Who I am

James McCormack
BSc (Pharm), PharmD
Professor
University of British Columbia
Vancouver, BC, Canada

therapeuticseducation.org
medicationmythbusters.com

MY BELIEF

All Health Care Providers should have their practice underpinned by the best available evidence

Evidence-Based Practice (EBP)

IT'S NOT ABOUT GUIDELINES

140/90
< 6.5%
< 2.0

GUIDELINES RARELY CONSIDER
PATIENT PREFERENCES

IT'S NOT CHECKBOX MEDICINE

PEOPLE DON'T FIT INTO BOXES

IT'S NOT SOMETHING "NEW"

DOING THE RIGHT THING
IS NOT A NEW IDEA

IT'S NOT ABOUT SAVING MONEY

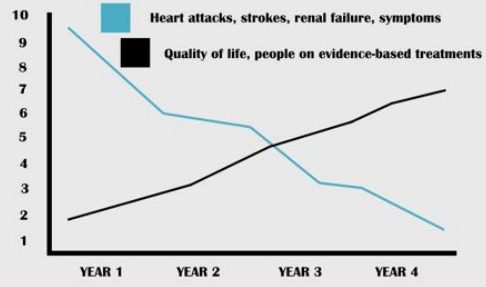
RATIONING
IS NOT THE MOTIVE

IT'S NOT ABOUT RCTs

RCTs ARE USEFUL
BUT THEY ONLY
HELP
INFORM DECISIONS

p<0.05 ≠ GOOD p>0.05 ≠ BAD

IT'S NOT NECESSARILY ABOUT INFLUENCING OUTCOMES



IT'S NOT ABOUT IGNORING BASIC SCIENCE

WE NEED TO UNDERSTAND
HOW IT WORKS

IT'S NOT ABOUT ZERO COMPETING INTERESTS

RESEARCH
COSTS MONEY
SOMEBODY HAS TO PAY FOR IT

WE NEED TO UNDERSTAND
BIAS IS
EVERYWHERE

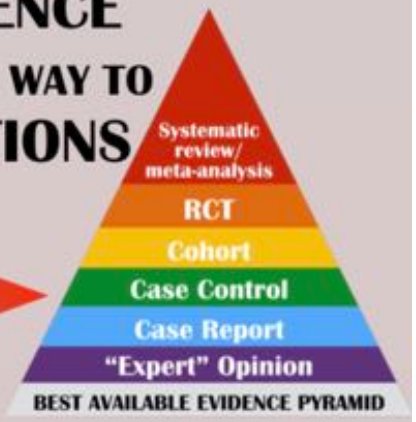
WHAT IT IS

IT'S A WAY OF THINKING

EVIDENCE-BASED PRACTICE

BEST AVAILABLE EVIDENCE
USED IN A HIERARCHICAL WAY TO ANSWER CLINICAL QUESTIONS

Patient
Intervention
Comparator
Outcome



USING CLINICAL EXPERTISE

Diagnostician
Knowledge Broker
Communicator
Being Kind & Careful

INFORMING PATIENTS & ELICITING & INTEGRATING PREFERENCES

How to Critically Appraise an RCT in 10 minutes - free iBook

Free Book

Get Sample

Send a sample of this book to iBooks on your devices that have Automatic Downloads enabled.

This book includes audio, video, and other interactive materials.

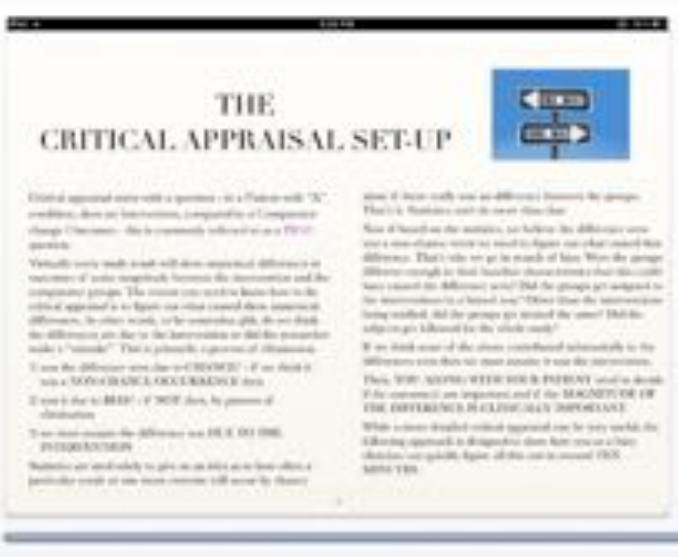
Category: Medical
Published: Jul 04, 2012
Publisher: James McCormack
Seller: Therapeutics Education Collaboration
Print Length: 17 Pages
Size: 79.1 MB
Language: English

Requirements: This book can only be viewed using iBooks 2 or later on an iPad with iOS 5 or later.

How to Critically Appraise an RCT In 10 Minutes

Description

If the thought of reviewing a clinical study seems like an insurmountable task, this book was developed to show you how to critically evaluate a randomized controlled trial in around 10 minutes.



