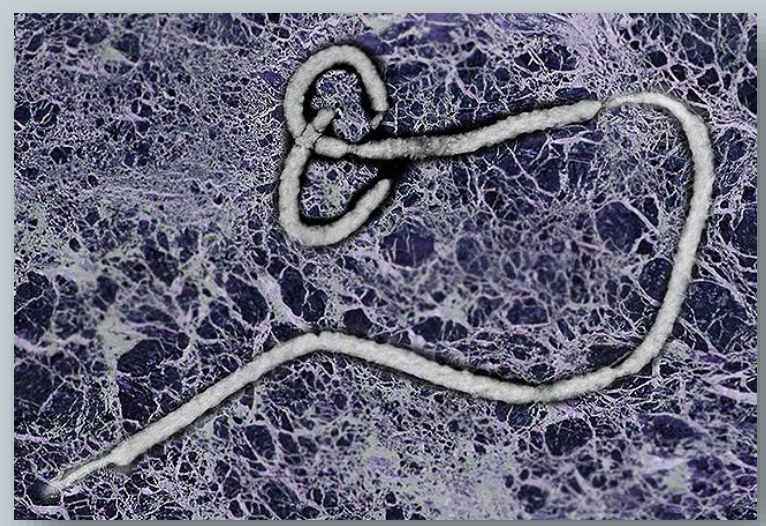
Key Articles & Clinical Developments of 2014 in Family Medicine

WHAT WAS IMPORTANT…

…AT LEAST TO SOME OF US

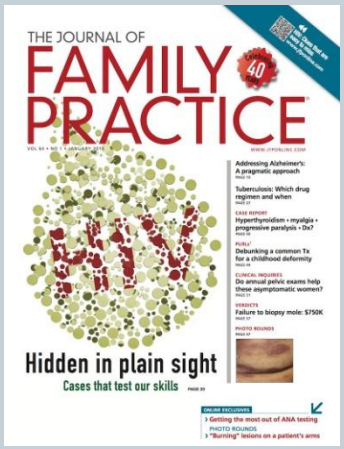
BY DAN WALDMAN, MD

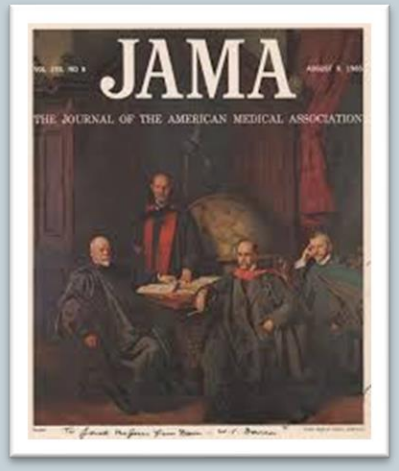
What This **Isn't** About…



What This **Isn't** About…

What This **Is** About…





How Did I Choose What I Chose?

- Our faculty*
- Essential Evidence
- Journal Watch
- Scouring “Top of 2014” Lists

- Prioritized:
  - key areas of FM practice
  - might directly change clinical practice
  - might be leading to paradigm changes
  - Fun

Important New Guidelines

BP & A BIT ON CHOLESTEROL (*LATE 2013*)

JNC8

JNC7: Classification and Treatment

EVALUATION

Classification of Blood Pressure (BP)*

Category	SBP mmHg		DBP mmHg
Normal	<120	and	<80
Prehypertension	120–139	or	80–89
Hypertension, Stage 1	140–159	or	90–99
Hypertension, Stage 2	≥160	or	≥100

* See *Blood Pressure Measurement Techniques* (reverse side)

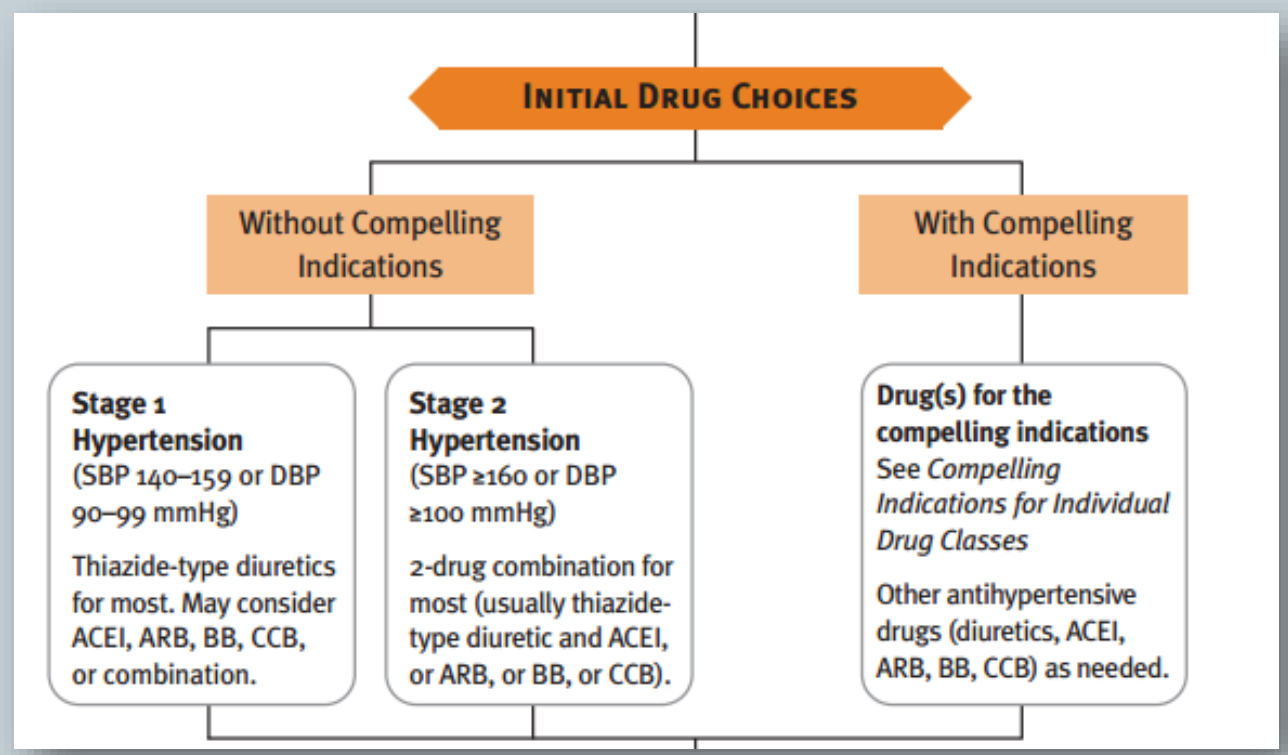
Key: SBP = systolic blood pressure DBP = diastolic blood pressure

TREATMENT

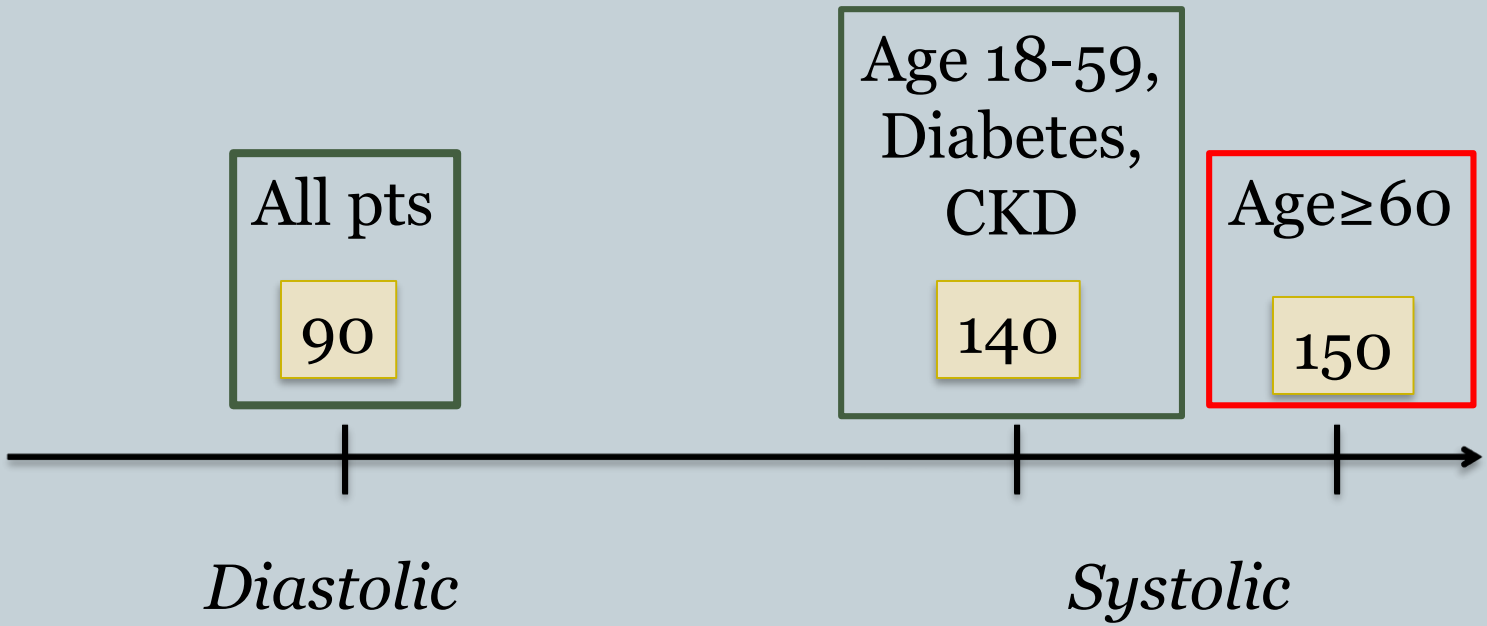
Principles of Hypertension Treatment

- Treat to BP <140/90 mmHg or BP <130/80 mmHg in patients with diabetes or chronic kidney disease.
- Majority of patients will require two medications to reach goal.

