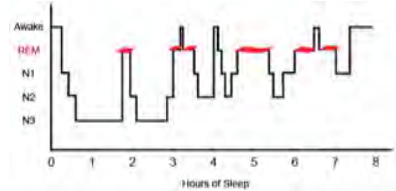
What to do when you can't stay asleep

Trouble staying asleep

- Understand the normal ultradian rhythm
- Consider a circadian advance
- Consider sleep apnea
- Cognitive Behavioral Therapy for Insomnia

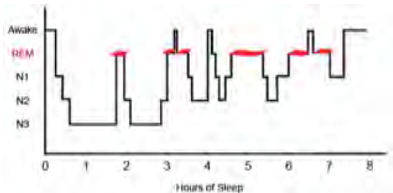
(Mitchel et al 2019)

Ultradian Rhythms-Normal Sleep Cycles



Wikimedia Commons

Ultradian Rhythms-Normal Sleep Cycles



Wikimedia Commons

- A brief awakening every 90 minutes or so does not, by itself, indicate pathology.

Advanced Circadian Rhythm

- Common problem particularly middle aged and elderly
- Trouble staying asleep but also sleepy and tired in the evening.
- Living in the wrong time zone
- Advance in bodies 24 hour clock.



Galileo Spacecraft-NASA

(AASM ICSD-3 2015)

Treatment-Circadian Rhythm Advance

- Avoid evening stimulants and middle of the night sleeping pills
- Evening
 - Sunlight or a 10,000-lux light box
 - Use at a consistent time (7 days a week) for 30–120 minutes
- Morning
 - Melatonin 0.5-1.0mg po during an early morning (for example 2AM) wakeup.
- Be mindful of meal timing

(Culnan et al 2019)

Snoring and obstructive sleep apnea (OSA)

- Collapse of the upper airway during sleep
- OSA is a common condition
 - Higher risk: men, weight gain, family history, increased neck circumference.
 - Women are more likely to present with middle of the night insomnia then men.



CBT-I for sleep maintenance Insomnia

- The same two rules:

CBT-I for sleep maintenance Insomnia

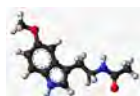
- The same two rules:
 - Get out of bed if you are not sleeping
 - Don't fall asleep outside of the bedroom.

Evidence based review on supplements for sleep and wakefulness

Supplements for sleep and wakefulness

- Melatonin
- Iron
- Vitamin D

Melatonin



- Endogenous compound released from the pineal gland
 - Located at the base of the brain
- Molecular signal of darkness.
 - Ganglion Cell Layer in retina → Suprachiasmatic nucleus → Pineal Gland → Melatonin secreted into vascular bed.

Melatonin-most important point

Melatonin-most important point

Melatonin is a circadian agent not a sleeping agent

Melatonin-evidenced based use

- For Circadian Disorders
 - Circadian Rhythm Delay
 - Small dose (0.5mg) 4-6 hours before bedtime
 - Circadian Rhythm Advance
 - Small dose (0.5mg) during middle of the night awakening
 - Jet Lag Disorder
 - Small dose (0.5mg) taken 1-2 hour before new bedtime.
 - If possible, begin 2-3 days prior to departure.

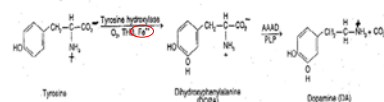
(Culnan et al 2019)

Melatonin-setting expectations

- Lower expectations that the treatment will immediately be effective.
- Increase expectations that treatment will be effective over days to weeks.
 - Especially when used in combination with light therapy.
 - Circadian Rhythm Delay-AM Light
 - Circadian Rhythm Advance-PM Light
 - Jet Lag Disorder-Light at time of desired destination wake up time.