FREE

http://therapeuticseducation.org/publications

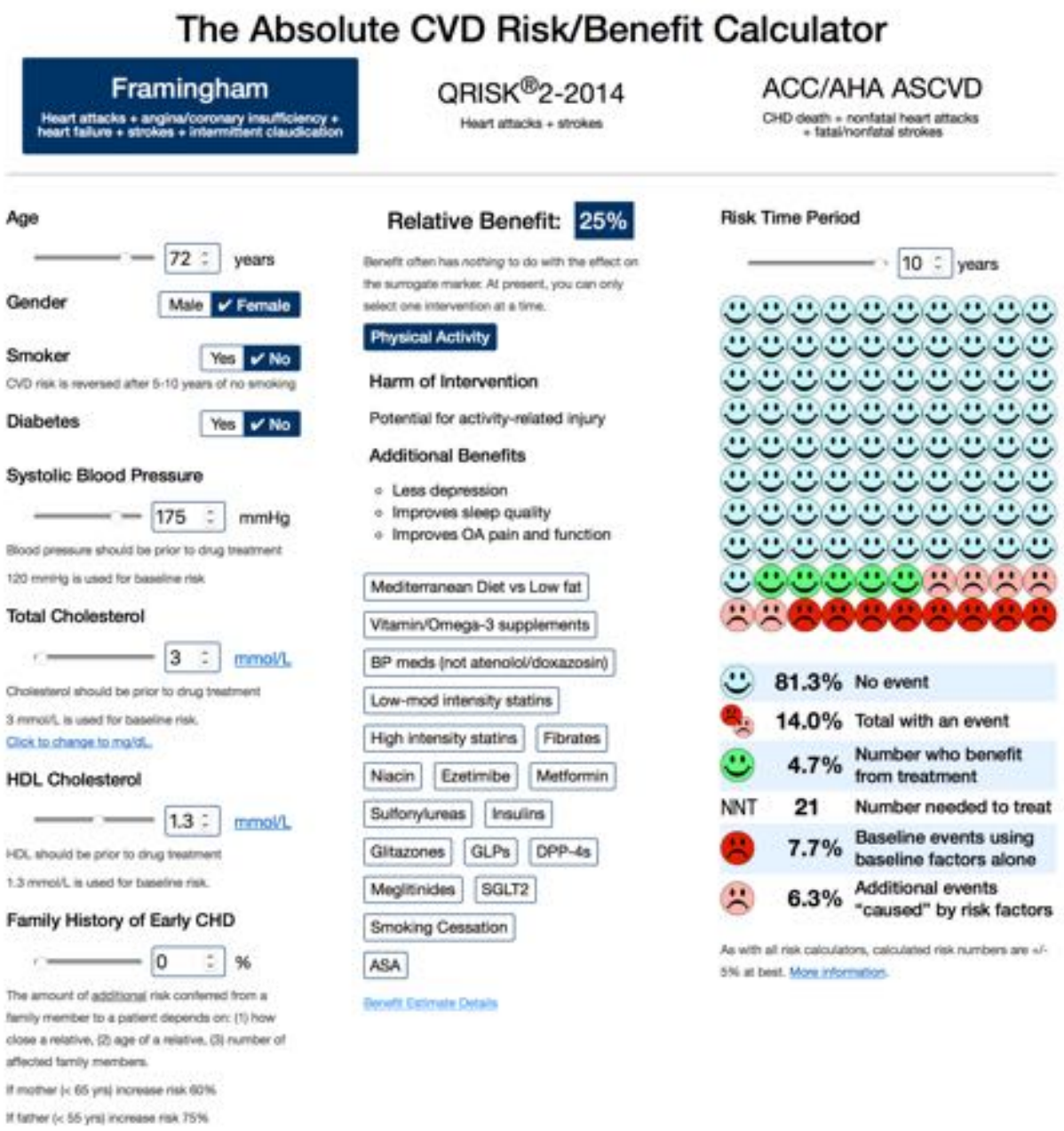
MyStudies

FREE

if use
@ubc.ca
@mail.ubc.ca
or
@alumni.ubc.ca
address

"a way to find data from medical studies that is RELEVANT and EASY to use at the point of patient care"

"this app is excellent for students, clinicians, educators and researchers who are looking for relevant and organized summaries of outcomes from many essential "need to know" studies"



FREE

cvdcalculator.com

We are knowledge brokers

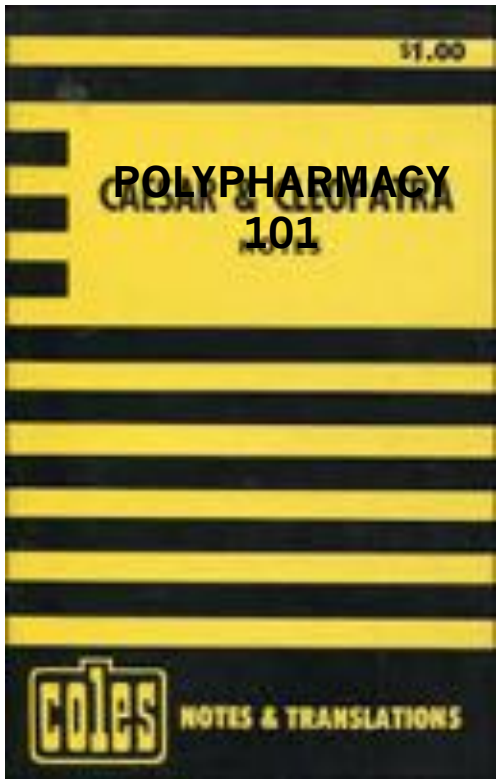
Healthcare should be all about
Figuring out AND Explaining about

The Chance of Something Happening
WITH NO TREATMENT
VS
The Chance of Something Happening
WITH TREATMENT
over a period of time

It's really THAT simple

Medication History

UNTIL PROVEN OTHERWISE



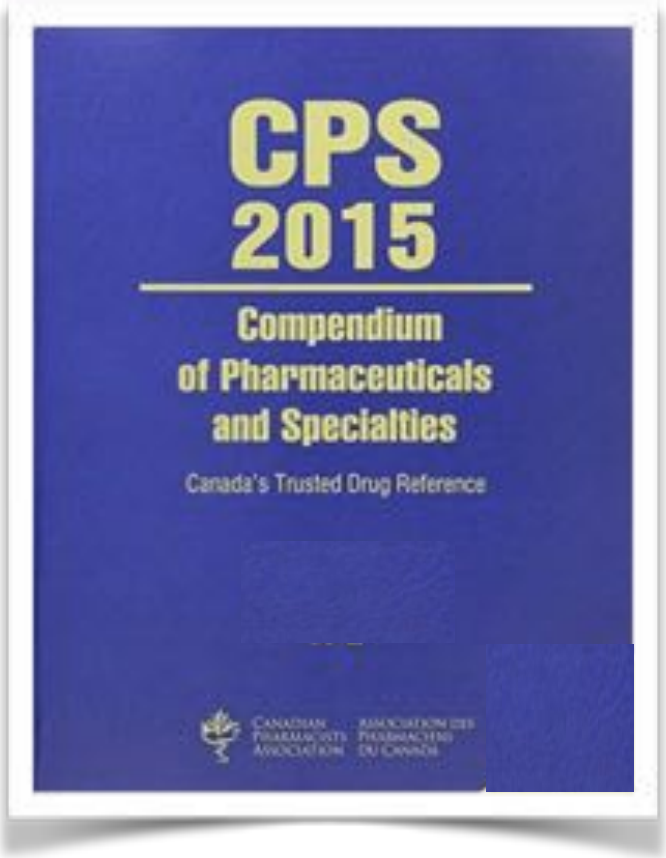
The drug AND the dose are WRONG!!!!!!

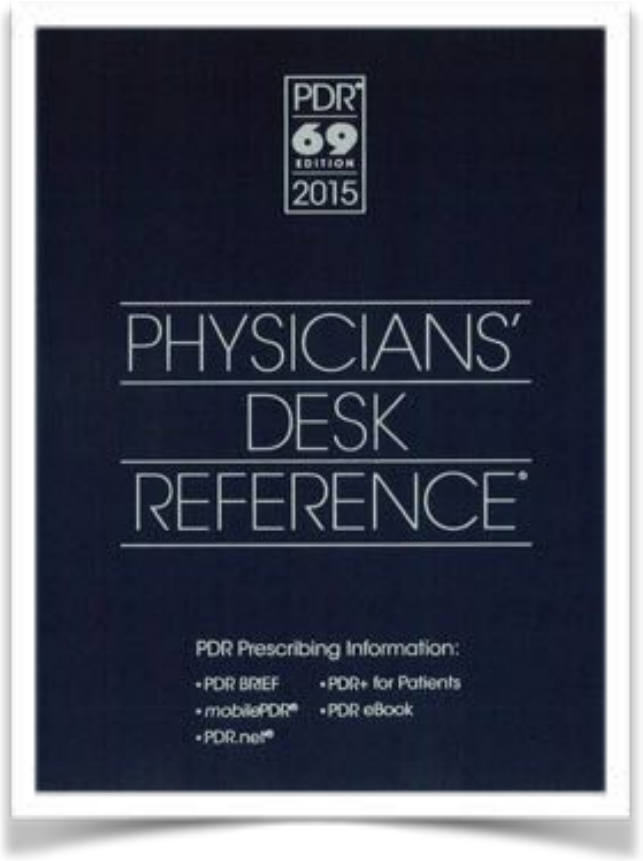
A Dose of Reality

When a new drug comes on the market almost never have more than 2 doses been studied

To get a drug on the market you have to show it works therefore one has to choose a dose that is high enough that if it is going to work it will work

The doses in these books





are all “WRONG” for individual patients

It's a dose thing

"more than 80% of ADRs causing admission or occurring in hospital ... are dose related, an 'accentuation' of the known pharmacological effect of the drug, and thus predictable and potentially avoidable"

