Making decisions in practice - is shared decision-making the only outcome that matters?

James McCormack, BSc(Pharm), PharmD
Professor, Faculty of Pharmaceutical Sciences,
University of British Columbia, Vancouver, BC

Ever wonder
if the
recommendations
from these shows
are evidence-based?

WE DID

Televised medical talk shows—what they recommend and the evidence to support their recommendations: a prospective observational study

OPEN ACCESS

thebmj 2014

Christina Korownyk *associate professor of family medicine*[1], Michael R Kolber *associate professor of family medicine*[1], James McCormack *professor of pharmacy*[3], Vanessa Lam *research assistant*[2], Kate Overbo *research assistant*[2], Candra Cotton *pharmacist*[1], Caitlin Finley *research assistant*[1], Ricky D Turgeon *pharmacist*[3], Scott Garrison *associate professor of family medicine*[1], Adrienne J Lindblad *associate clinical professor of family medicine*[1], Hoan Linh Banh *associate professor of family medicine*[1], Denise Campbell-Scherer *associate professor of family medicine*[1], Ben Vandermeer *biostatistician*[4], G Michael Allan *professor of family medicine*[1]

Brit Med J 2014;349:g7346 doi: 10.1136/bmj.g7346 (Published 17 December 2014)

“Believable” Evidence for Recommendations

	EVIDENCE			
	Supports	Contradicted	Not Found	Believable or somewhat believable
Dr Oz	46%	15%	39%	33%
The Doctors	63%	14%	24%	53%

BMJ 2014;349:g7346

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 Phy 2015;61:857-67

Simplified guideline for prescribing medical cannabinoids in primary care

G. Michael Allan MD CCFP Jamil Ramji Danielle Perry Joey Ton PharmD Nathan P. Beahm PharmD
Nicole Crisp RN MN NP-Adult Beverly Dockrill RN Ruth E. Dubin MD PhD FCFP DCAPM Ted Findlay DO CCFP FCFP
Jessica Kirkwood MD CCFP Michael Fleming MD CCFP FCFP Ken Makus MD FRCPC Xiaofu Zhu MD FRCPC
Christina Korownyk MD CCFP Michael R. Kolber MD CCFP MSc James McCormack PharmD Sharon Nickel
Guillermina Noël MDes PhD Adrienne J. Lindblad ACPR PharmD

Can Fam Phy 2018;64:111-120

My Simple Philosophy on Treatments

These sorts of terms are uniformly uninformative - allopathic, conventional, mainstream, Western medicine, complementary, integrative, naturopathy, Chinese medicine, homeopathy, herbal

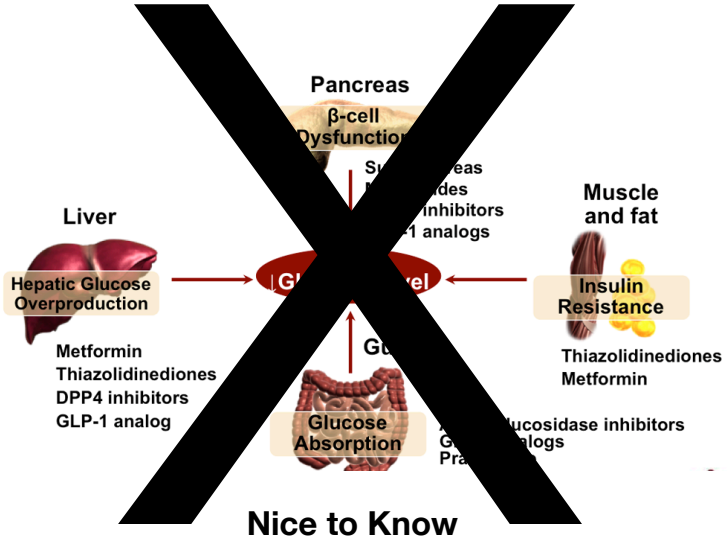
We all treat people with “things” - oral/IV/IM/topical, nutrition, surgery, talk, physical manipulations etc