(Culnan et al 2019)

Iron



- Co-factor in the tyrosine hydroxylase
 - Rate limiting step in the production of CNS dopamine
 - In addition to its essential role in Red Blood Cells
- CNS dopamine deficiency a primary cause of restlessness.
 - Common in young healthy women.
 - Vegans/Vegetarians at higher risk.
 - Pregnancy exacerbates relative iron deficiency

Iron and restlessness

- Common reason for trouble falling asleep
- Often difficulty for patients to describe the discomfort
 - Discomfort causes an urge to move
 - Movement relieves the urge (although often only momentarily)
 - Worsens at night thus interferes with sleep
- Frequently the presenting complaint is often only “I can't fall asleep”

(Avni et al 2019)

Iron

- Difficult to measure
 - CNS iron stores v. serum iron
- Serum ferritin is the most readily available marker
 - However, hospital labs base low thresholds for iron deficiency anemia not for healthy CNS iron stores.
 - Low normal values are often listed at 10mcg/L.
 - More appropriate low value would be 50mcg/L.
 - Sleep medicine consensus is even higher at 75mcg/L.

(Allen et al 2018, Avni et al 2019)

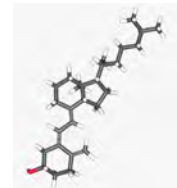
Iron-supplementation

- Oral supplementation is challenging
 - Poor intestinal absorption of elemental iron
 - GI side effects.
- Increased absorption with iron gluconate formulation.
 - Recommend 325mg
 - Absorption improved when combined with 100mg Vitamin C.
- IV Iron replacement an option
 - Ferric carboxymaltose

(Avni et al 2019)

Vitamin D

- Collection of fat-soluble hormones
 - Diet
 - UV exposed skin
- DNA transcription Effects
 - Mineralization
 - Inflammation
 - Immune function
 - Muscle tissue



(McCarty et al 2014)

Vitamin D-severe deficiency

- Demineralization
 - Osteomalacia
 - Rickets
- Myopathy
- Hyperparathyroidism

(McCarty et al 2014)

Vitamin D deficiency and the immune system

- Low levels promote Th-1 over Th-2 immunity
 - Pro-inflammatory
 - TNF-alpha promotes tissue destruction
- Upper airway inflammation
 - Asthma
 - Allergic Rhinitis

(McCarty et al 2014)

Vitamin D deficiency and sleep disorders

- Promote obstructive sleep apnea
 - Due to
 - tonsillar hypertrophy
 - rhinitis
 - upper airway myopathy
- Excessive daytime sleepiness
 - Small studies suggest vitamin D replacement can address hypersomnia in some cases.

(McCarty et al 2014)

Vitamin D

- Measuring Vitamin D
 - Conventional definition of deficiency <20ng/ml
 - Based primarily upon rickets demineralization data
- Limitations on single point testing
 - Variations by season and uncertain durations
- Dosing recommendations (primarily based upon consensus)
 - < 12 ng/ml=50,000 IU for 8 weeks
 - 12-20ng=5,000 IU
 - 20-30ng/ml=3,000 IU
 - 30-40ng/ml=1,000 IU

(McCarty et al 2014)

Screening for sleep disorders across the day

In the morning and during the day

- When you wake up in the morning
 - You should feel like you are done sleeping.
 - Could not sleep in longer even if you tried
 - Should feel hungry within an hour
- During the day
 - You should feel alert even when sedentary and without caffeine or other stimulant
 - Exception: afternoon nap time

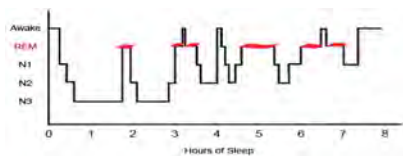
In the evening

- Should feel alert after dinner
 - Able to stay awake even during passive activities
 - Watching a show or sporting event
 - Reading
- In the hour leading up to sleep
 - Should feel progressively sleepy
- Climbing into bed
 - Should feel comfortable
 - Should feel somnolent

At night-breathing

- Watch for snoring
 - Labored breathing
 - Gasping
- Apneas
 - May be silent

Sleep Cycle



At night-behaviors

- Normal to wake up intermittently at night
 - Abnormal to wake up and not be able to fall back asleep
- Amnestic behaviors
 - Sleepwalking
 - Sleep eating
- Dream enactment
 - Common-1% general population; 5% in the elderly
 - Potentially injurious and can be a prodromal syndrome for Parkinson's disease

Become a good napper

How do you know if you are a bad napper?