Br J Clin Pharmacol 2004; 57:121–6

CMAJ ANALYSIS

Is bigger better? An argument for very low starting doses

James P. McCormack PharmD, G. Michael Allan MD, Adil S. Virani PharmD

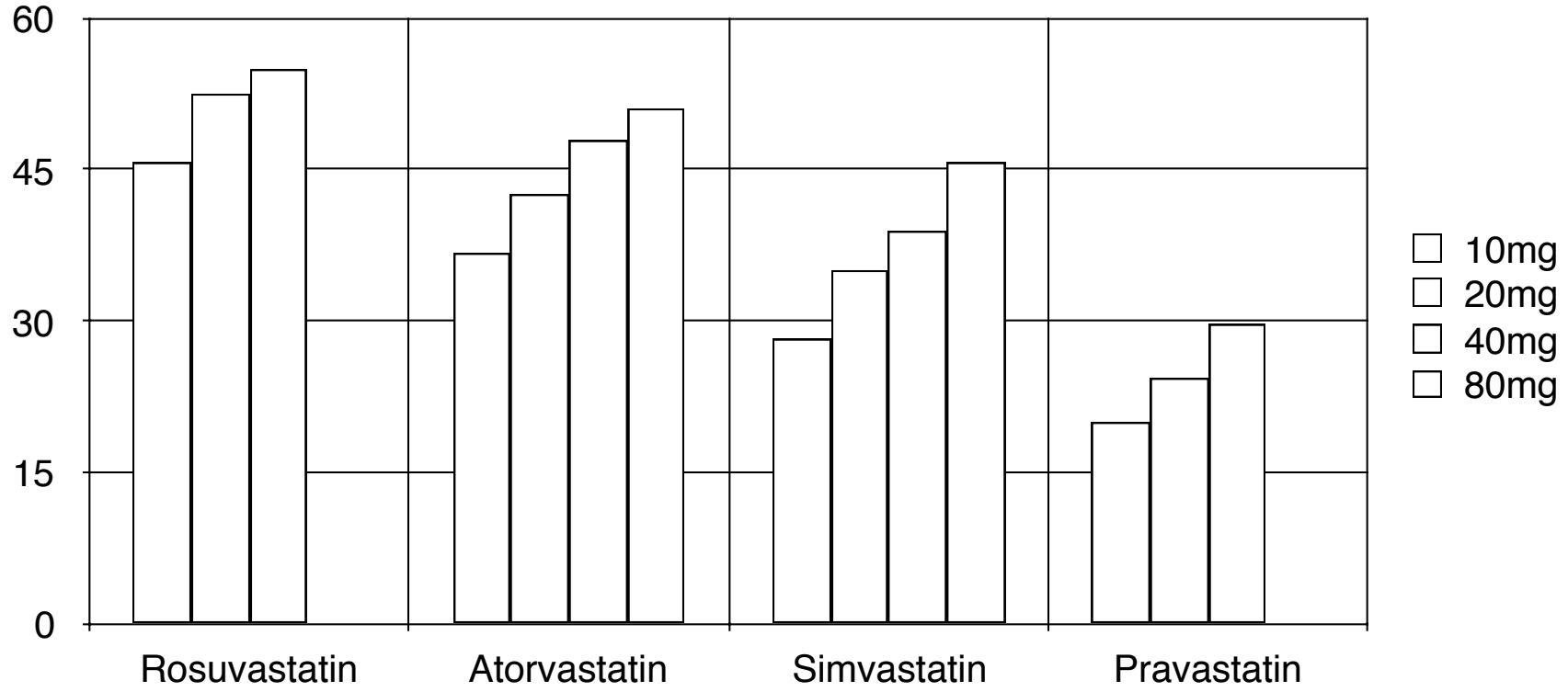
”Unless the condition is severe or life-threatening, drug treatment can be started at a very low dose (half or one-quarter the recommended starting dose)”

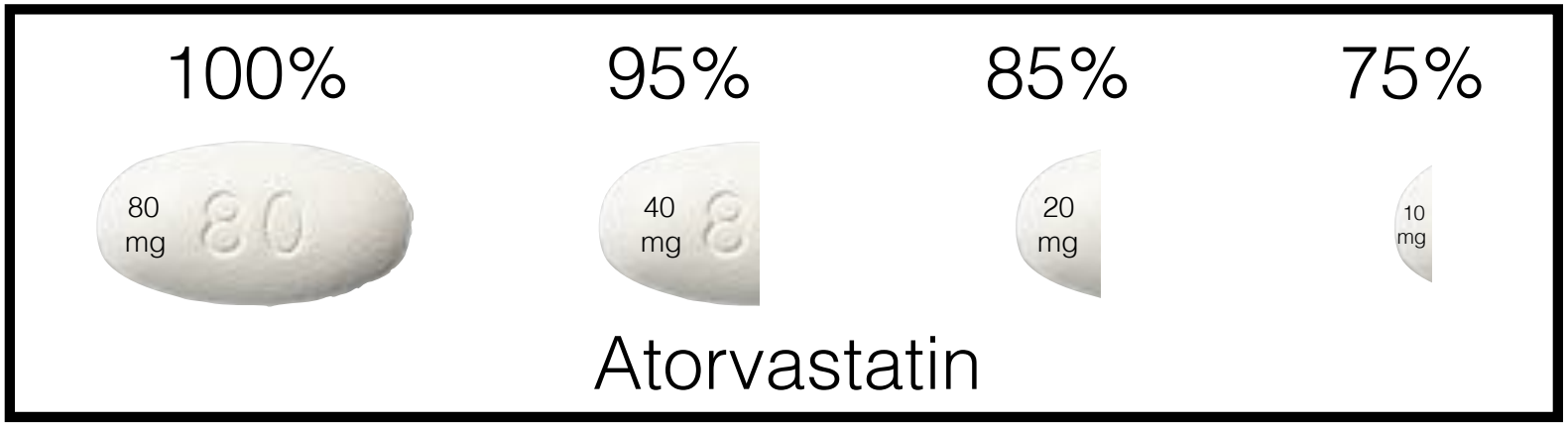
CMAJ 2011. DOI:10.1503 /cmaj.091481

Most of the effect of a medication comes from the “low” starting doses AND doubling a dose never doubles the effect - in fact it sometimes has no additional effect

DOSE reductions do not lead to proportional EFFECT reductions

% reduction in LDL cholesterol





This simple concept can eliminate most medication problems

USE VERY LOW DOSES

Clinical Practice Guidelines in Practice and Education

Alfred O. Berg, MD, MPH, David Atkins, MD, MPH, William Tierney, MD

1997 - THE REASONS FOR INTEREST IN QUALITY CLINICAL PRACTICE GUIDELINES

"medical history is littered with clinical practice guidelines that have been fatally incorrect"

"the physician's ability to keep up with the medical literature erodes with each year's burden"

"costly and unexplained variability in medical practice"

"growing demand from patients for greater participation in medical decisions"

J Gen Intern Med 1997;12(Suppl 2):S25–S33

What is a Clinical Practice Guideline (CPG)?