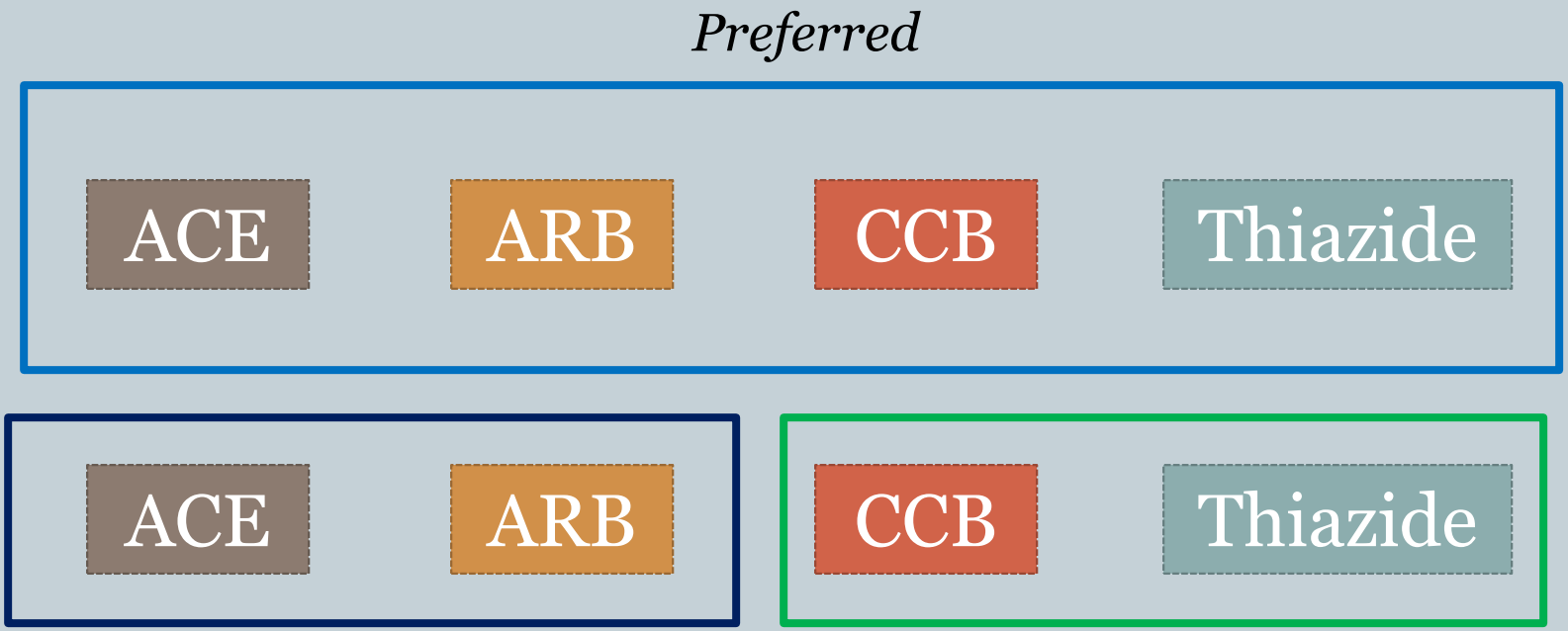
JNC7: Med Choices



JNC8: BP Goals



JNC8: Initial Preferred Meds



Some Issues With JNC8

- Controversy? (endorsed by……)
- 5 of 17 JNC8 authors wrote commentary rejecting 150mmHg target for >60

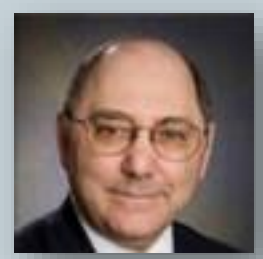
Jackson T. Wright Jr., MD, PhD; Lawrence J. Fine, et al. "Evidence supporting a systolic blood pressure goal of less than 150 mm Hg in patients aged 60 years or older: the minority view." *Ann Intern Med*. Published online 14 January 2014 doi:10.7326/M13-2981.

- Others say "There is no evidence supporting drug treatment for patients of any age with mild hypertension" (SBP: 140-159 and/or DBP 90-99)

Diao D, Wright JM, Cundiff DK, Gueyffier F. Pharmacotherapy for mild hypertension. Cochrane Database of Systematic Reviews 2012, Issue 8. Art. No.: CD006742. DOI: 10.1002/14651858.CD006742.pub2.

Will JNC8 Last?

- AHA President: *"We are concerned that relaxing the recommendations may expose more persons to the problem of inadequately controlled blood pressure."*



- ACC/AHA anticipates new guideline late 2015

ACC/AHA Cholesterol Guidelines (late 2013)

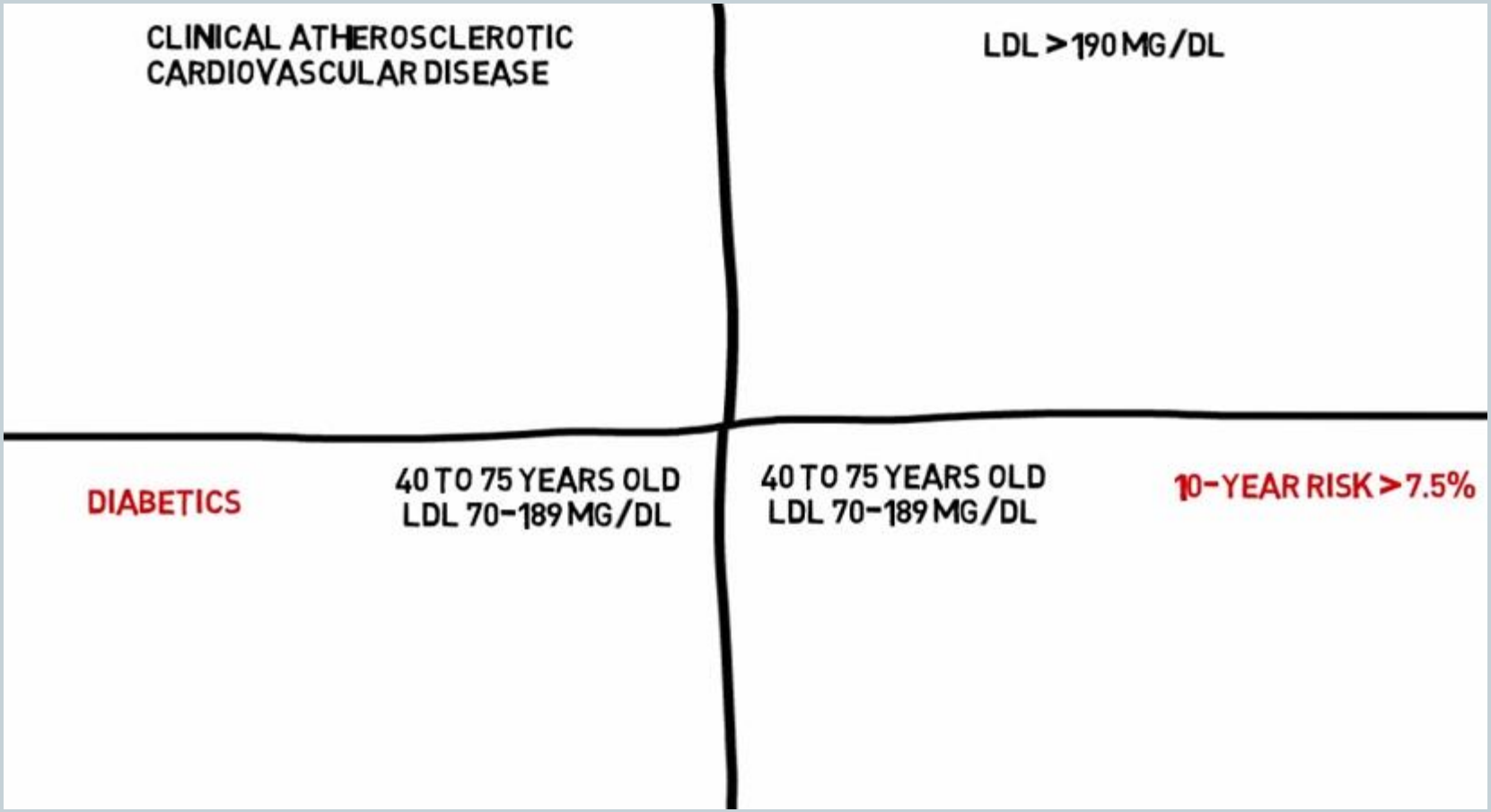
2013 ACC/AHA Lipid Guidelines

PROS	CONS
• EBM Approach • Move away from number LDL targets	• Industry connections • Good risk calculator? • Low 10 year risk cutoff for treatment (7.5%) • Failure to communicate risks/harms of treatment • Most Panelists subspecialists • No draft recs and time for public comment