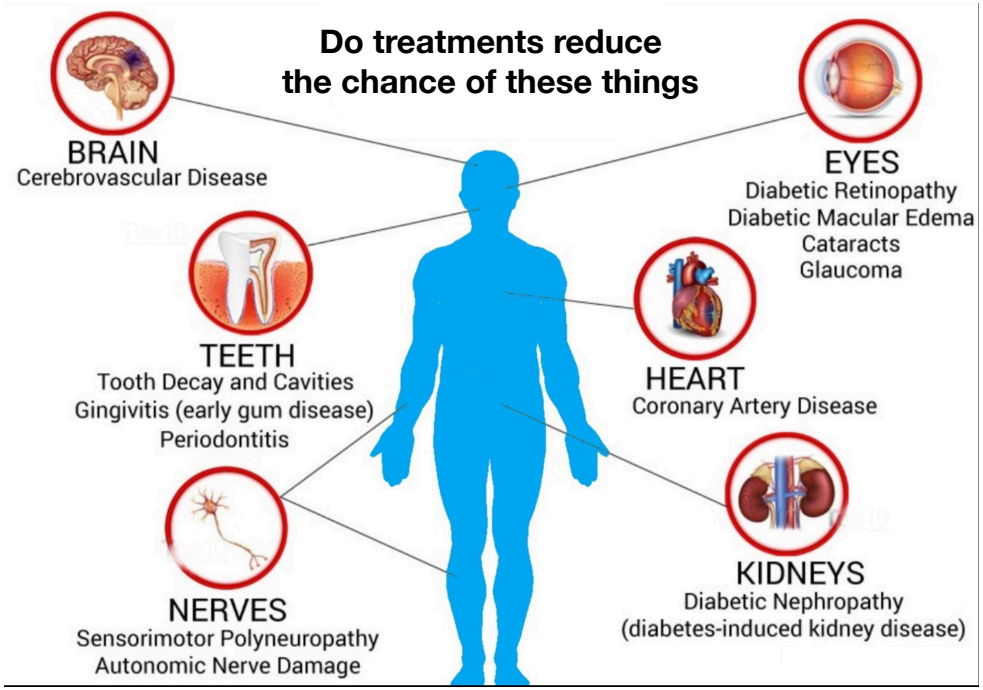
I don’t care HOW treatments work, I care IF treatments work

We need to figure out if treatments “work” = have an effect above what happens in the placebo group

The placebo group response can vary from 0% (general anesthesia) to close to 40-50% (anxiety, depression etc) - however, with the exception of pain, there is very little true placebo effect

How Does It Work?





Absolutely !@#$% Crucial to Know

My Simple Philosophy on Treatments

IMHO there are only 2 classes of treatments - those that that have been shown to work (or not work) and those that haven't been properly studied

IMHO the vast majority of treatments CAN and SHOULD be evaluated by an RCT

HOWEVER, to see if a treatment works for symptoms in a specific person you can only tell by trying it - "N of 1 trial"

My Specific Philosophy on Medications


Some medications are incredibly useful


Most medications don’t work nearly as well as you think


Most new medications are no better than what we already have


Most of the starting doses in the PDR are TOO HIGH

Our Top 20 Medications by “patented” year

Medication	Indication	Made/Patented
Morphine (oral, parenteral)	Pain	1827
ASA	Pain	1899
Epinephrine	Hormone	1904
Insulin	Hormone	1920
Diphenhydramine (oral, topical, parenteral)	Antihistamine	1946
Dexamethasone (oral, topical, inhaler,	Steroid	1957
Levothyroxine	Hormone	1958
Birth control pill	Contraception	1960
Metronidazole (oral, topical, parenteral)	Antibiotic	1960
Furosemide (oral, parenteral)	HF	1962
Lorazepam (oral, parenteral)	Anxiety	1963
Doxycycline (oral, topical, parenteral)	Antibiotic	1967
Salbutamol (inhaler, oral, parenteral)	Asthma/COPD	1968
Metoprolol (oral, parenteral)	HF/angina/PostMI	1969
Amoxicillin/clavulanate (oral, parenteral)	Antibiotic	1985
Omeprazole (least expensive PPI)	Heartburn	1989
Fluconazole (oral, topical, parenteral)	Antifungal	1990
Losartan (least expensive ARB)	CVD risk/HF	1995
Quetiapine	Antipsychotic/	1997
Polyethylene glycol	Laxative	??