The Institute of Medicine definition:

"…statements that include recommendations, intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options”

Risk of future illness
CVD risk/benefit

(most people don't benefit despite a lifetime of treatment)

Challenging treatment thresholds

James McCormack PharmD, Aseem Malhotra MRCP and David Newman MD

Assume a person's lifetime risk of CVD is that of a male with two CVD risk factors - roughly 50% (NEJM 2012;366:321-9)

Assume that with multiple risk factor modification we can reduce that risk relatively by 60% (VERY optimistic)

Risk goes from 50% ➡ 20%

30% of individuals BENEFIT

70% DO NOT despite a LIFETIME of treatment

Prescriber September 2015

“We should stop using clinical practice guidelines when it comes to teaching health care providers - or should we?”

James McCormack, BSc(Pharm), Pharm D
Professor, Faculty of Pharmaceutical Sciences, UBC

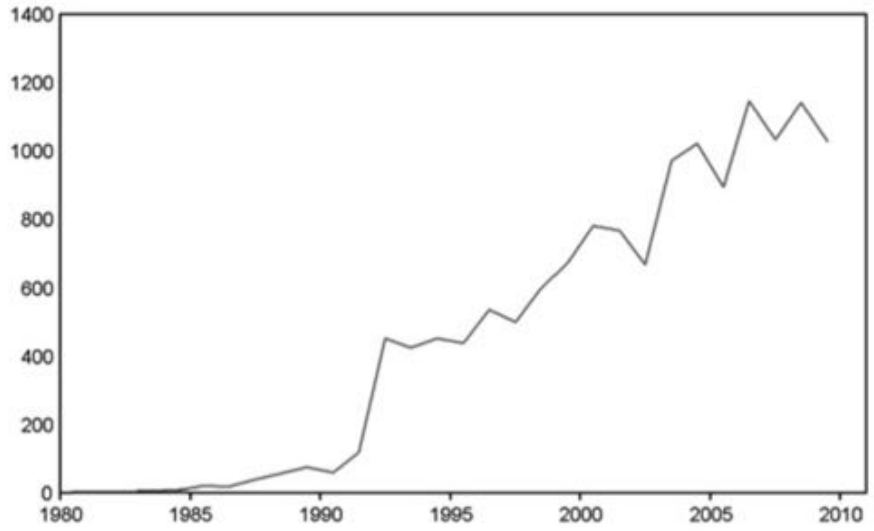


Figure 1 Number of guidelines in PubMed.

For HANDOUT material go here https://therapeuticseducation.org/handouts

National Guideline Clearinghouse

The Number of Guidelines

Diseases/conditions - 2,983

Treatments/interventions - 7,364

~10,000 guidelines ~10 pages each?

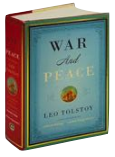
~100,000 pages

500 pages ~ 2 inches

400 inches ~ 33 feet ~10 meters

Highest pole vaulter ~ 20 feet ~ 6 meters

War and Peace is ~1500 pages ~ 70 copies



Wrong guidelines: why and how often they occur

Primiano Iannone,[1] Nicola Montano,[2] Monica Minardi,[3] James Doyle,[3] Paolo Cavagnaro,[4] Antonino Cartabellotta[5]

"Unfortunately, depending on how their reliability is measured, up to 50% of guidelines can be considered untrustworthy. This carries serious consequences for patients' safety, resource use and health economics burden."

EBM 2017;22:1-3

Wrong guidelines: why and how often they occur

Primiano Iannone,[1] Nicola Montano,[2] Monica Minardi,[3] James Doyle,[3] Paolo Cavagnaro,[4] Antonino Cartabellotta[5]

"guideline reliability is largely over-stated, and guidelines still suffer methodological flaws, limited panel composition and conflicts of interests, making their conclusions often untrustworthy. Even when evidence-based methodology is claimed, it is often not fully adopted and the 'evidence-based quality mark' gets misappropriated by vested interests"

EBM 2017;22:1-3

Wrong guidelines: why and how often they occur

Primiano Iannone,[1] Nicola Montano,[2] Monica Minardi,[3] James Doyle,[3] Paolo Cavagnaro,[4] Antonino Cartabellotta[5]

"Furthermore, no official, publicly accountable, reliable, independent and unconflicted rating agency of published guidelines exists."

EBM 2017;22:1-3

How to assess CPGs

Appraisal Tools for Clinical Practice Guidelines: A Systematic Review

"the most comprehensively validated appraisal tool is the AGREE II instrument

PLoS ONE 8(12): e82915. doi:10.1371/journal.pone.0082915

Appraisal of Guidelines for Research and Evaluation (AGREE) II

DOMAIN 1. SCOPE AND PURPOSE

DOMAIN 2. STAKEHOLDER INVOLVEMENT

DOMAIN 3. RIGOUR OF DEVELOPMENT

DOMAIN 4. CLARITY OF PRESENTATION

DOMAIN 5. APPLICABILITY

DOMAIN 6. EDITORIAL INDEPENDENCE

OVERALL GUIDELINE ASSESSMENT

How to use CPGs

Is the CPG trustworthy?

Is the CPG applicable to your patient?

Is the CPG setting similar to your practice?

Does the CPG reflect you or your patient's values and preferences?

Reassessment of Clinical Practice Guidelines

Go Gently Into That Good Night

Terrence M. Shaneyfelt, MD, MPH
Robert M. Centor, MD

of 44 guidelines, 87% of the guideline authors had some form of industry tie.[6]

Other biases are also important. The specialty composi-

often “have a one-size-fits-all mentality and do not build flexibility or contextualization into the recommendations”

“greater concern, however, is that some of these consensus statements are being turned into performance measures”

JAMA 2009;301:868-9

STATEMENT

Rethinking the Role of Clinical Practice Guidelines in Pharmacy Education

Daniel L. Brown, PharmD

Palm Beach Atlantic University Lloyd L. Gregory School of Pharmacy, West Palm Beach, Florida

"CPGs can undermine clinical growth by providing a tempting academic short-cut: memorizing clinical facts rather than learning clinical principles"

Amer J Pharmaceutical Education 2015;79

July 8, 2009

Clinical Practice Guidelines and Scientific Evidence

Francesco Enia, MD

JAMA. 2009;302(2):142-147. doi:10.1001/jama.2009.910

"Rather than endeavor to design a map with an answer for every question, I believe that it would be preferable to educate clinicians to handle clinical reality directly and without filtered advice"

JAMA July 8 2009

Clinical Practice Guidelines and Scientific Evidence

Shyam S. Kothari, MD

"Bombarding students with guidelines for all scenarios … may seem more efficient in the short-term but does little to enhance discriminatory skills and numbs the facility for critical thinking."

JAMA 2009;302:145

Spectrum of Decisions

Immediate life-threatening issues or very "technical" work - surgery, dispensing etc - YES

Guidelines, even policies, are likely very useful

Symptom treatment - SORT OF

Each person is an experiment - need to know just what has the potential to work and the safety

Risk factor interventions - NO

At least not what CPGs are now

Guidelines would be awesome if they…

Were developed primarily by, and definitely for, the people that ultimately end up using them

Were a credible synopsis of the best available evidence presented in a way that clinicians could easily access and interpret

Allowed patient values and preferences to be taken into account

Combine Evidence with Common Sense

Common Sense

"So rare that it's a superpower"

Typically “evidence-based” guideline recommendations are not based on “solid” evidence

Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines

Pierluigi Tricoci; Joseph M. Allen; Judith M. Kramer; et al.