Nap drunkenness

Nap drunkenness

- Occurs when napping brain is trying to fall asleep for the “night”
- Occurs when naps are
 - Out of timing
 - Out of duration
 - Out of practice
- Untreated sleep disorder
 - Sleep deprived

Nap timing and duration

- Circadian Rhythm of Naps
 - Varies person to person
 - 12 hours from midpoint of natural sleep rhythm
- Duration
 - 10-20 minutes
 - Stages N1 and N2 Sleep (light NREM sleep)
 - Power Nap
 - 70-90 minutes
 - Stages N1, N2, N3 (Light and Deep NREM sleep), R (REM sleep)

Power napping routine

- Identify and practice during ideal nap timing
- Don't lay down or cover yourself
 - Drop in body temperature (0.5C) during N1 and N2 will act as a snooze alarm.
- Practice, Practice, Practice



Thank You



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SELF EVALUATION

Sleep and Circadian Wellbeing

1. Iron is a critical cofactor for the metabolism of which neurotransmitter?
 - a. Dopamine
 - b. Acetyl choline
 - c. Gaba
 - d. All of the above
 - e. Non-of the above
2. Vitamin D Deficiency can promote obstructive sleep apnea through the following pathway(s)
 - a. Tonsillar hypertrophy
 - b. Upper airway myopathy
 - c. Rhinitis
 - d. All of the above
 - e. Non-of the above
3. A person with a Circadian Rhythm Advance...
 - a. Will have difficulty falling asleep at night
 - b. Will wake up several hours early and have trouble falling aback asleep.
 - c. Will sleep in late into the morning when
 - d. given the opportunity (weekends, vacation)
 - e. Non-of the above
4. Improved sleep can...
 - a. Decrease suicidal ideation
 - b. Decrease the likelihood of developing chronic pain
 - c. Decrease pain burden for those already
 - d. in chronic pain.
 - e. Non-of the above
5. Waking up extra early in the morning is helpful for those trying to lose weight because...
 - a. They will get exercise and burn more calories
 - b. Establishes the discipline to limit caloric intake.
 - c. They will make better food choices.
 - d. Non-of the above
 - e. All of the above.
6. The following strategy(s) have been demonstrated to be effective in treating a Circadian Rhythm Delay.
 - a. 10,000 lux light box for 60 minutes at the same time in the morning.
 - b. 10,000 lux light box for 60 minutes when ever an individual wakes up in the morning.
 - c. 10,000 lux light box for 60 minutes in the evening
 - d. Melatonin 0.5 mg at bedtime.
 - e. All of the above
7. The following strategy(s) have been demonstrated to be effective in helping people with insomnia fall asleep.
 - a. An evening bath and chamomile tea.
 - b. Evening exercise
 - c. Bedroom restriction
 - d. Take afternoon naps
 - e. Non-of the above
8. Evening melatonin is effective for people with
 - a. A Circadian Rhythm Advance
 - b. A Circadian Rhythm Delay
 - c. Hypervigilant Insomnia
 - d. Restless Legs Syndrome
 - e. All of the above
9. Napping...
 - a. In an adult is indicative of excessive daytime sleepiness
 - b. In a child is Indicative of excessive daytime sleepiness
 - c. Is a normal human physiological need
 - d. across the lifespan
 - e. Is to be avoided if a person has to perform (such as an athlete) in the evening.