ATP-III Guidelines	
Patient Type	Treatment Recommendation
Known CHD or CHD equivalent (Coronary heart disease)	Goal LDL <100 *<70 for "highest risk individuals" Start meds at 130
10yr Framingham risk >20%	Goal LDL <100 Start meds at 130
2+ CHD risk factors (10 yr Framingham risk <20%)	Goal LDL <130 Start meds at 160
0-1 CHD risk factors	Goal LDL <160 Start meds at 190

2013 ACC/AHA Guidelines	
Patient Type	Treatment Recommendation
Known ASCVD (Atherosclerotic cardiovascular disease)	Start HIGH potency statin
LDL >190	Start HIGH potency statin
Diabetes Age 40-75	Start MODERATE potency statin
10yr risk ASCVD >7.5% using Pooled Cohort Equation	Start MODERATE to HIGH potency statin

Another way to look at the 4 groups



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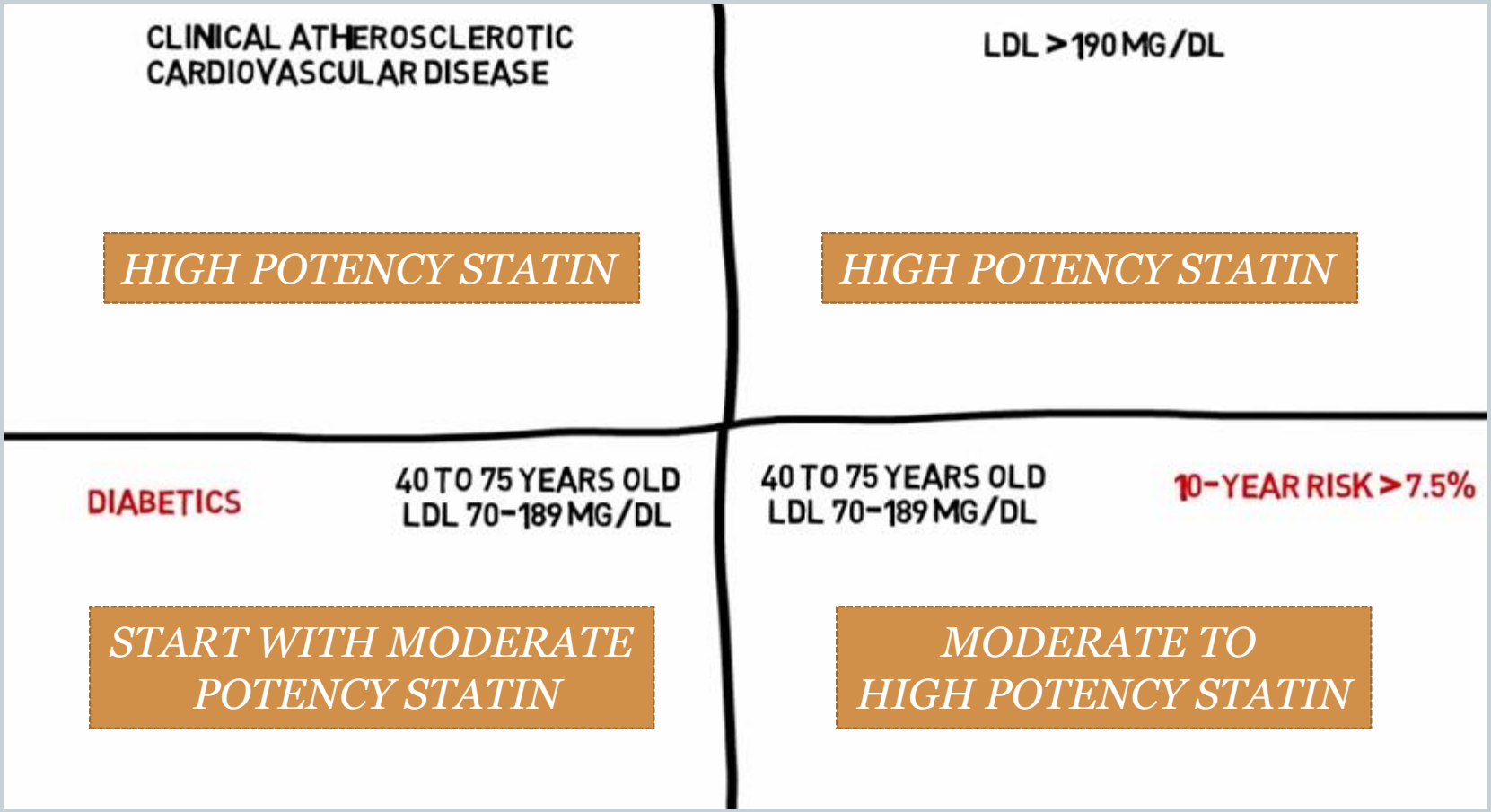


Statins Specified

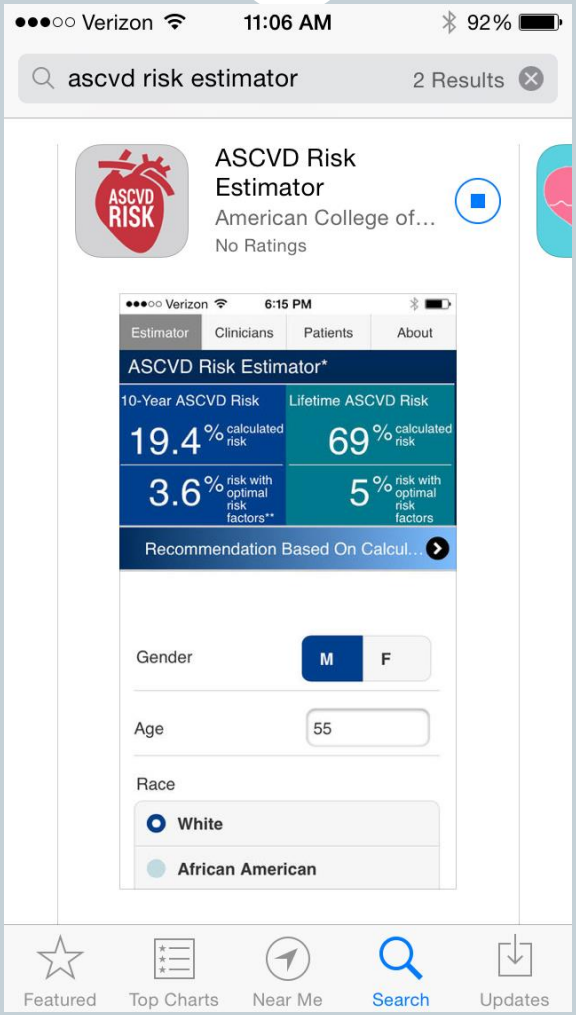
High potency statin *(lower chol by >50%)*

- Atorvastatin 80mg (40 if can't tolerate)
- Rosuvastatin 20mg

Moderate potency statin *(lower chol by ~30-50%)*

- Atorvastatin 10-20mg
- Rosuvastatin 5-10mg
- Simvastatin 20-40mg
- Pravastatin 40-80mg
- Lovastatin 40mg
- Fluvastatin 40mg bid

SmartPhone App for 10 Year Risk



More Controversy/Perspectives

- UK (and other) guidelines uses risk cutoff of 20% for statin initiation
  - Pretest 20%->16%. (NNT 25)
  - Pretest 7.5%->5% (NNT 67)

- Risk calculator puts all men >70 and *all* African-American men >65 on statins (even with nl BP/chol)

Controversial Guidelines…What's Our Job?

Meserve C, Kalet A, Zabar S, Hanley K, Schwartz MD. Clever Nihilism Cynicism in evidence based medicine learners.

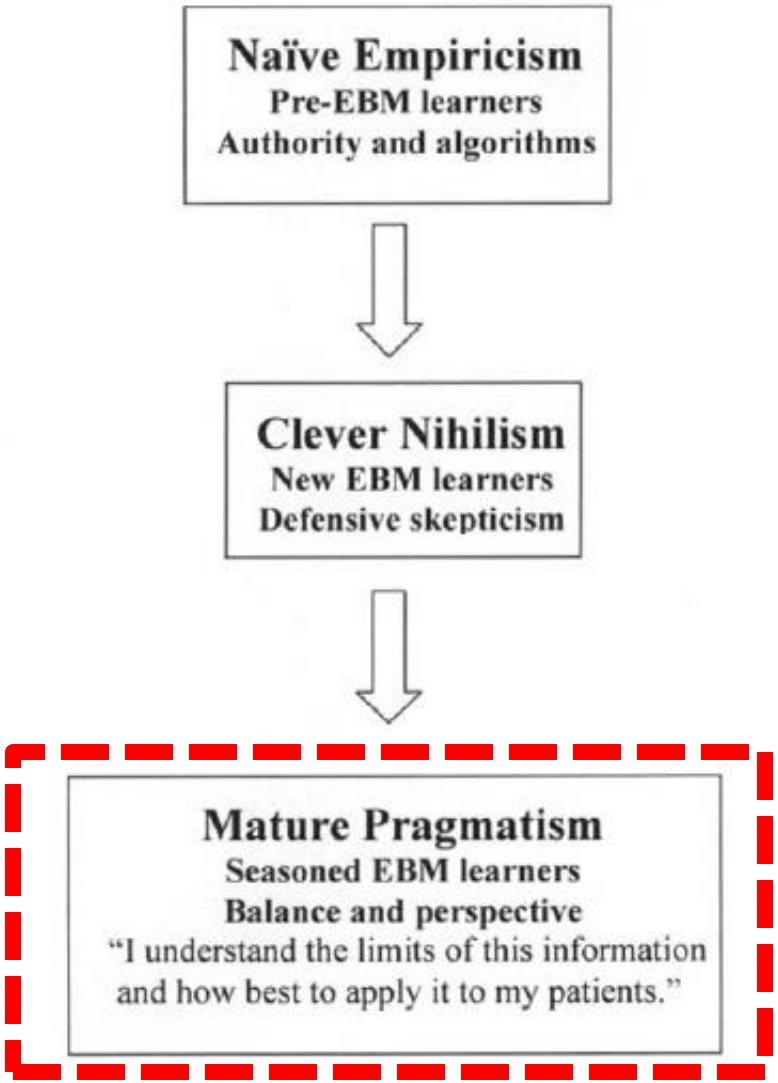


Figure 1: Developmental model of attitudes regarding learning of evidence-based medicine (EBM)

Some Important Studies

Aspirin for Primary Prevention

Ikeda Y, Shimada K, Teramoto T, et al. Low-dose aspirin for primary prevention of cardiovascular events in Japanese patients 60 years or older with atherosclerotic risk factors. A randomized clinical trial. JAMA 2014;312(23):2510-2520.