JAMA. 2009;301(8):831-841 (doi:10.1001/jama.2009.205)

Analysis of Overall Level of Evidence Behind Infectious Diseases Society of America Practice Guidelines

Dong Heun Lee, MD; Ole Vielemeyer, MD *Arch Intern Med. 2011;171(1):18-22*

Clinical Endocrinology (2013) 78, 183–190 doi: 10.1111/j.1365-2265.2012.04441.x

METHODOLOGICAL ASSESSMENT IN ENDOCRINOLOGY

A comparative quality assessment of evidence-based clinical guidelines in endocrinology

EVIDENCE LEVEL	Cardiology	Infectious disease	Endocrinology
1 or A based on RCTs	11%	14%	6%
3 or C based on opinion	48%	55%	35%

BMJQS

The quality of clinical practice guidelines over the last two decades: a systematic review of guideline appraisal studies

Table 2 Appraisal of Guidelines, Research and Evaluation domain scores of guidelines over time (total sample=608)

	1988–1992 (n=9)	1993–1997 (n=102)	1998–2002 (n=291)	2003–2007 (n=206)	p Value for trend
Domain scores					
Scope and purpose	44	61	60	71	<0.001
Stakeholder involvement	18	38	33	37	0.01
Rigour of development	14	41	43	44	0.003
Clarity and presentation	32	56	55	68	<0.001
Applicability	10	30	18	23	<0.001
Editorial independence	17	30	28	33	0.26

Top Score = 100%

Engaging the right people, quality of evidence appraisal, providing useful tools, and competing interests have not improved in 14 years (1993-2007)

Qual Saf Health Care 2010;19:e58. doi:10.1136/qshc.2010.042077

Recent examples of Guideline **Quality/Rigour**

AGREE II (Appraisal of Guidelines for Research and Evaluation)

is the instrument typically used ***- 207 guidelines***

avg 55% - neuropathic pain - 16 CPGs - range 27%-88% - BMC Anesthesiology 2016;16:12

avg 30% - hypertension - 11 CPGS - range 8%-86% - PLoS ONE 2013 8(1): e53744

avg 32% - asthma - 18 CPGs - range 8%-64% - Chest 2013 144: 390-7

avg 48% - diabetes - 24 CPGs - range 0%-81% - PLoS ONE 2013 8(4): e58625

avg 20% - vancomycin - 12 CPGs - range 4%-73% - PLoS ONE 2013 9(6): e99044

avg 18% - hypertension (China) - 17 CPGs - range 1-36% - BMJ Open 2015;5:e008099

avg 8% - respiratory (China) - 109 CPGs - range 0%-27%- Chest 2015;148:759-766

August 2016

Original Article

Glycemic Control for Patients With Type 2 Diabetes Mellitus

Our Evolving Faith in the Face of Evidence

René Rodríguez-Gutiérrez, MD, MSc; Victor M. Montori, MD, MSc

Evidence since 1998 for
Tight glycemic control (A1c 6.5%-7%) vs less tight (A1c 7%-8.5%)

Endpoints - End Stage Renal Disease/dialysis, renal death, blindness or clinical neuropathy

5 large trials, 8 meta-analyses, 2 follow-up trials

31 estimates of outcomes

- 2 (6%) suggested benefit
- 29 (94%) suggested NO benefit

Endpoints - all-cause mortality, CV mortality, non-fatal MIs, stroke, amputations/ PVD

5 large trials, 10 meta-analyses, 5 follow-up trials

78 estimates of outcomes

- 10 (13%) suggested benefit
- 64 (82%) suggested NO benefit
- 4 (5%) suggested harm

Circ Cardiovasc Qual Outcomes. 2016;9:00-00. DOI: 10.1161

Overall estimates of benefits and harms (micro and macro)

11% of estimates = a benefit

4% of estimates = harm

85% of estimates = no benefit

despite this, over the last 10 years -
"practice guidelines and published statements offer a consistent and confident consensus, with 100% of the guidelines and 77% to 100% of the statements in favor of tight glycemic control to prevent microvascular complications"

Circ Cardiovasc Qual Outcomes. 2016;9:00-00. DOI: 10.1161

Research

Contributors to primary care guidelines

What are their professions and how many of them have conflicts of interest?

G. Michael Allan MD CCFP Roni Kraut Aven Crawshay Christina Korownyk MD CCFP
Ben Vandermeer MSc Michael R. Kolber MD CCFP MSc

176 PRIMARY CARE guidelines in the CMA database

CONTRIBUTORS

54% non–family physician specialists
17% family physicians - 8% if industry sponsored
11% other clinicians
8% non-clinician scientists
6% nurses
3% pharmacists

69% of guidelines didn't report conflicts of interest

Can Fam Physician 2015;61:52-8

Guideline sponsorship

2009 - 2,300 guidelines in the National Guideline Clearinghouse

Guideline development

- 41% - medical speciality societies
- 22% - government agencies/nonprofit
- 17% - professional associations
- 9% - disease specific societies
- 4% - independent expert panels

at least 2/3 are being developed by groups with a clear potential for important biases

http://www.ncbi.nlm.nih.gov/books/NBK22928/

Prevalence of financial conflicts of interest among panel members producing clinical practice guidelines in Canada and United States: cross sectional study

~50-80% of panel members on guidelines have financial COIs

BMJ 2011;343:d5621 doi: 10.1136/bmj.d5621

EVIDENCE BASED MEDICINE

Why we can't trust clinical guidelines BMJ;2013:346

Despite repeated calls to prohibit or limit conflicts of interests among authors and sponsors of clinical guidelines, the problem persists. **Jeanne Lenzer** investigates

Adding "value" to clinical practice guidelines

James P. McCormack PharmD Peter Loewen PharmD

5 Canadian Guidelines for
blood pressure, cholesterol, glucose, and bone density

197 PAGES - 90,000 WORDS

99(0.1%) words - relevant to
patients' values and preferences

Can Fam Physician 2007;53:1326-27

Management of Hyperglycemia in Type 2 Diabetes, 2015: A Patient-Centered Approach

Update to a Position Statement of the American Diabetes Association and the European Association for the Study of Diabetes

Diabetes Care 2015;38:140–149 | DOI: 10.2337/dc14-2441

Diabetes Care
THE JOURNAL OF CLINICAL AND APPLIED RESEARCH AND EDUCATION
January 2015 Volume 38, Supplement 1

Standards of Medical Care in Diabetes—2015

Diabetes Care January 2015

113 PAGES

Looked for info on

- Risk estimation (magnitude)
- Impact of treatment on risk
- Potential harms (magnitude)

"The information presented in these documents is glucose-centric and not organized or presented in a way that could be construed as supporting shared decision making"

Their response

“would like to thank McCormack et al for their thoughtful letter regarding the American Diabetes Association’s Standards of Medical Care in Diabetes”

“agrees that shared decision making is a valuable aspect of diabetes care … that process would be incredibly labor intensive and would make the Standards long and unwieldy”

“Clinical guidelines are the foundation for evidence-based medicine”

Guidelines

Hypertension Canada's 2016 Canadian Hypertension Education Program Guidelines for Blood Pressure Measurement, Diagnosis, Assessment of Risk, Prevention, and Treatment of Hypertension

~11,800 words - 20 pages

Total mention of values and preferences - 0.19% of the words

"Practitioners are advised to consider patient preferences, values, and clinical factors when determining how to best apply these recommendations at the bedside"

"In the absence of Canadian data to determine the accuracy of risk calculations, **avoid using absolute levels of risk** to support treatment decisions"

ACP American College of Physicians — Leading Internal Medicine, Improving Lives

2017 CLINICAL GUIDELINE

Treatment of Low Bone Density or Osteoporosis to Prevent Fractures in Men and Women: A Clinical Practice Guideline Update from the American College of Physicians