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

FACULTY

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

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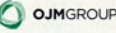
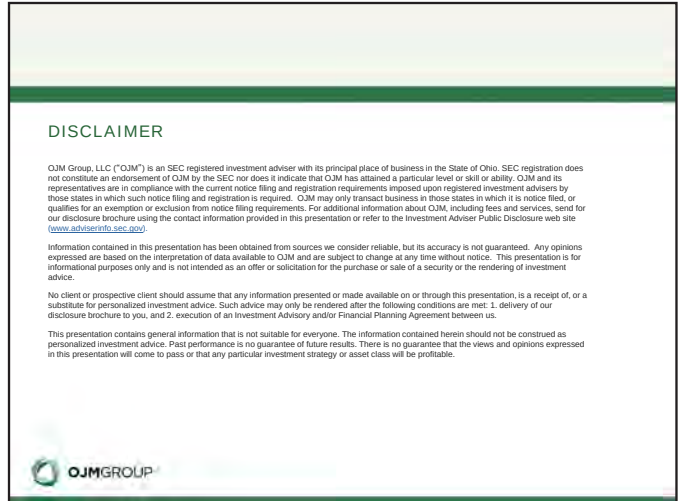
Selling to Private Equity: The Pros and the Cons

Carole C. Foos, CPA



**SELLING TO PRIVATE EQUITY
THE PROS AND THE CONS**

PRESENTED BY:
CAROLE C. FOOS, CPA
Partner, OJM Group

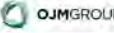
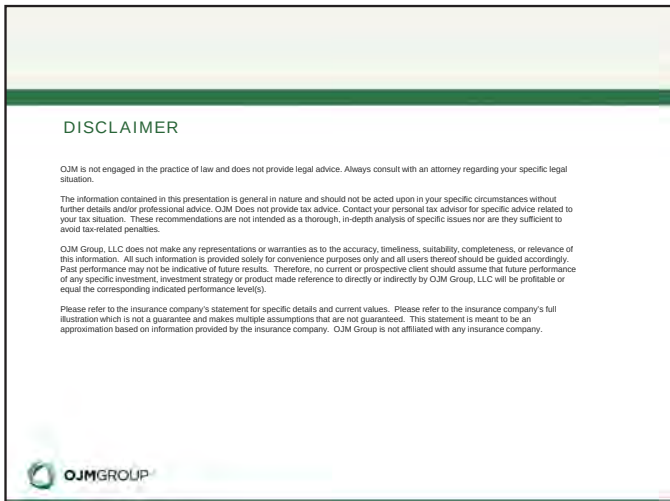
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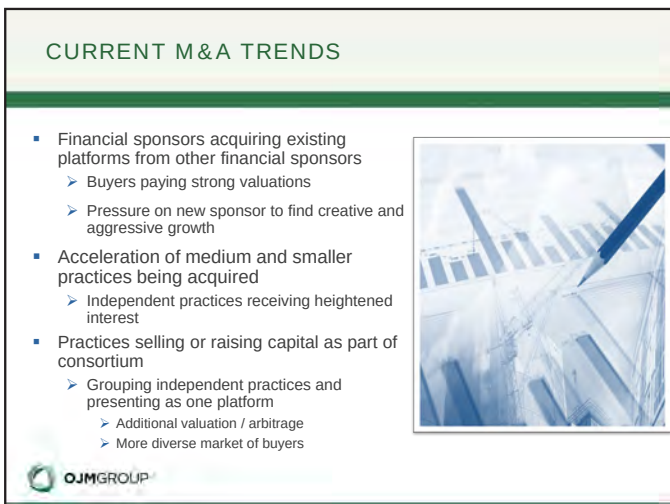
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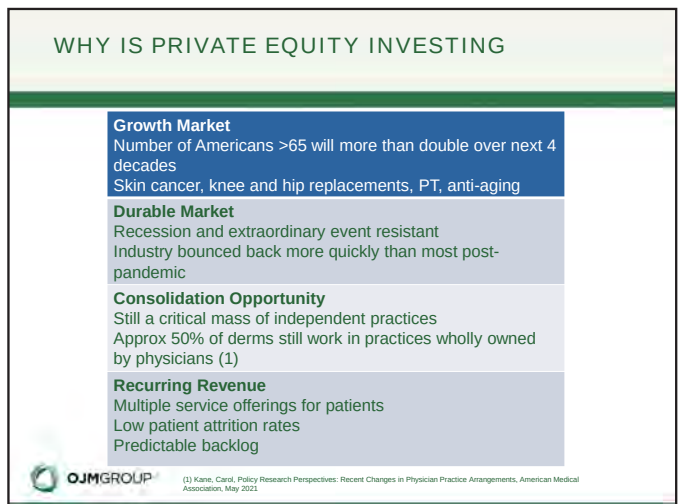