Average year of “patenting” 1956

2 -1800s
1-1900s
1-1920s
1-1940s
3-1950s
7-1960s
2-1980s
3-1990

Golden Pill Award

PRESCRIRE AWARDS

	Major advance - 1	Clear advance - 7	Modest improvement -13
2011	0	0	0
2012	0	0	2 abiraterone (prostate CA) boceprevir (Hep C)
2013	0	0	1 meningococcal conjugate vaccine (infant immunization)
2014	1 cholic acid (hereditary bile acid deficiency)	3 imatinib (ALL) artesunate (malaria) sofosbuvir (HepC)	1 sodium phenylbutyrate coated granules (urea cycle disorders)
2015	0	1 propranolol (severe infantile hemangioma)	2 permethrin (scabies) ketoconazole HRA (endogenous Cushing's syndrome)
2016	0	0	2 nivolumab (inoperable melanoma) trametinib (inoperable melanoma)
2017	0	1 asfotase alfa (perinatal and infantile forms of hypophosphatasia)	2 pertuzumab (metastatic breast cancer) emtricitabine/tenofovir (HIV transmission)
2018	0	2 sebelipase alfa (lysosomal acid lipase deficiency) naloxone nasal spray (emergency treatment of opioid overdose)	3 lidocaine + prilocaine combination (primary premature ejaculation) naloxone IM kit (emergency treatment of opioid overdose) arsenic trioxide (acute promyelocytic leukaemia)

So now what?