~8,700 words - 27 pages

Benefits

No numbers whatsoever for fracture risk or fracture benefit

Do present info in an appendix - new studies

Harms

2017

28 numeric mentions of side effects

6 absolute numbers

22 relative numbers

One mention of patient preferences

Recommendation 6: *ACP recommends that clinicians should make the decision whether to treat osteopenic women 65 years of age or older who are at a high risk for fracture based on a discussion of patient preferences, fracture risk profile, and benefits, harms, and costs of medications. (Grade: weak recommendation; low-quality evidence)*

ACP American College of Physicians
Leading Internal Medicine, Improving Lives

2017

CLINICAL GUIDELINE

Treatment of Low Bone Density or Osteoporosis to Prevent Fractures in Men and Women: A Clinical Practice Guideline Update from the American College of Physicians

Recommendations: Recommendation 1: *ACP recommends that clinicians offer pharmacologic treatment with alendronate, risedronate, zoledronic acid, or denosumab to reduce the risk for hip and vertebral fractures in women who have known osteoporosis. (Grade: strong recommendation; high-quality evidence)*

"Evidence is insufficient to determine the comparative effectiveness of pharmacologic therapy or the superiority of one medication over another, within the same class or among classes, for prevention of fractures"

ACP American College of Physicians
Leading Internal Medicine, Improving Lives

2017 CLINICAL GUIDELINE

Treatment of Low Bone Density or Osteoporosis to Prevent Fractures in Men and Women: A Clinical Practice Guideline Update from the American College of Physicians

2017

"The data do not support monitoring BMD during the initial 5 years of treatment in patients receiving pharmacologic agents to treat osteoporosis."

Patients' Expectations of the Benefits and Harms of Treatments, Screening, and Tests
A Systematic Review

Tammy C. Hoffmann, PhD; Chris Del Mar, MD, FRACGP

BENEFIT - 88% of study authors concluded that participants **overestimated benefits**

HARM - 67% **underestimated harm**

JAMA Intern Med 2015;175:274-286

Evaluating physician understanding of harms and benefits of common tests and therapies

Paper survey to residents and attending internal medicine physicians
– 18 questions – 117 people responded

	Estimate of benefit in absolute terms						
Green cells are the correct answer	<1%	1 to 5%	5 to 10%	10 to 20%	20 to 45%	45 to 70%	70 to 100%
	Percent of respondents						
Mild HTN 5 years	11	35	28	19	7	1	1
Aspirin with risk factors 5 years	8	32	29	17	8	3	3
Aspirin in CVD 5 years	0	16	29	30	16	8	0
Warfarin Afib 1 year	3	31	29	17	12	8	0
Hip fracture osteoporosis 5 years	3	24	30	24	13	5	0
Death from bleed with PPI 5 years	21	22	20	19	9	9	1
Cancer diagnosis among + screening	4	14	23	35	18	7	0
Major bleeding with ASA 5 years	21	46	21	8	3	0	0
Major bleeding with warfarin 1 year	14	42	30	11	2	2	0
Unneccessary biopsy with screening 10 years	1	9	15	33	26	15	0

79% overestimated benefit

66% overestimated harm

67% were unconfident

JAMA Aug 29 2016

307 subjects using a written questionnaire and interview

Results

Patients	Median acceptable absolute % benefit threshold	% that would take a "safe" drug for 5 years		Absolute % benefit they felt they were getting from their drug	% who wanted to be told percent chance of benefit
		If benefit over 5 years was < 5%	If benefit over 5 years was < 5% AND their MD recommended it		
Post MI patients	20	32	69	70	79
On drugs	20	29	74	68	72
No drugs	30	21	56	-	84

Clin Med 2002;2:527-33

Ability of clinicians to make an estimate of CHD risk

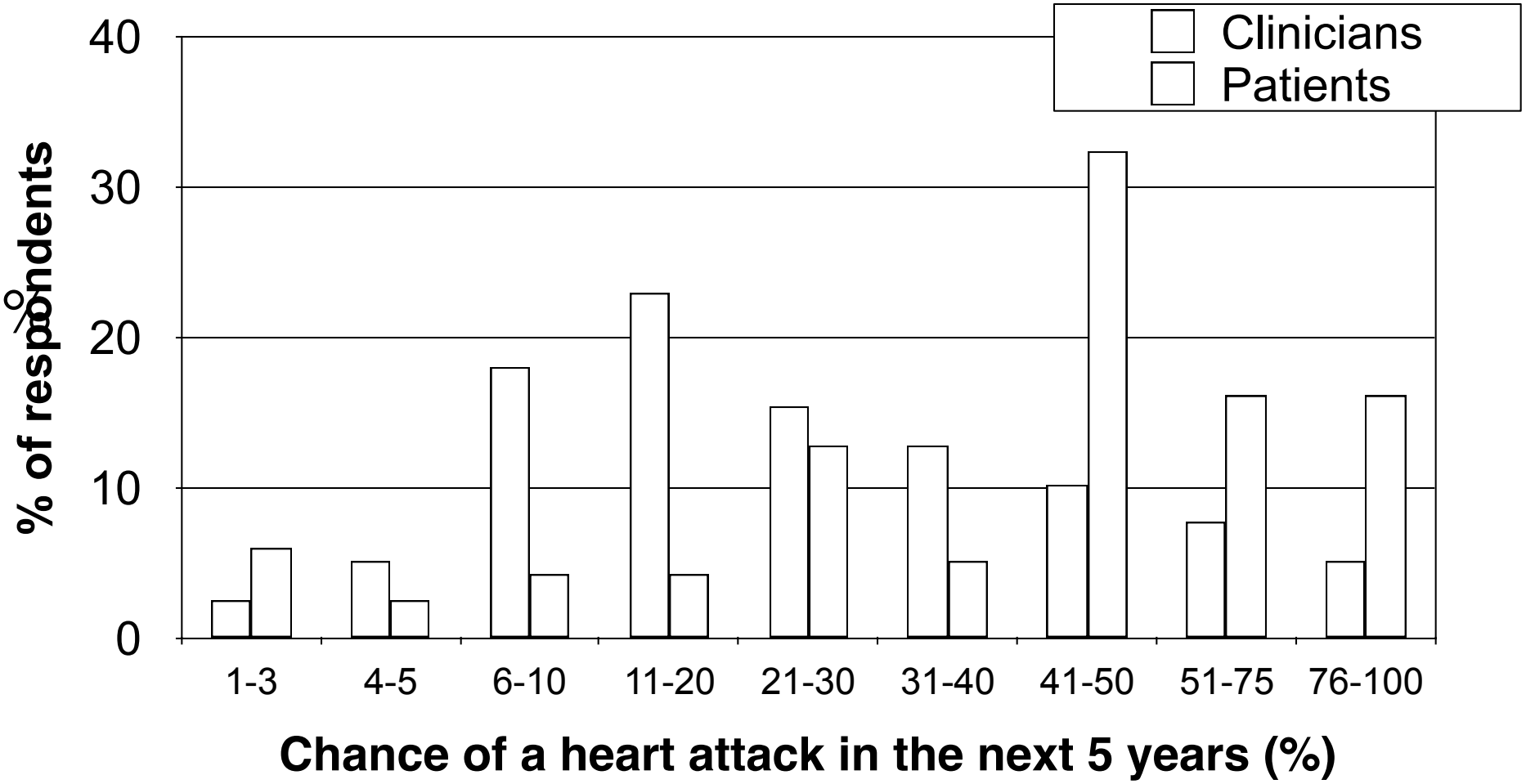
53 residents, 8 fellows, 18 attending physicians