CURRENT M&A TRENDS

- Financial sponsors acquiring existing platforms from other financial sponsors
 - Buyers paying strong valuations
 - Pressure on new sponsor to find creative and aggressive growth
- Acceleration of medium and smaller practices being acquired
 - Independent practices receiving heightened interest
- Practices selling or raising capital as part of consortium
 - Grouping independent practices and presenting as one platform
 - Additional valuation / arbitrage
 - More diverse market of buyers





WHY IS PRIVATE EQUITY INVESTING

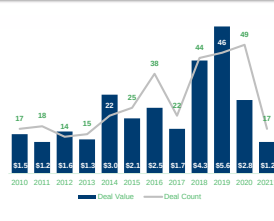
Growth Market Number of Americans >65 will more than double over next 4 decades Skin cancer, knee and hip replacements, PT, anti-aging
Durable Market Recession and extraordinary event resistant Industry bounced back more quickly than most post-pandemic
Consolidation Opportunity Still a critical mass of independent practices Approx 50% of derms still work in practices wholly owned by physicians (1)
Recurring Revenue Multiple service offerings for patients Low patient attrition rates Predictable backlog

(1) Kane, Carol, Policy Research Perspectives: Recent Changes in Physician Practice Arrangements, American Medical Association, May 2021

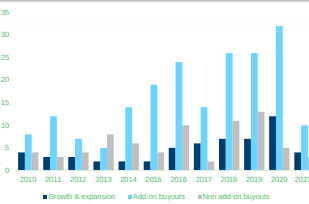


ORTHOPAEDIC MARKET EXAMPLE

US Private Equity Activity in Orthopaedic Healthcare ⁽¹⁾



US Private Equity Activity (#) in Orthopaedic Healthcare by Type



Strong Market Fundamentals

Approximately 80% of 2020 private equity activity in the Orthopaedics market was related to healthcare services. ⁽²⁾

Despite the disruption of COVID-19, 49 orthopaedic transactions closed in 2020. ⁽³⁾

Orthopaedic practices are among the best at establishing multiple profit centers through robust, ancillary service offerings.

Over the past 10 years, the number of non-health system physician practice acquisitions in orthopaedics has increased from 2 to 7 per year. ⁽⁴⁾



⁽¹⁾ Source: PitchBook | Geography: US | * As of May 25, 2021
⁽²⁾ "Private Equity Investment As A Driving Red For Market Failure: Policy Responses to Harmful Physician Practice Acquisitions," USC Brookings, Schaeffer Institute for Health Policy, October 2021

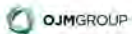
THE UPSIDE OF A SALE TO PRIVATE EQUITY

- Significant Cash Infusion
 - Pay down debt
 - Invest in new technology
 - Expand the practice
 - Fund retirement
 - Succession / exit plan
- Gain management expertise
 - Improve efficiencies
 - Increase profitability
- Offload back-office headaches
- Potentially increase revenue due to greater ability to negotiate with payors, reduce expenses through vendor negotiations / block purchases