Low Dose Aspirin Not Helpful for Primary Prevention

- Japanese RCT of adults 60-85, >14k pts, Confirmed findings of 2011 systematic review
- Enrolled pts had ASCVD risk factors but no ASCVD
  - Removed pts with GI Bleeding Hx
  - Used 100mg enteric coated aspirin
- No difference in all cause mortality
  - Some other smaller endpoint differences
- FDA had actually reversed rec's in May: Aspirin *"not for primary prevention"*

Position Paper: Opioids for Chronic Non Cancer Pain

Franklin, G. Opioids for chronic noncancer pain: A position paper of the American Academy of Neurology. Neurology 2014;83;1277-1284

FIGURE 1: Hospitalizations from opioid overdose (Washington State, 1987–2008)

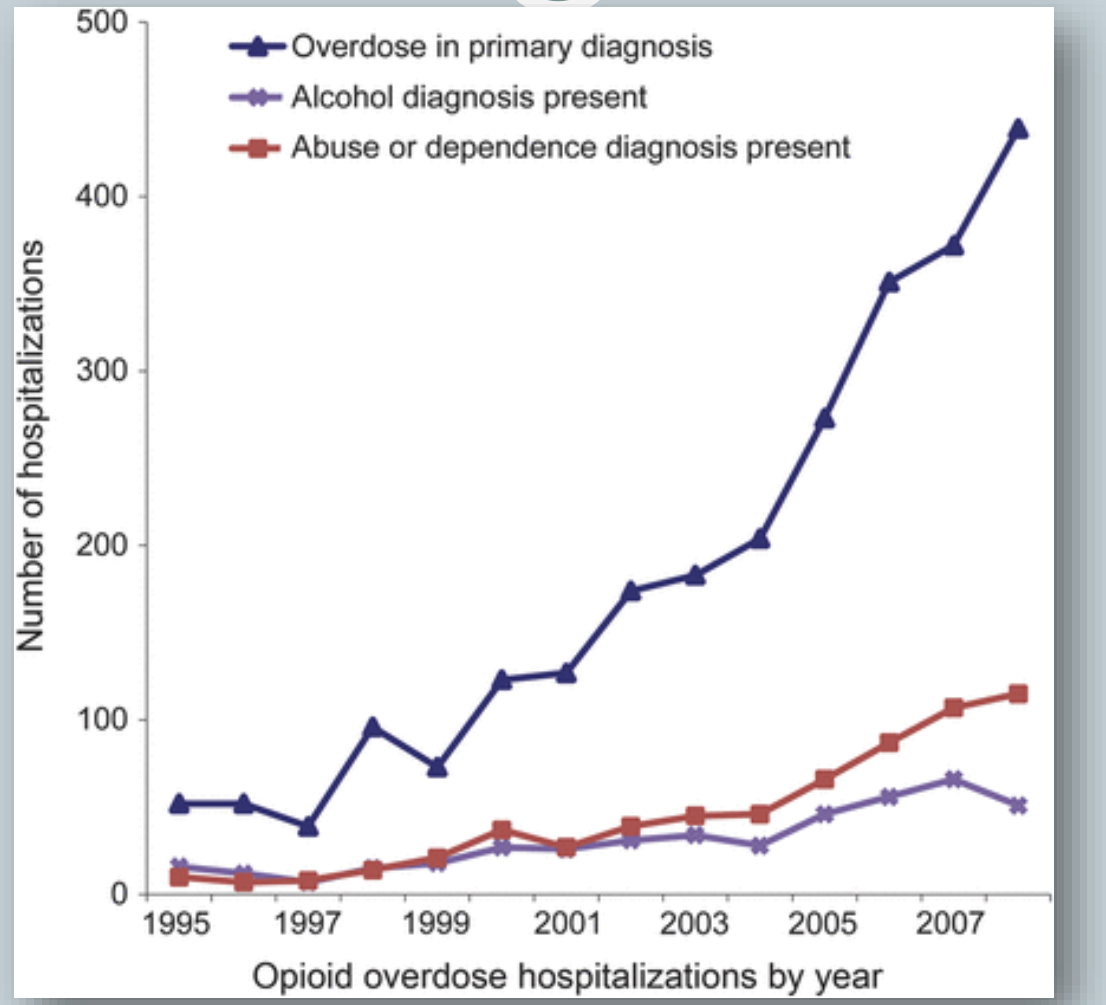


FIGURE 2: Risk/benefit of opioids for chronic noncancer pain

Some Tidbits

- Use of chronic opiates (>3 months) not allowed before latter part of 1990s
- Some lobbying organizations/individuals have recently come under press/US Senate scrutiny
- Opioid-related deaths in the US between 1999-2010 is almost 2x US deaths in the Vietnam War
- By 2005: national opiate related deaths > both firearm and motor vehicle accident related deaths in those 35-54
- Trend of evidence: more efficacy studies done → more unclear evidence regarding long term benefits
- There **is** evidence for short term pain relief in acute situations

More Tidbits

- Substantially increased risk of adverse events with >100 morphine equivalents/day, though risks 3.7 fold even at 50 morphine equiv. per day compared to doses <20

Table 1 Opioid equianalgesic doses[a]

Opioid	Approximate equianalgesic dose (oral and transdermal)[a]
Morphine (reference)	30 mg
Codeine	200 mg
Fentanyl transdermal	12.5 μg/h
Hydrocodone	30 mg
Hydromorphone	7.5 mg
Oxycodone	20 mg
Oxymorphone	10 mg

Main Recommendations

Table 2	What prescribers can do to safely and effectively use opioids for CNCP[a]
Opioid treatment agreement	
Screen for prior or current substance abuse/misuse (alcohol, illicit drugs, heavy tobacco use)	
Screen for depression	
Prudent use of random urine drug screening (diversion, nonprescribed drugs)	
Do not use concomitant sedative-hypnotics or benzodiazepines	
Track pain and function to recognize tolerance and track effectiveness	
Track daily MED using an online dosing calculator	
Seek help if MED reaches 80–120 mg and pain and function have not substantially improved	
Use the state Prescription Drug Monitoring Program to monitor all sources of controlled substances	

Other Important Points

- "The risk of chronic opioid therapy for some chronic conditions such as **headache**, **fibromyalgia**, and **chronic low back pain** likely outweigh the benefits"

- Proper management may help some, with some conditions, with some risk of addiction and other side effects, but evidence based guidance is limited right now

Annals of Family Medicine

MOST READ

Most read in "Annals of Family Medicine"

- Sowmya R. Rao. A Tale of 2 Countries: *The Cost of My Mother's Cardiac Care in the United States and India*. Ann Fam Med Sep 01, 2014; 12: 470-472.

- Gowtham A. Rao, Joshua R. Mann, Azza Shoaibi, Charles Lee Bennett, Georges Nahhas, S. Scott Sutton, Sony Jacob, Scott M. Strayer *Azithromycin and Levofloxacin Use and Increased Risk of Cardiac Arrhythmia and Death*. Ann Fam Med Mar 01, 2014; 12: 121-127.

- Julia T. Schiele, Hendrik Schneider, Renate Quinzler, Gabriele Reich, Walter E. Haefeli. *Two Techniques to Make Swallowing Pills Easier*. Ann Fam Med Nov 01, 2014; 12: 550-552. (lots of media attention on this one, as you may have seen; NPR posted a video of two of their commentators, pill-phobes, testing the techniques)

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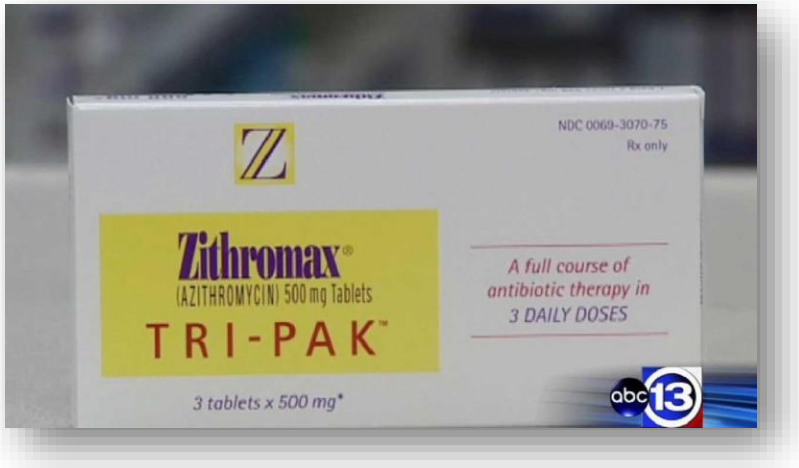
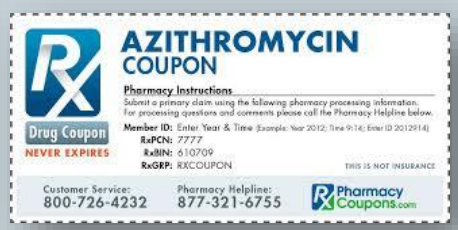
So…what's up with azithromycin?