The **mean degree of over-estimation** compared to the Framingham estimate:

low-risk scenarios - **7.8 times**
medium-risk scenarios - **2.8 times**
high-risk scenarios - **1.5 times**

BMC Health Services Research 2003;3:13

What is "High Risk"



Factors involved in deciding to start preventive treatment: qualitative study of clinicians' and lay people's attitudes

David K Lewis, Jude Robinson, Ewan Wilkinson

Qualitative study using semi-structured interviews

"Many of the preferences expressed by the clinicians and lay people in this study are at odds with recommendations in guidelines"

BMJ 2003;327:841

Differing perceptions of intervention thresholds for fracture risk: a survey of patients and doctors

Did NOT ask patients to consider side effects or drug cost, just the dosing regimen, in the decision

"A typical patient in our study required a
50% absolute fracture risk and
50% relative risk reduction (giving an absolute risk reduction of 25%)
before considering long-term drug therapy"

A prominent current guideline …
recommends pharmacologic intervention at thresholds of
10- year risk of 20% for major osteoporotic fracture or
3% for hip fracture

125 (77%) of doctors would recommend treatment
24 (21%) of our patient cohort would consider treatment justified

Osteoporos Int 2012;23:2135–40

20 "NEGATIVE" STUDIES IN A ROW

LIPIDS

AIM-HIGH, HPS2-THRIVE (niacin)

ACCORD (fibrates)

dalOUTCOMES (dalcetrapib)

STABILITY (darapladib)

DIABETES

ACCORD, ADVANCE, VADT

(aggressive A1c lowering)

ROADMAP (olmesartan)

ORIGIN (insulin)

SAVOR-TIMI 53 (saxagliptin)

EXAMINE (alogliptin)

ALECARDIO (aleglitazar)

BLOOD PRESSURE

ALTITUDE (aliskiren)

VALISH, AASK, ACCORD

(aggressive BP lowering)

GENERAL

ACTIVE (irbesartan/afib)

CRESCENDO (rimonabant)

VISTA-16 (varespladib)

182,000+ patients

FINALLY!!!!!

1) EMPA-REG OUTCOME (empagliflozin) -1.6% ARR over 3 years

2) LEADER (liraglutide) - 1.8% ARR over 4years

3) SPRINT (120mmHg vs 140mmHg) - 1.6% ARR (CVD over 3 years but also 1.8% ARI (Kidney)

4) HD, BUT blood pressure measure no benefit

5) TECOS - 1.6% ARR over 2 years (saves YES, BUT $16,000/year

6) ACCELERATE (evacetrapib - increased HDL (+130%), reduced LDL (-40%) - no CVD benefit

BUT!!!!!

Patient preferences for shared decisions: A systematic review

Betty Chewning [a,*], Carma L. Bylund [b], Bupendra Shah [c], Neeraj K. Arora [d], Jennifer A. Gueguen [e], Gregory Makoul [f]

"In three quarters of the cancer studies … the majority of patients preferred shared or autonomous decision making. In contrast, this was true for only about half of the studies with non- disease specific study populations"

"the number of patients who prefer participation has increased over the past three decades so that the majority of patients prefer to participate in decisions"

Patient Educ Couns (2011), doi:10.1016/j.pec.2011.02.004

Guidelines and the Law

"As per the Canadian Medical Association Handbook on Clinical Practice Guidelines, guidelines should NOT be used as a legal resource in malpractice cases as "their more general nature renders them insensitive to the particular circumstances of the individual cases."

CJD
Canadian Journal of Diabetes
A Publication of the Professional Sections of the Canadian Diabetes Association
Une publication des sections professionnelles de l'Association canadienne du diabète
CONTENTS: April 2013 ▪ Volume 37 ▪ Supplement 1

CMPA
Empowering
better healthcare

The Bottom Line

Sep 2011

Even an authoritative CPG may NOT be found to be determinative of a standard of care.

It is prudent for physicians to be aware of authoritative clinical practice guidelines relevant to their practices. If a clinical decision may be perceived as being contrary to a recognized and accepted CPG, a physician, where appropriate, may consider the following steps: consult with a colleague or relevant specialist, discuss reasonable treatment options with the patient, and document the patient's consent for the chosen treatment.

If deviating from an established CPG, physicians should consider documenting the rationale for doing so, as well as any discussions with the patient about such variance.

Many courts (UK, US, CA)

"The reasonable-patient standard … requires physicians and other health care practitioners to disclose all relevant information about the risks, benefits, and alternatives of a proposed treatment that an **OBJECTIVE PATIENT** would find material in making an intelligent decision as to whether to agree to the proposed procedure"

JAMA 2016;315:2063-4

OPEN ACCESS Freely available online

PLOS | MEDICINE

Expanding Disease Definitions in Guidelines and Expert Panel Ties to Industry: A Cross-sectional Study of Common Conditions in the United States

2013

Raymond N. Moynihan[1]*, Georga P. E. Cooke[1], Jenny A. Doust[1], Lisa Bero[2], Suzanne Hill[3], Paul P. Glasziou[1]

1 Bond University, Robina, Australia, 2 University of California, San Francisco, San Francisco, California, United States of America, 3 Australian National University, Acton, Australia

Of 16 publications on 14 common conditions, 10 widened and 1 narrowed definitions.

Widen by 3 methods: (i) "pre-disease"; (ii) lowering thresholds; (iii) earlier or new diagnostic methods.

None had rigorous assessment of potential harms of proposed changes.

The average proportion of members with industry ties was 75%; 12/16 chairs had ties.

CONCLUSION:

"research and policy attention might be directed at designing new processes for reviewing disease definitions, free of financial conflicts of interest and informed by rigorous analysis of benefits and harms."

FRAMEWORK CONVENTION ON TOBACCO CONTROL

Guidelines for Guidelines

Guidelines for Guidelines
We've Come a Long Way

GUIDELINES FOR WHO GUIDELINES

Global Programme on Evidence for Health Policy
World Health Organization
Geneva, Switzerland

Guidelines for Guidelines

W.-I. Steudel and K. Schwerdtfeger

Department of Neurosurgery, Saarland University Medical School, Homburg/Saar, Germany

Guidelines for Guidelines: Are They Up to the Task? A Comparative Assessment of Clinical Practice Guideline Development Handbooks

Guidance for updating clinical practice guidelines: a systematic review of methodological handbooks

Robin WM Vernooij[1,2], Andrea Juliana Sanabria[1], Ivan Solà[1], Pablo Alonso-Coello[1*] and Laura Martínez García[1]

There are LOTS of guidelines

Often don't provide a solid synopsis/ systematic review of the best available evidence

Often don't provide sufficient information to do shared-decision-making or even support the concept

Many "conflicts" and ownership issues

Patient expectations are often at odds with guideline recommendations

Legal precedents are leaning in favour of benefit/harm communication

Education and Guidelines

Obviously inform you that CPG's exist

We all need to discuss up front the limitations and issues of clinical practice guidelines

We need to know how to appraise and integrate the best available evidence

Admit we don't have answers for everything

We need to help you think for yourselves and use common-sense

Need to be allowed to make "mistakes"

It is totally OK to go "against" the guidelines

The Guideline Solution?

What should guidelines contain?

Who should write them?