DOWNSIDE OF A PRIVATE EQUITY SALE

- New focus on returns and profitability
 - Could be a conflict with doctor's view of patient care
- Loss of full managerial control for owner(s)
- Changes to practice culture and priorities, employee retention
- Loss of control over practice operations
- Change in owner compensation and retirement plans
- Concern over long term impact on healthcare services
- More vigorous and regular reporting



PRACTITIONER'S PERSPECTIVE

Regulation:

- Increasing percentage of burnout among dermatologists
- Drivers include fraud and abuse statutes governing compensation methodologies, licensing and reporting obligations, and regulations governing uses of patient health information

Focus on the Patients:

- Shedding of administrative duties
- Patient service delivery and revenue collection become the priority

Personal Financial Goals:

- Practice owners can receive attractive all cash payments
- Exit strategy for practice owners
- Physicians have the opportunity to receive a "second bite of the apple" with a private equity group



THE PRIVATE EQUITY MODEL

- Funds of money, managed by finance and operating professionals, backed by high-net-worth individuals, pension funds, and university endowments (to name a few).
- Acquire a majority equity stake in a physician practice (i.e. platform investment) while leaving the physicians with a minority equity position in the practice.
- Over a three to seven year period, the private equity group wants to increase the value of the practice in order to resell the platform investment and receive an attractive return.
- Means of increasing Adjusted EBITDA ⁽¹⁾ and value for a medical practice investment:
 - Acquiring additional practices (i.e. add-on acquisitions)
 - Open new locations and bring on additional talent
 - Expand and diversify services (Mohs, cosmetic, dermatopathology lab, clinical trials, etc.)
 - Synergies: Cost savings or new revenue created by the combination of one medical practice with another.

Synergies → **Increased Adjusted EBITDA** → **Higher Practice Valuation**

⁽¹⁾ Earnings before Interest Expenses, Income Taxes, Depreciation and Amortization Expense. Adjustments can include excess physician owner's compensation, and one-time expenses



STRATEGIC OPTIONS

Status Quo	Continue to execute current operating plan and retain existing structure
Sale to Strategic Buyer or Financial Sponsor	Sell to a larger practice and become a subsidiary OR sell to private equity to gain capital and management expertise
Recapitalization	Utilize debt or combo of debt and minority equity



VALUE DRIVERS

Owners should constantly evaluate ways to build value, beginning with 3 core pillars of value assessment

Stability	Profitability	Growth
- Talented core provider team with diversification across specialties. - Established organizational structure with both executive and physician leadership in place. - Existing footprint in a competitive regional market. - Consistent track record of historical financial performance and production levels across providers.	- Organization has demonstrated ability to achieve profit milestones over a multi-year period. - Financial and operational data reflect industry best-practices and provide meaningful insights as to the operational health of the practice. - Adjusted EBITDA margins are ideally achieving, or are on a path towards, 20% Adjusted EBITDA margin or greater.	- Practice has a proven ability to add providers, expand specialties, and add ancillary service offerings. - The financial and operational performance of the practice reflects a historical track record of growth, and ideally a forecast supported by historical trends. - Leadership has a clearly articulated growth plan to continue to build value as a platform or under the umbrella of a larger organization.



STEPS TO BUILDING VALUE

Build talent throughout the provider, mid-level and administrative ranks. Create a system of evaluating and recruiting and retaining talent.

Bench Depth

Whether it be operating in a distinct geography, or performing a unique set of services, a practice should strive to be a leader in a defined niche.

Establish a Niche

Create an organization that offers diversified revenue sources, which could include pain management, physical therapy, Orthopaedic Urgent Care, and ownership of Ambulatory Surgical Centers (ASCs).

Ancillary Services

With the industry migration towards value-based care, it is important that practices can demonstrate a path to success under this new system.

Success Under Value Based Care Model

Quality of actionable information is critical for both managing and selling a practice. Key steps to take include utilizing a fractional or full-time CFO to serve as an advisor to practice owners and establishing systems and process for financial and operational management.