Background

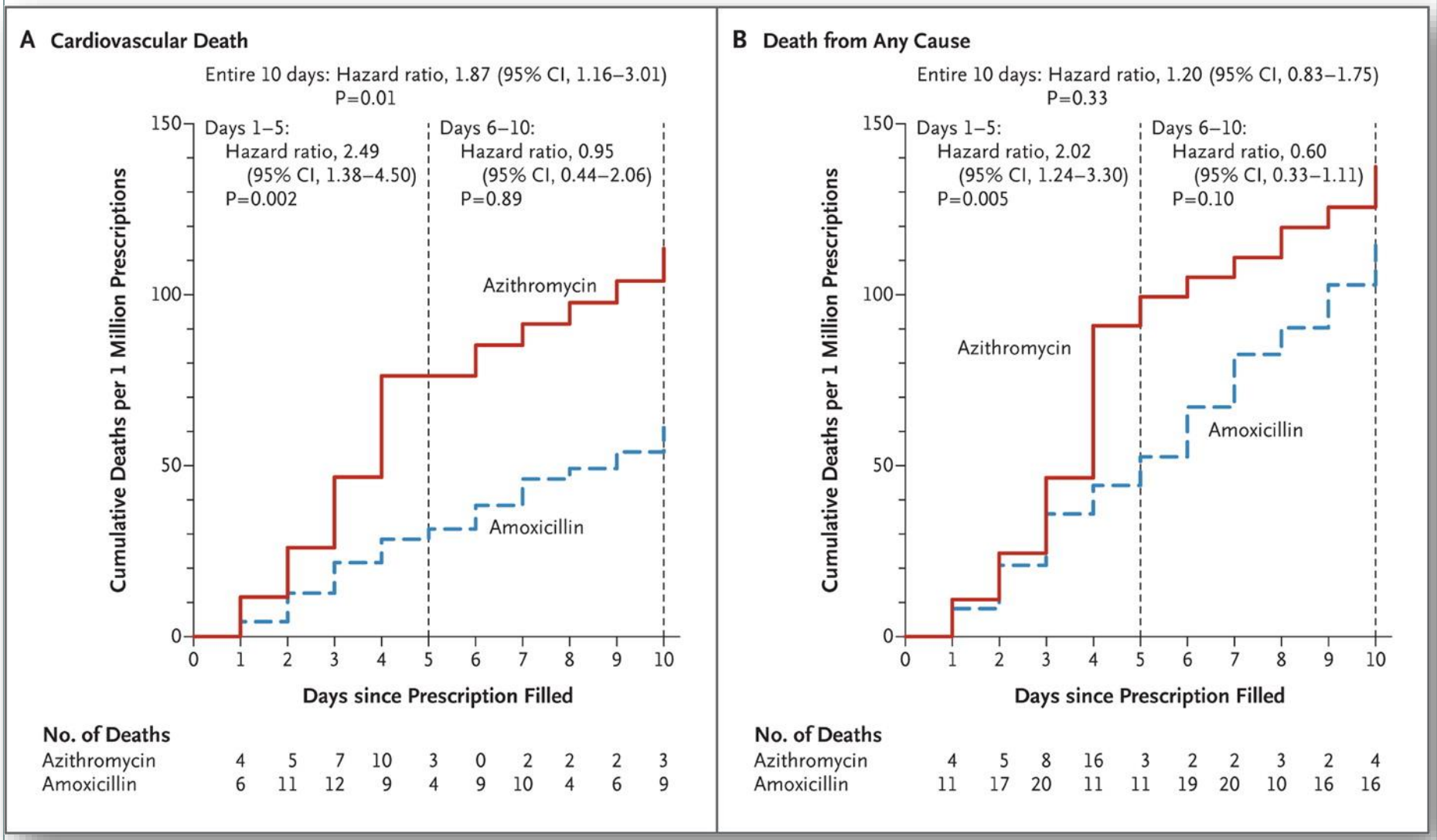
- 2001-current: 7 studies show Azithro may be proarrhythmic
- 2011: 40.3 million prescriptions in the US!
- In 2010, azithromycin was the most prescribed antibiotic for outpatients in the US.
  - Comparison: Sweden. (Outpatient antibiotic use is 1/3 US) macrolides are 3% of antibiotic prescriptions (vs 22% in US)



Background

- 2012: NEJM Article. Large Tennessee Medicaid cohort study, ages 30-74. 5 days Azithro, vs no abx, vs other abx.
  - For every 1 million coures of azithro for adults, additional 47 CV deaths, higher in high risk CV groups. Also increase in all cause mortality. Non significant *trend* seen for levofloxacin
- MUCH lower risk in pts without CV risks (1 in 144k)
- Most common indication for azithro in study:
  - infections of the ear, nose, or throat
  - bronchitis

Ray WA, Murray KT, Hall K, Arbogast PG, Stein CM. Azithromycin and the risk of cardiovascular death. N Engl J Med 2012;366(20):1881-1890.


A Cardiovascular Death
Entire 10 days: Hazard ratio, 1.87 (95% CI, 1.16–3.01)
P=0.01
Days 1–5:
Hazard ratio, 2.49
(95% CI, 1.38–4.50)
P=0.002
Days 6–10:
Hazard ratio, 0.95
(95% CI, 0.44–2.06)
P=0.89
Azithromycin
Amoxicillin
Cumulative Deaths per 1 Million Prescriptions
Days since Prescription Filled
No. of Deaths
Azithromycin 4 5 7 10 3 0 2 2 2 3
Amoxicillin 6 11 12 9 4 9 10 4 6 9
B Death from Any Cause
Entire 10 days: Hazard ratio, 1.20 (95% CI, 0.83–1.75)
P=0.33
Days 1–5:
Hazard ratio, 2.02
(95% CI, 1.24–3.30)
P=0.005
Days 6–10:
Hazard ratio, 0.60
(95% CI, 0.33–1.11)
P=0.10
Azithromycin
Amoxicillin
Cumulative Deaths per 1 Million Prescriptions
Days since Prescription Filled
No. of Deaths
Azithromycin 4 5 8 16 3 2 2 3 2 4
Amoxicillin 11 17 20 11 11 19 20 10 16 16

Drug Safety Communications

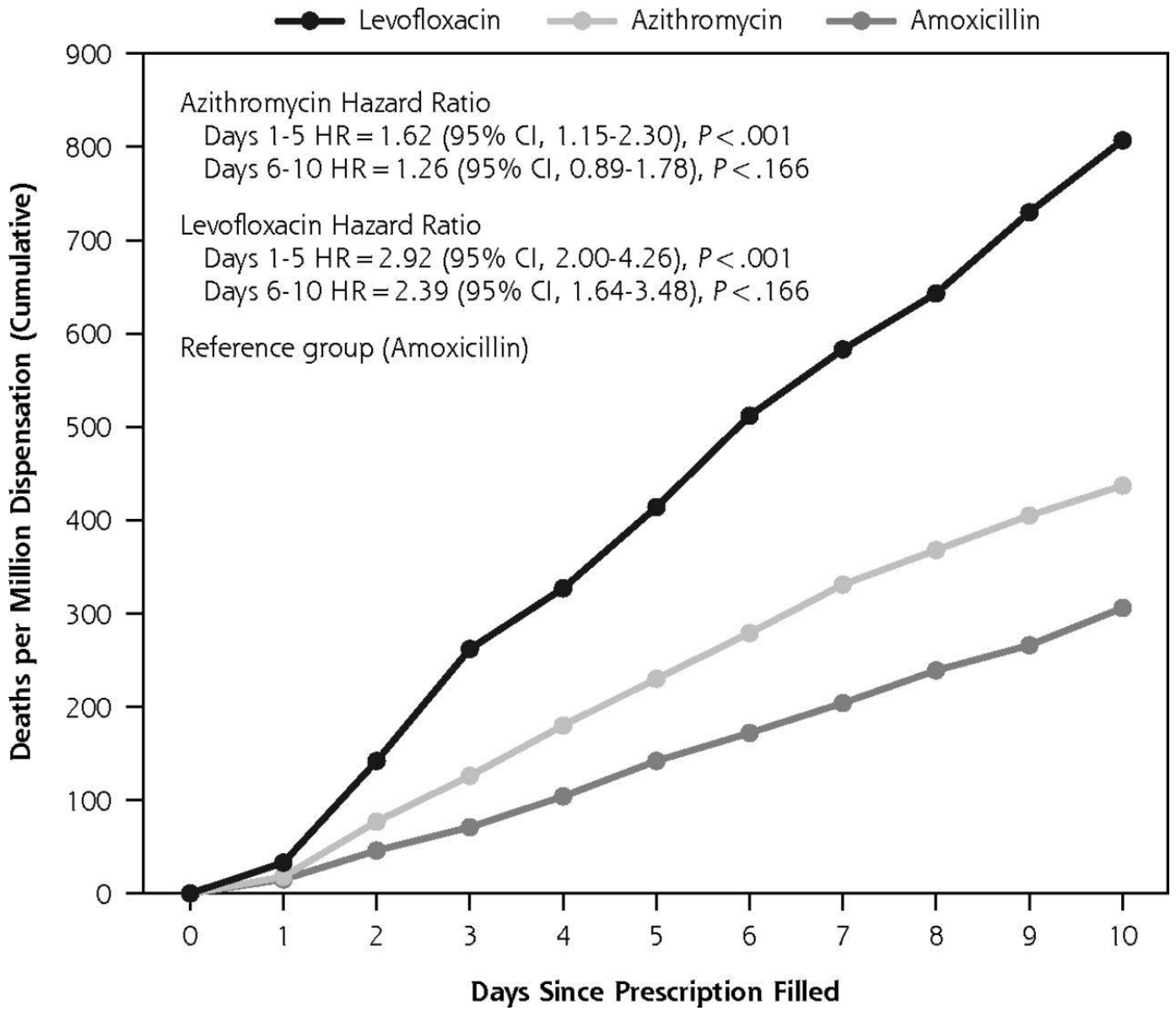
FDA Drug Safety Communication: Azithromycin (Zithromax or Zmax) and the risk of potentially fatal heart rhythms