What should they not contain?

Are there examples of well-done guidelines?

Guidelines would be awesome if they…

Were developed primarily by, and definitely for, the people that ultimately end up using them

Were a credible synopsis of the best available evidence presented in a way that clinicians could easily access and interpret

Allowed patient values and preferences to be taken into account

An Example of a Guideline that Promotes Discussion Rather than Treatment

Simplified lipid guidelines

Prevention and management of cardiovascular disease in primary care

G. Michael Allan MD CCFP Adrienne J. Lindblad ACPR PharmD Ann Comeau MN NP CCN(C) John Coppola MD CCFP
Brianne Hudson MD CCFP Marco Mannarino MD CCFP Cindy McMinis Raj Padwal MD MSc
Christine Schelstraete Kelly Zarnke MD MSc FRCPC Scott Garrison MD PhD CCFP Candra Cotton
Christina Korownyk MD CCFP James McCormack PharmD Sharon Nickel Michael R. Kolber MD CCFP MSc

Can Fam Physician 2015;61:857-67

Reducing Your Risk for Heart Attacks & Strokes

A SHIFT IN THINKING...

What's Changed?

If you asked anyone how to reduce your risk of a heart attack or stroke you'd likely hear them mention the need to lower your cholesterol.

However, many studies have shown improving cholesterol does not always reduce risk of cardiovascular disease (heart attack or stroke). By worrying only about cholesterol we might miss helping the right people because cholesterol is only one risk

CHOLESTEROL ONLY TELLS US PART OF YOUR HEART HEALTH STORY

Medication

Statin therapy should be discussed with all people with moderate to high cardiovascular risk (10% or more). Your healthcare provider can explain your risk and how statins can reduce that risk by 25-35%.

STATINS CAN REDUCE YOUR RISK OF HEART ATTACK AND STROKE BY 25% TO 35%

A low-dose of ASA (Aspirin®) may also be recommended for further risk reduction if you are at high cardiovascular risk (20% or more) or have had a heart attack or stroke. ASA reduces cardiovascular risk by about 12.5% (half or third as effective as statins). Note – ASA can cause bleeding.

What are the side effects of statins?

All drugs come with

Most Common — **1 in every 10 to 20 people – muscle aches or stiffness***

1 in every 10,000

Are statins right for you?

You decide. Speak with your healthcare provider about your risk of cardiovascular disease and the benefits and risks of taking statins. Regardless of your decision, your healthcare provider will support you!

This number is an educated guess of your chances of developing cardiovascular disease in the next 10 years. For example, a 10% risk means you have about a 1 in 10 chance of having a heart attack or stroke in the next 10 years.

What can you do to reduce your risk of heart attack or stroke?

Eat healthy – be active – don't smoke

These lifestyle choices reduce your risk of cardiovascular disease and benefit your overall health.

EXERCISE OR A MEDITERRANEAN DIET CAN REDUCE YOUR RISK OF HEART ATTACK AND STROKE BY 30%

tested?

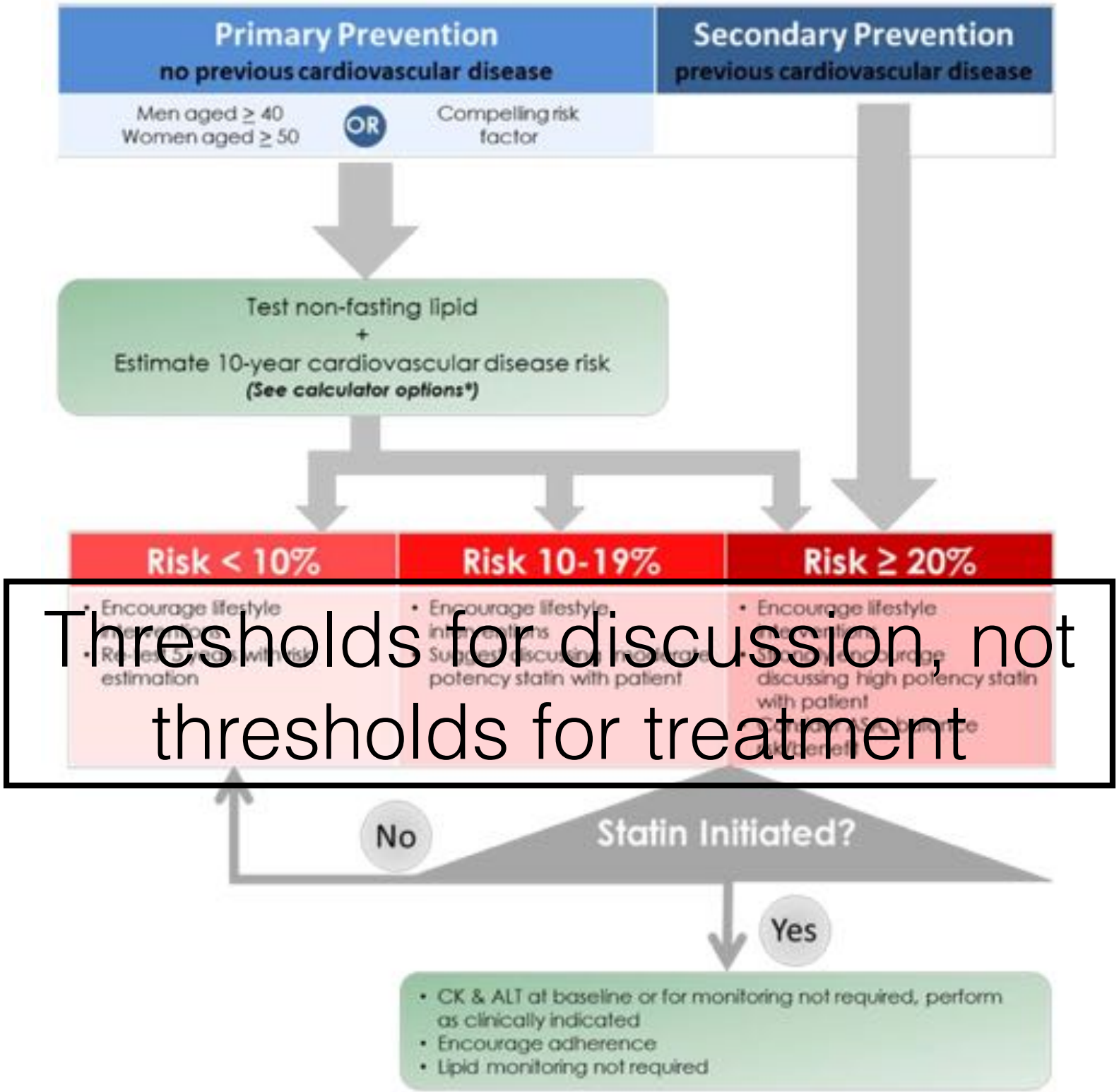
Not taking a statin → You should continue to have your cholesterol tested every 5 years.

Taking a statin → No. Once you have decided to take a statin a cholesterol test is unnecessary – statins help to reduce your cardiovascular risk no matter what your cholesterol level. So knowing your cholesterol level would not change your treatment plan.

Are statins right for you?

You decide. Speak with your healthcare provider about your risk of cardiovascular disease and the benefits and risks of taking statins. Regardless of your decision, your healthcare provider will support you!

Alberta College of Family Physicians
The College of Family Physicians of Canada / Le Collège des médecins de famille du Canada
TOP Toward Optimized Practice



Thresholds for discussion, not thresholds for treatment