LET THE PATIENT REVOLUTION BEGIN

PATIENT REVOLUTION

=

Clinicians and patients working in partnership

KNOWING THE MAGNITUDE OF THE BENEFIT OF TREATMENT

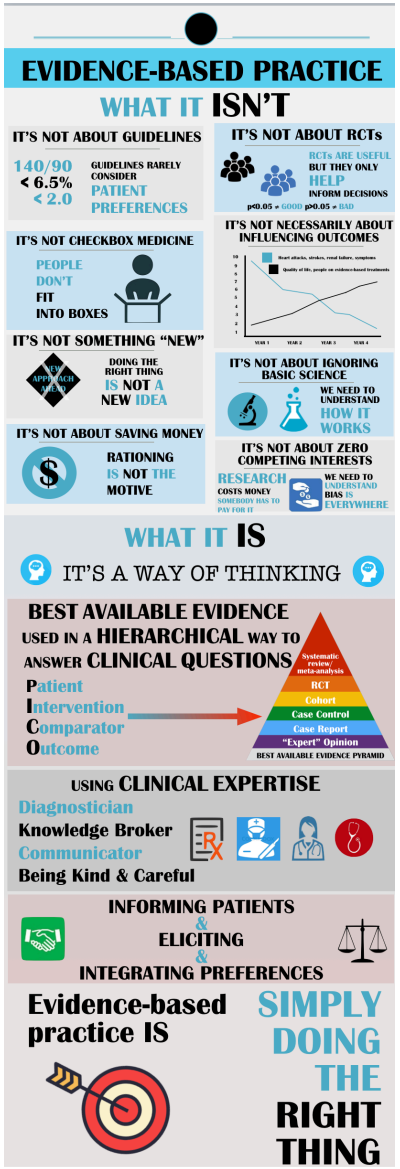
KNOWING the POTENTIAL HARMS - SIDE EFFECTS, COST AND INCONVENIENCE

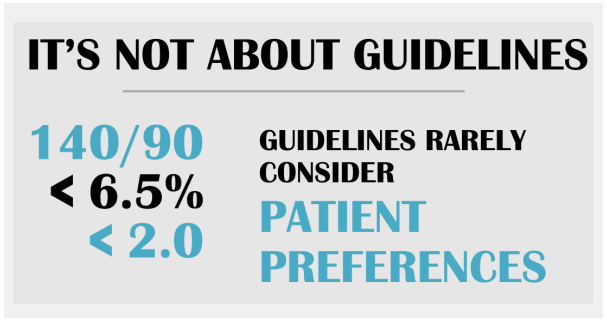
REALIZING HEALTH DECISIONS ARE YOUR DECISIONS

May 2013

THREE PARTS

Best Available Evidence


EVIDENCE-BASED PRACTICE
WHAT IT ISN'T
IT'S NOT ABOUT GUIDELINES
140/90
< 6.5%
< 2.0
GUIDELINES RARELY CONSIDER
PATIENT PREFERENCES
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 CHECKBOX MEDICINE
PEOPLE DON'T FIT INTO BOXES
IT'S NOT NECESSARILY ABOUT INFLUENCING OUTCOMES
IT'S NOT SOMETHING "NEW"
NEW APPROACH AHEAD
DOING THE RIGHT THING IS NOT A NEW IDEA
IT'S NOT ABOUT IGNORING BASIC SCIENCE
WE NEED TO UNDERSTAND HOW IT WORKS
IT'S NOT ABOUT SAVING MONEY
RATIONING IS NOT THE MOTIVE
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
BEST AVAILABLE EVIDENCE
USED IN A HIERARCHICAL WAY TO ANSWER CLINICAL QUESTIONS
Patient
Intervention
Comparator
Outcome
Systematic review, meta-analysis
RCT
Cohort
Case Control
Case Report
"Expert" Opinion
BEST AVAILABLE EVIDENCE PYRAMID
USING CLINICAL EXPERTISE
Diagnostician
Knowledge Broker
Communicator
Being Kind & Careful
INFORMING PATIENTS
&
ELICITING
&
INTEGRATING PREFERENCES
Evidence-based practice IS
SIMPLY DOING THE RIGHT THING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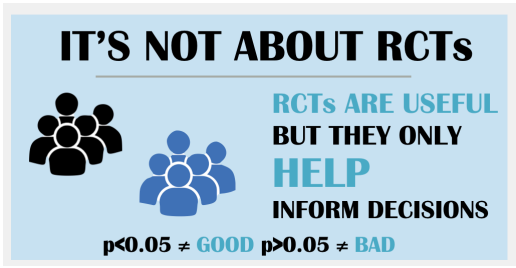
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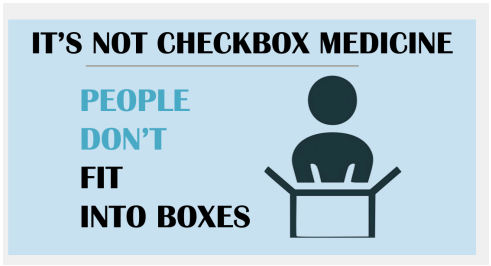
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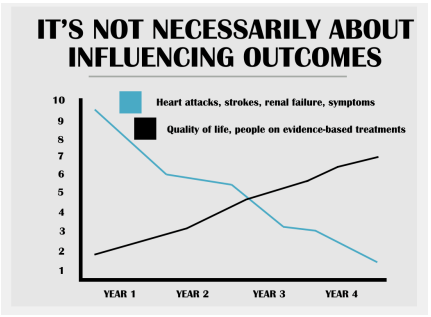
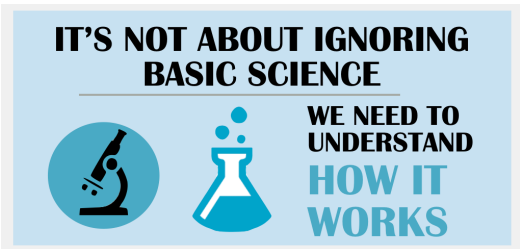

IT'S NOT NECESSARILY ABOUT INFLUENCING OUTCOMES
Heart attacks, strokes, renal failure, symptoms
Quality of life, people on evidence-based treatments
10
9
8
7
6
5
4
3
2
1
YEAR 1
YEAR 2
YEAR 3
YEAR 4


IT'S NOT SOMETHING "NEW"
NEW APPROACH AHEAD
DOING THE RIGHT THING
IS NOT A NEW IDEA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INFORMING PATIENTS
&
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&
INTEGRATING PREFERENCES

WHAT IT IS

IT'S A WAY OF THINKING

EVIDENCE-BASED PRACTICE

Evidence Issues

Much of research is not going to be “right”