Safety Announcement

[3-12-2013] The U.S. Food and Drug Administration (FDA) is warning the public that azithromycin (Zithromax or Zmax) can cause abnormal changes in the electrical activity of the heart that may lead to a potentially fatal irregular heart rhythm. Patients at particular risk for developing this condition include those with known risk factors such as existing QT interval prolongation, low blood levels of potassium or magnesium, a slower than normal heart rate, or use of certain drugs used to treat abnormal heart rhythms, or arrhythmias. This communication is a result of our review of a study by medical researchers as well as another study by a manufacturer of the drug that assessed the potential for azithromycin to cause abnormal changes in the electrical activity of the heart.

Annals of FM Article

- April 2014. VA Cohort study, mean age 56.8, also very large study
- Azithro (mostly 5 days), vs Amox and Levo (mostly 10d
- Most common indications:
  - azithromycin and amoxicillin: most common is ear-nose-throat infection
  - Levofloxacin: genitourinary infection


Levofloxacin
Azithromycin
Amoxicillin
Azithromycin Hazard Ratio
Days 1-5 HR = 1.62 (95% CI, 1.15-2.30), P < .001
Days 6-10 HR = 1.26 (95% CI, 0.89-1.78), P < .166
Levofloxacin Hazard Ratio
Days 1-5 HR = 2.92 (95% CI, 2.00-4.26), P < .001
Days 6-10 HR = 2.39 (95% CI, 1.64-3.48), P < .166
Reference group (Amoxicillin)
Deaths per Million Dispensation (Cumulative)
900
800
700
600
500
400
300
200
100
0
0
1
2
3
4
5
6
7
8
9
10
Days Since Prescription Filled

What about Azithro 1g once for STDs?

NEJM 5/14. 1x dose for STDs

Table 1. Cumulative Incidence of Death among 260,048 Patients with Chlamydia, Gonorrhea, or Both, According to Prescribed Treatment (Oregon, 1996–2012, and King County, Washington, 1993–2010).*

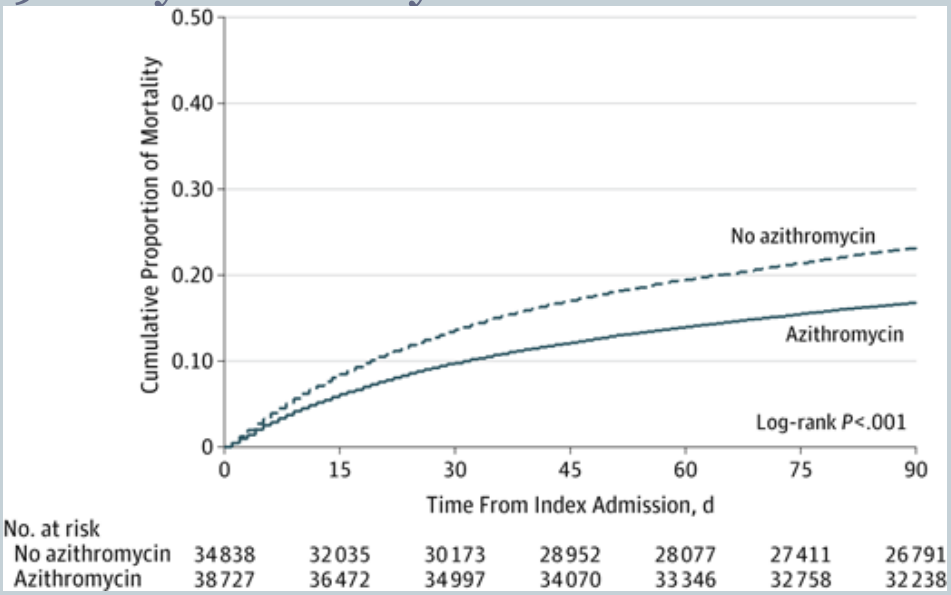
Deaths	Azithromycin (N = 162,385)	Other Drug (N = 97,663)	Relative Risk (95% CI)†
Cardiovascular cause			
No. of deaths	0	0	Not determined
No. of deaths per 1 million doses (95% CI)	0 (0–18.5)	0 (0–30.7)	
Other cause			
No. of deaths	3	2	0.90 (0.15–5.40)
No. of deaths per 1 million doses (95% CI)	18.5 (3.8–54.0)	20.5 (2.5–74.0)	

* CI denotes confidence interval.
† The group of patients who received other treatment was the reference group.

Khosropour et al. Lack of Association between Azithromycin and Death from Cardiovascular Causes N Engl J Med 2014; 370:1961-1962. May 15, 2014. DOI: 10.1056/NEJMc1401831

Another study: Azithro in hospitalized pts with pneumonia

- JAMA, June 2014. Retrospective cohort study, ~30k in each group. 65 yo or older, hospitalized with pneumonia
  - **Lower** 30/90 day mortality



Mortensen EM. Association of Azithromycin With Mortality and Cardiovascular Events Among Older Patients Hospitalized With Pneumonia. JAMA. 2014;311(21):2199-2208. doi:10.1001/jama.2014.4304.

So…..What to do?

- Consider alternate antibiotics when possible, especially in high risk cardiac patients
- Subgroups important:
  - Seems ok in younger pts with STDs
  - Seems like a good med in hospitalized older pts with pneumonia
  - NOT OK for viral illnesses! (*especially* those with CV risk factors).
  - In other conditions: if going to use in a patient with significant cardiac risk factors, consider alternatives

From an Editor of "Annals of Family Medicine"

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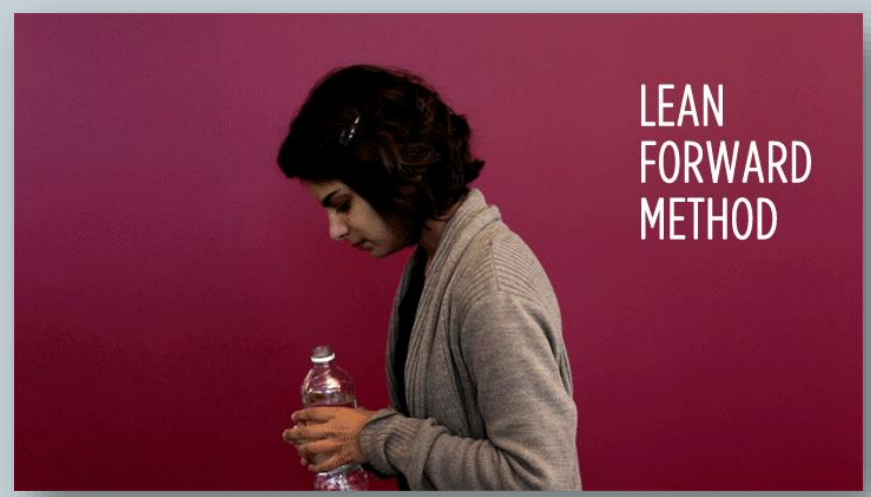
From NPR

Helped 60% of study participants
(for larger pills)



Helped 60% of study participants
(for capsule style pills)

http://www.npr.org/blogs/health/2014/11/11/363024822/trouble-swallowing-pills-try-the-pop-bottle-or-the-lean-forward

Quicker Summaries

Women's Health

- ACP recommends *against* routine screening pelvic exam. Harms likely outweigh benefits. (*refers to pelvic exams, not cervical cancer screening*)

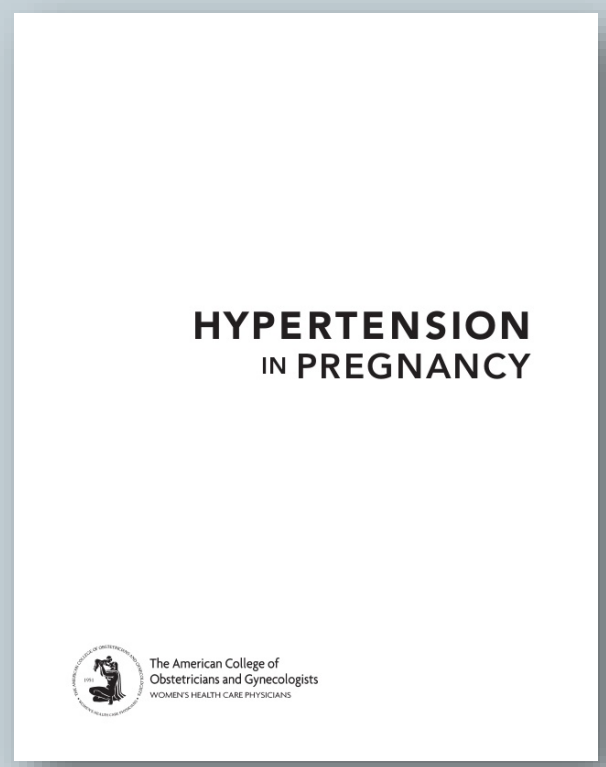
  Qaseem A, Humphrey LL, Harris R, Starkey M, Denberg TD; Clinical Guidelines Committee of the American College of Physicians. Screening pelvic examination in adult women: a clinical practice guideline from the American College of Physicians. Ann Intern Med 2014;161(1):67-72. Bloomfield HE, Olson A, Greer N, et al. Screening pelvic examinations in asymptomatic, average risk adult women: an evidence report for a clinical practice guideline from the American College of Physicians. Ann Intern Med 2014;161(1):46-53.