Financial Controls and Operating Metrics

Develop a detailed strategic growth plan, supported by financial projections. Highlight what added resources can do to improve practice performance. Working with advisors, practice owners should periodically reevaluate options that could help drive or present optimal exit / liquidity solutions.

Strategic Planning



IMPROVING PRACTICE VALUE

- **Talent**
 - Hire and retain physicians, PA's other medical talent
 - Balanced ratio of physicians to PA's, etc.
- **Financials**
 - Transparent books and records
 - Reviewed or audited financial statements
 - Perform diligence in preparation of sales transaction
 - External firm can provide credibility to numbers
 - Adjusted EBITDA margin of 20% or greater
 - Periodic review and elimination of overhead
 - Avoid legal and regulatory issues
- **Diversification**
 - Range of services
 - Mohs, laser, spa, PT, research, radiology
- **Geographic Market**
 - Size and location
 - Additional locations



IMPROVING PRACTICE VALUE

- **Strategic Plan**
 - Written strategic plan provides steps for efficient operation and growth
 - Offers buyer a roadmap
 - Utilize as a "map" to know where practice is going
- **Growth**
 - Ability to grow substantially over 3-7 years
 - Maintain historical practice performance
 - Articulate future growth opportunities
- **Synergies**
 - Cost savings or new revenue
 - Improved negotiating leverage
 - Referrals
 - New in house capabilities



EBITDA

Adjusted Earnings Before Interest Expense, Taxes, Depreciation & Amortization Expense

Practice Net Income
+ Interest Expense
+ Income Taxes
+ Depreciation Expense
+ Amortization Expense
+ Excessive Physician Owner Compensation
+ Non-Recurring Practice Expenses
+ Extraordinary Practice Expenses
+ Synergies with a Buyer's Platform



SUMMARY

- Sale can provide cash infusion, growth and succession opportunities
- Sale will also bring a reduction in control and changes to practice dynamics
- Multiple options for sales: another practice, private equity, consortium merger
- Regardless of interest in selling, makes good business sense to increase practice value
- Ways to increase value include acquisition and use of talent, strong financials, diversification and strategic plan for growth

Synergies → Increased Adjusted EBITDA → Higher Practice Valuation



CORPORATE PLANNING PROCESS

DIAGNOSTIC vs. TREATMENT
ADVICE & EXPERTISE FOR A FLAT FEE
BUILDING A RELATIONSHIP

ASSET PROTECTION
CORPORATE STRUCTURE & TAX PLANNING
INVESTMENT MANAGEMENT
CORPORATE BENEFITS PLANNING
RISK MANAGEMENT ANALYSIS

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PERSONAL WEALTH PLANNING

DIAGNOSTIC vs. TREATMENT
ADVICE & EXPERTISE FOR A FLAT FEE
BUILDING A RELATIONSHIP

ASSET PROTECTION
TAX
INVESTMENTS
INSURANCE
FINANCIAL MODELING

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SELF EVALUATION

Selling to Private Equity: The Pros and the Cons

1. What is a primary goal of private equity firms after acquiring a medical practice?
 - a. Maintain current operations indefinitely
 - b. Increase value and resell the practice within 3–7 years
 - c. Convert the practice into a nonprofit entity
 - d. Eliminate all physician ownership
2. T/F - Physicians typically retain a minority ownership stake after selling to private equity.
3. Which of the following is a commonly cited downside of selling to private equity?
 - a. Reduced access to capital
 - b. Decreased operational efficiency
 - c. Loss of full managerial control
 - d. Elimination of reporting requirements
4. Which of the following contributes to increasing a practice's valuation?
 - a. Reducing patient volume
 - b. Lowering EBITDA
 - c. Increasing Adjusted EBITDA
 - d. Eliminating ancillary services
5. One potential benefit of selling to private equity is the ability to negotiate more effectively with payors.

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