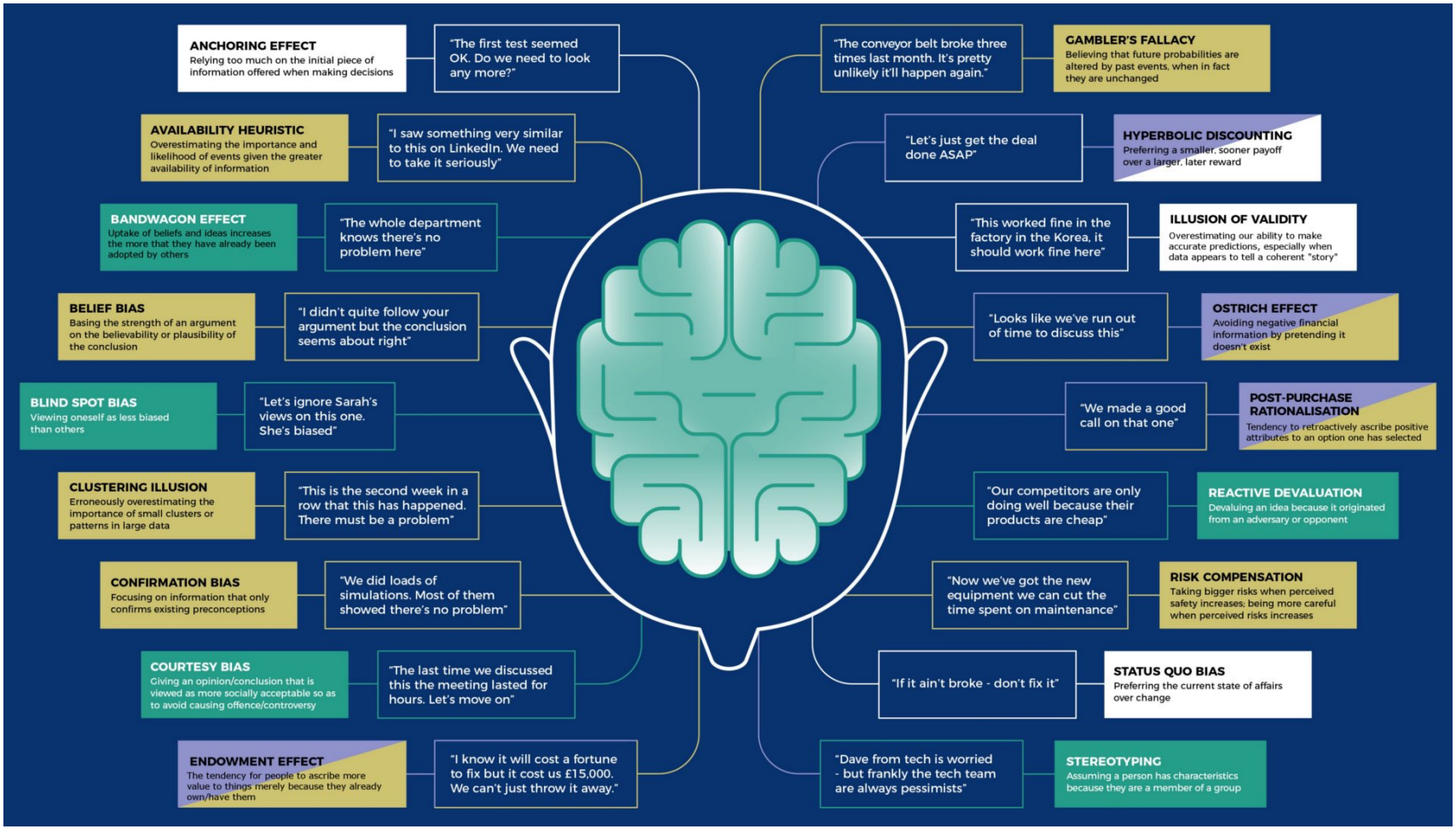
One study likely proves nothing - need reproducibility

“The evidence for nonreproducibility in basic and preclinical biomedical research is compelling” John Ioannidis

Cohort trials don't prove causation

Research does go unpublished - but large studies do get reported

There are 100s of biases - these are some main ones



“Science can be used to inform clinical decisions, but cannot definitively inform value judgements, because the significance of potential benefits and harms of a therapy are in the eye of the beholder and will differ across individuals.”