- Almost 90k women followed for 22 years in Canadian National Breast Screening Study:
  - Annual mammography screening: detected a significant number of small non-palpable breast cancers, but half of these were examples of over-diagnosis
  - 22% of screen-detected invasive cancers in the mammography arm were "over-diagnosed," representing one over-diagnosed breast cancer for every 424 women who received mammography screening in the trial
  - Annual mammography screening had no significant effect on breast cancer mortality

  Miller AB, Wall C, Baines CJ, Sun P, To T, Narod SA. Twenty five year follow-up for breast cancer incidence and mortality of the Canadian National Breast Screening Study: randomised screening trial. BMJ 2014;348:g366.

Maternity Care

- Hypertension in Pregnancy Task Force (ACOG).
- Technically Nov 2013



Diet and Nutrition

- Low-carb diet: better for sustained weight loss than low-fat diet. 40g carbs/day vs. diet where fat ≤30% of total calories. Also better for HDL and TG

Bazzano LA, Hu T, Reynolds K, et al. Effects of low-carbohydrate and low-fat diets: A randomized trial. Ann Intern Med 2014;161(5):309-318.

More Diet and Nutrition

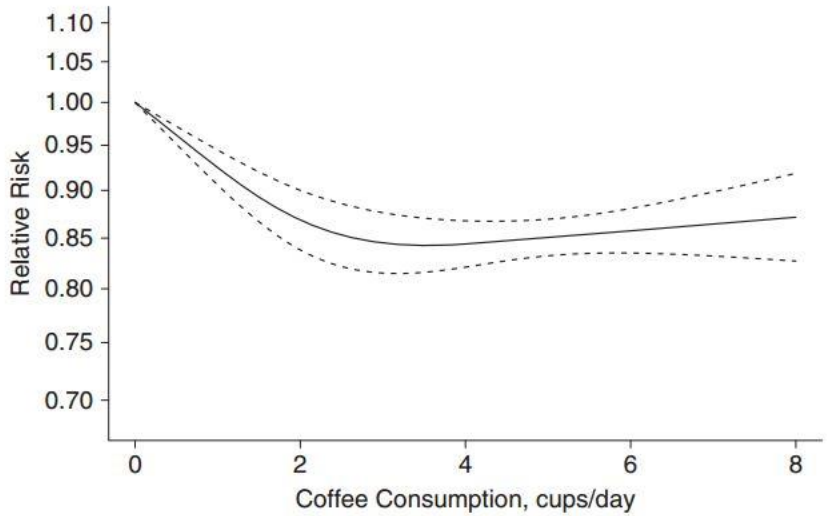


Figure 2. Pooled dose-response association between coffee consumption and all-cause mortality (solid line) in a meta-analysis, 1966–2013. Coffee consumption was modeled with restricted cubic splines in a multivariate random-effects dose-response model. The relative risks are plotted on the log scale. Dashed lines represent the 95% confidence intervals for the spline model. No coffee consumption (0 cups/day) served as the referent group.

Crippa A. Coffee Consumption and Mortality From All Causes, Cardiovascular Disease, and Cancer: A Dose-Response Meta-Analysis. American Journal of Epidemiology. Vol 180, No 8. August 24, 2014

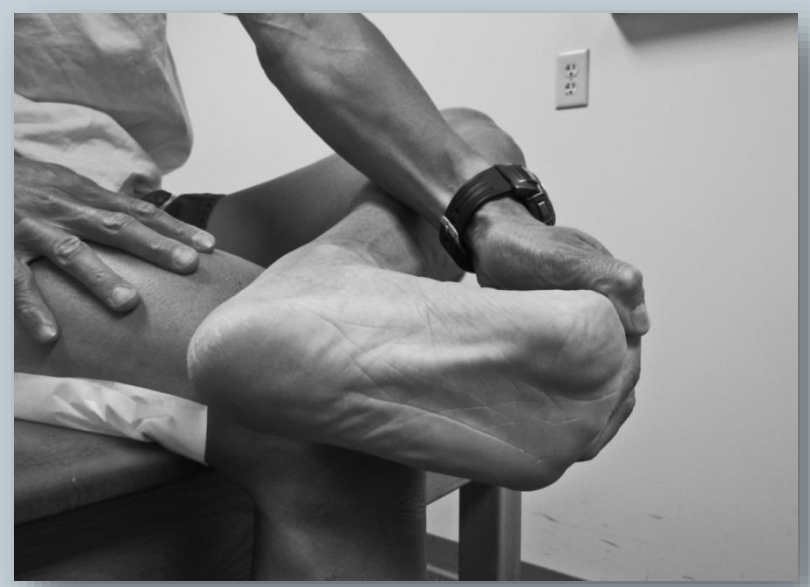
Pediatrics

- Kids 4 weeks to 12 months, presenting to ED with mild to moderate bronchiolitis. ~105 kids in each group.
- Took out pts with sats <88%
- "Altered Saturation" group had O2 sat monitors that reported 3% higher than reality
- More pts in the true sat group hospitalized, but otherwise outcomes the same

Schuh S, Freedman S, Coates A, et al. Effect of oximetry on hospitalization in bronchiolitis. A randomized clinical trial. JAMA 2014;312(7):712-18.

Musculoskeletal: Plantar Fasciitis

vs



Nice video demo: https://www.youtube.com/watch?v=sqxLXgAChto

Rathleff MS, Molgaard CM, Fredberg U, et al. High-load strength training improves outcome in patients with plantar fasciitis: A randomized controlled trial with 12-month follow-up. Scand J Med Sci Sports 2014 (e-publication). doi: 10.1111/sms.12313

Adult Medicine

- While both ACEIs and ARBs decrease HF incidence in diabetic pts, only ACEIs decreased mortality (13%) and major CV events (14%).

Cheng J, Zhang W, Zhang X, et al. Effect of angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers on all-cause mortality, cardiovascular deaths, and cardiovascular events in patients with diabetes mellitus. JAMA Intern Med 2014;174(5):773-785. doi:10.1001/jamainternmed.2014.348

- Evidence for Vitamin D supplementation and bone health remains somewhat controversial. Small effect on BMD in femoral neck, nowhere else, and no strong fracture findings. Better studies needed.

Reid IR, Bolland MJ, Grey A. Effects of vitamin D supplements on bone mineral density: a systematic review and meta-analysis. Lancet 2014;383(9912):146-155.

Addiction

- Gabapentin 1800mg TID significantly improved abstinence and heavy drinking rates in a 12 week study. 1800mg TID more than 900mg TID
  - Abstinence: 17% treatment vs 4.1% placebo NNT=8.
  - No heavy drinking rate: 44.7% treatment vs 22.5% placebo NNT 5
  - About ½ didn't complete the study in both groups

Mason BJ. Gabapentin treatment for alcohol dependence: a randomized clinical trial. JAMA Intern Med. 2014 Jan;174(1):70-7. doi: 10.1001/jamainternmed.2013.11950.

Gabapentin Schedule

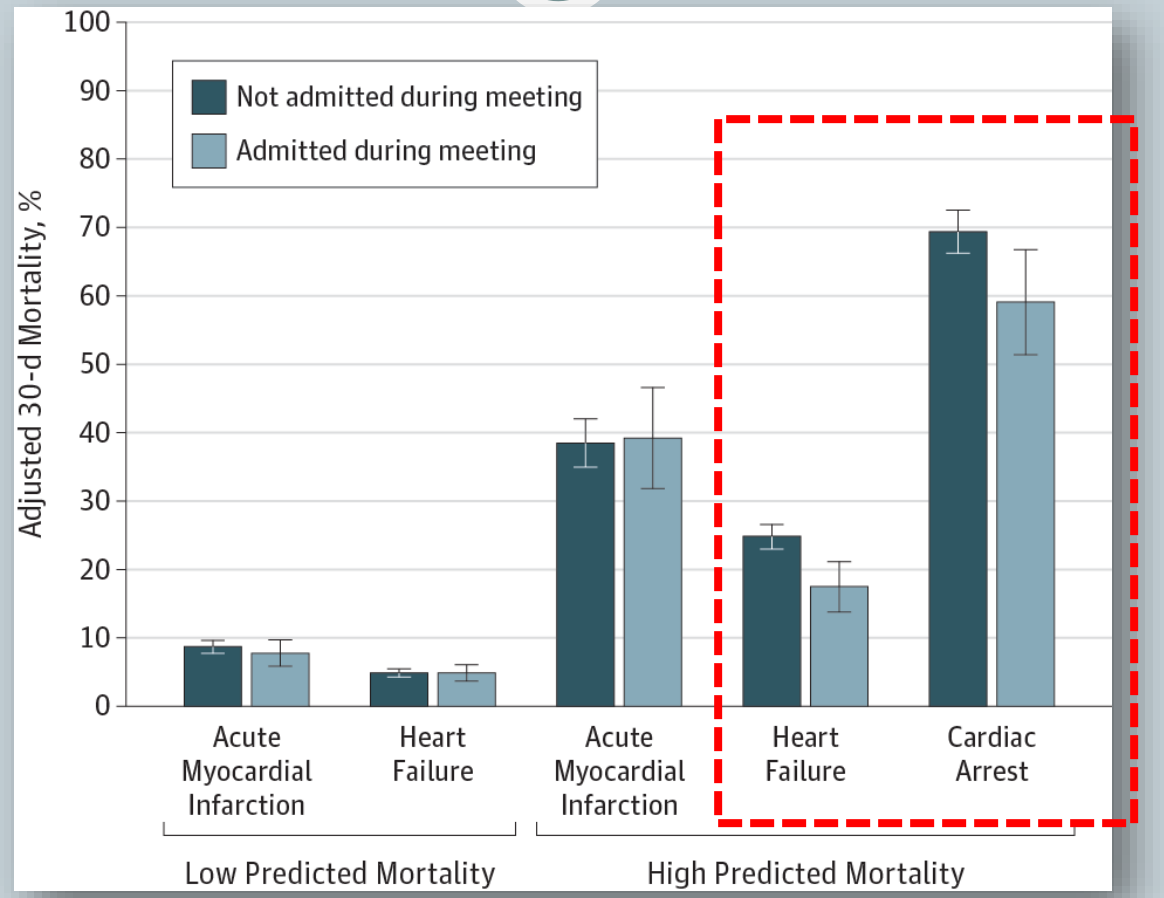
eTable 1. Gabapentin dose titration schedule: number of 300-mg capsules dispensed.

	Morning Dose		Afternoon Dose		Evening Dose		Total Daily Dose	
	900-mg Group	1800-mg Group	900-mg Group	1800-mg Group	900-mg Group	1800-mg Group	900-mg Group	1800-mg Group
Week 0:								
Day 1	0	0	0	0	1	1	1	1
Day 2	1	1	0	0	1	1	2	2
Day 3	1	1	1	1	1	1	3	3
Day 4	1	1	1	1	1	2	3	4
Day 5	1	2	1	1	1	2	3	5
Day 6-7	1	2	1	2	1	2	3	6
Weeks 1-10:	1	2	1	2	1	2	3	6
Week 11:								
Day 1	1	2	0	1	1	2	2	5
Day 2	0	1	0	1	1	2	1	4
Day 3	0	1	0	1	0	1	0	3
Day 4	0	1	0	0	0	1	0	2
Day 5	0	0	0	0	0	1	0	1
Day 6-7	0	0	0	0	0	0	0	0

The placebo and gabapentin groups received the same number of identical capsules (6 per day).

…and Finally…

Don't Get Hospitalized When….



Jena AB. Mortality and Treatment Patterns Among Patients Hospitalized With Acute Cardiovascular Conditions During Dates of National Cardiology Meetings. JAMA Intern Med. 2014 Dec 22. doi: 10.1001/jamainternmed.2014.6781

MARCH 14 – 16, 2015

SAN DIEGO CALIFORNIA

How can you stay current?

THANKS!

New Anticoagulants

- New oral anticoagulants in afib: meta-analysis. Reductions in stroke and all-cause mortality, increased GI bleeding (and trials likely were in pts with low GIB risk). Other bleeding risks otherwise favorable.

Ruff CT, et al. Comparison of the efficacy and safety of new oral anticoagulants with warfarin in patients with atrial fibrillation: a meta-analysis of randomised trials. Lancet 2014 Mar 15;383(9921):955-62. doi: 10.1016/S0140-6736(13)62343-0. Epub 2013 Dec 4.

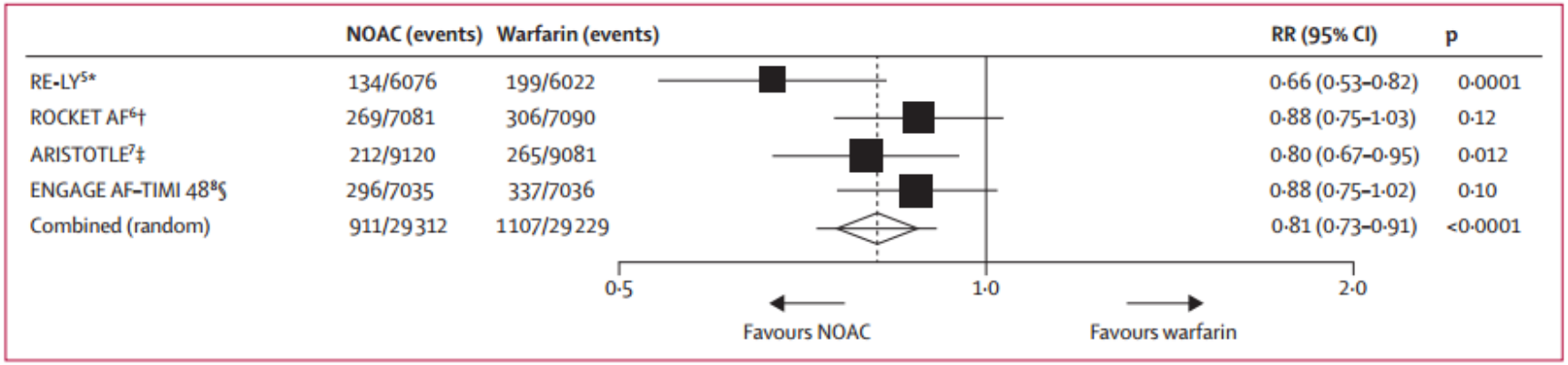


***Figure 1*: Stroke or systemic embolic events**

Data are n/N, unless otherwise indicated. Heterogeneity: I^2=47%; p=0·13. NOAC=new oral anticoagulant. RR=risk ratio. *Dabigatran 150 mg twice daily. †Rivaroxaban 20 mg once daily. ‡Apixaban 5 mg twice daily. §Edoxaban 60 mg once daily.

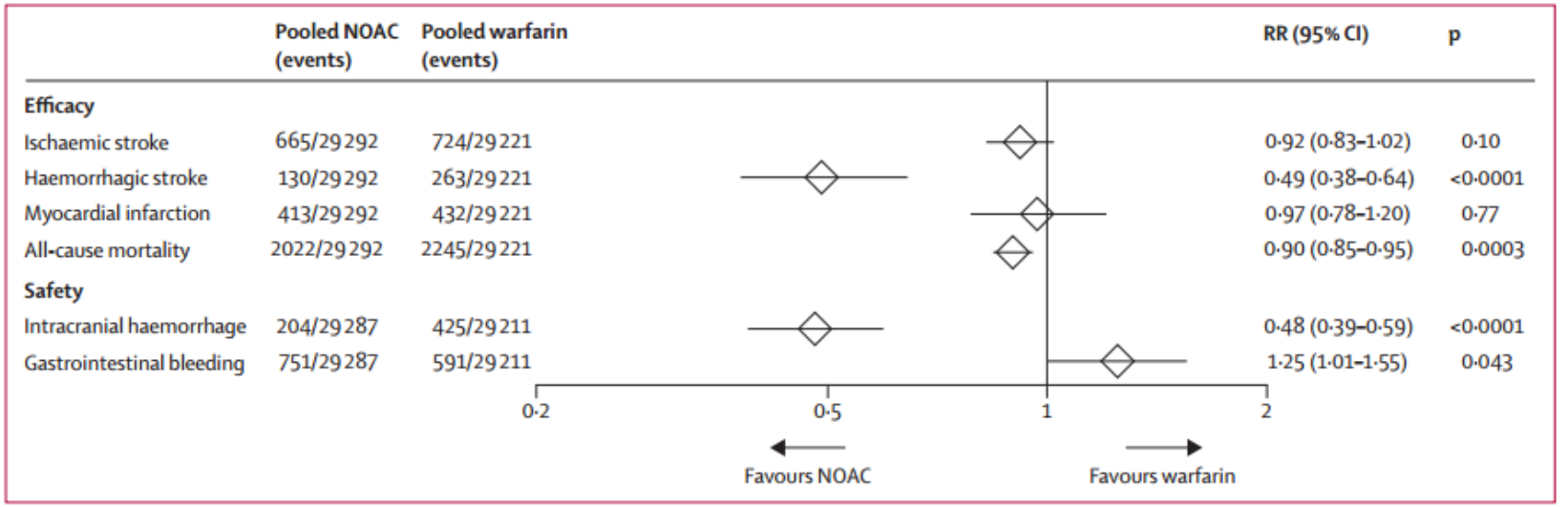


***Figure 2*: Secondary efficacy and safety outcomes**

Data are n/N, unless otherwise indicated. Heterogeneity: ischaemic stroke I^2=32%, p=0·22; haemorrhagic stroke I^2=34%, p=0·21; myocardial infarction I^2=48%, p=0·13; all-cause mortality I^2=0%, p=0·81; intracranial haemorrhage I^2=32%, p=0·22; gastrointestinal bleeding I^2=74%, p=0·009. NOAC=new oral anticoagulant. RR=risk ratio.