Circulation. 2017;135:180–195. DOI: 10.1161/CIRCULATIONAHA.116.022622

“Choice is a gift from the patient to the doctor, not the other way around”

BMJ 2000;320:874

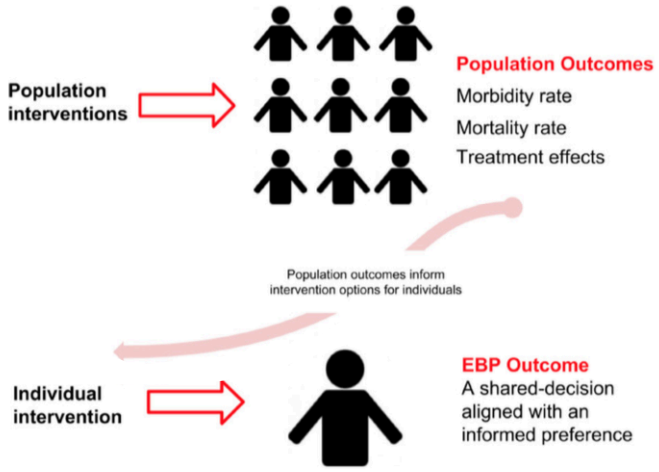
EBM analysis

OPEN ACCESS

Shared decision is the only outcome that matters when it comes to evaluating evidence-based practice

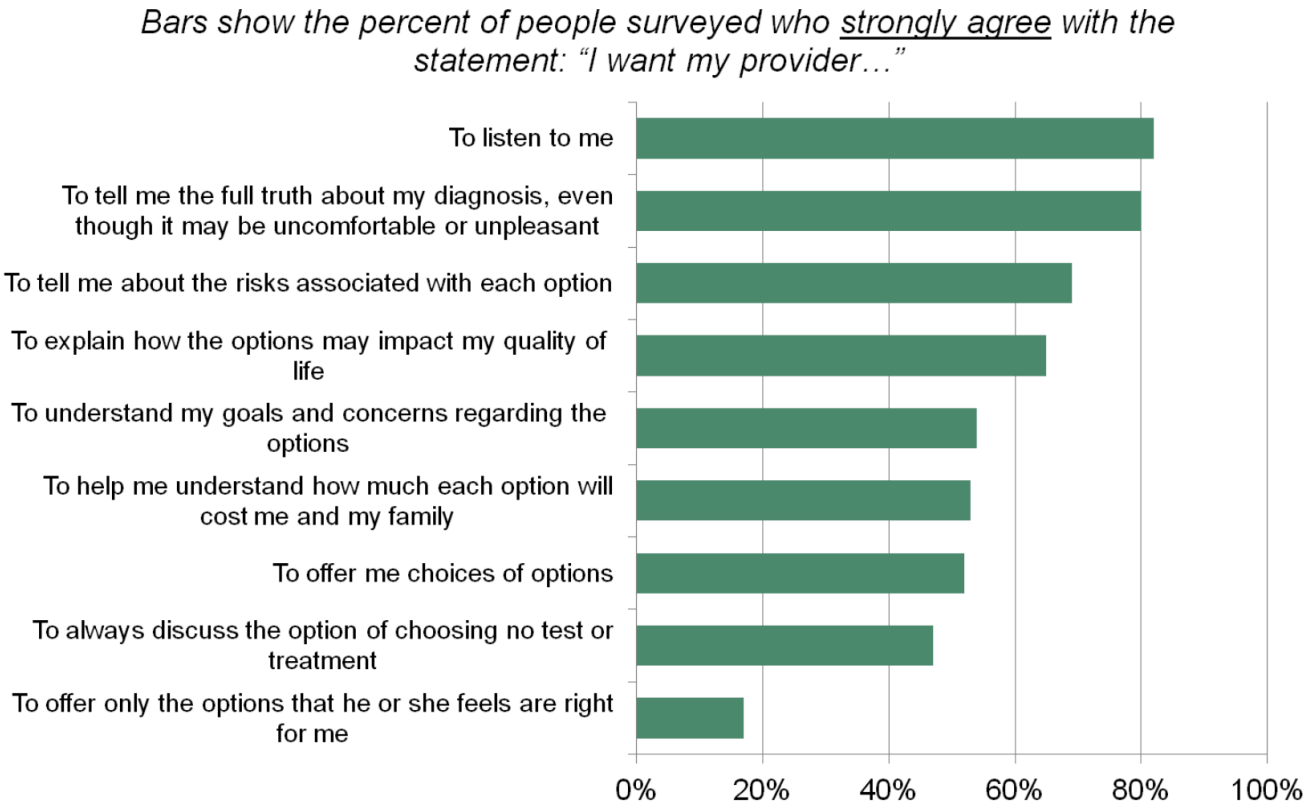
James McCormack,[1] Glyn Elwyn[2]

"in the vast majority of circumstances, the only outcome of relevance for EBP is to measure whether a shared decision was made"



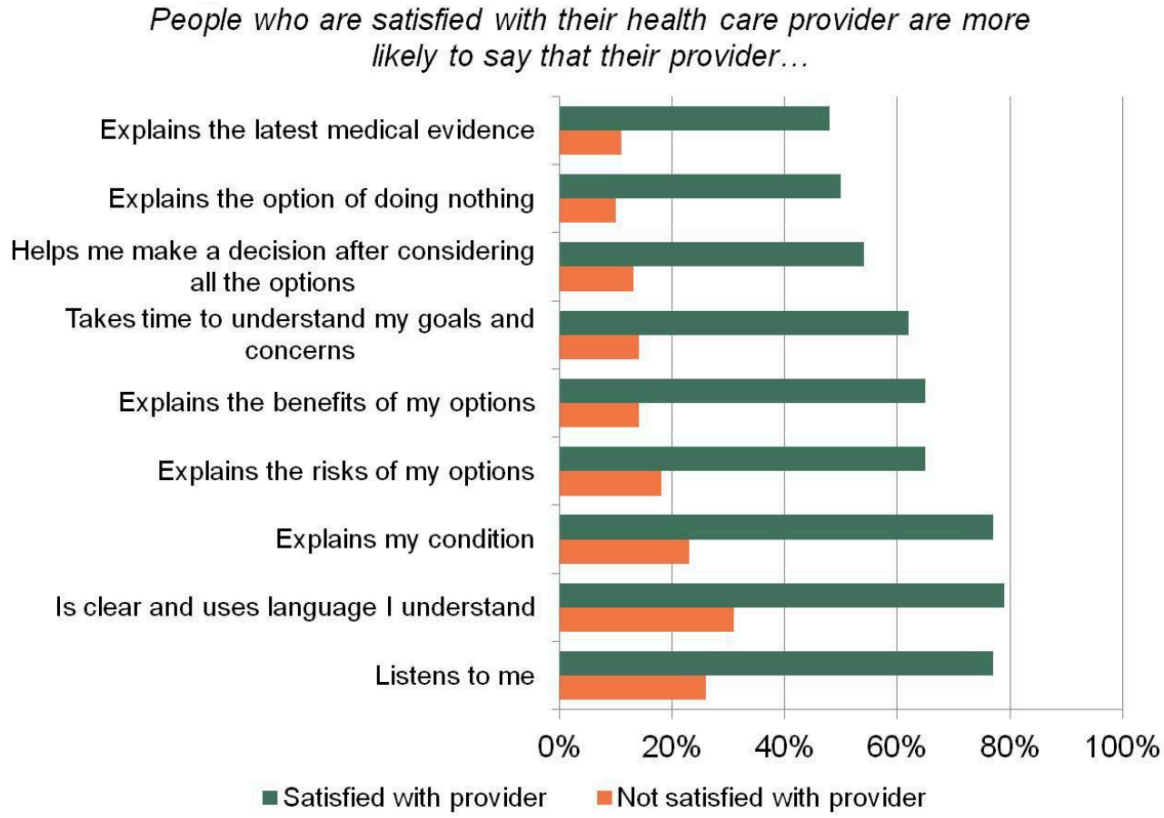
doi:10.1136/ bmjebm-2018-110922

People want involvement in evidence and decisions



Communicating with patients on health care evidence.
Discussion Paper, Institute of Medicine, Washington, DC 2012

Satisfaction is linked to shared decisions



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“Most patients cannot recall a time when their care provider discussed scientific evidence as the basis for better care”

Communicating with patients on health care evidence.
Discussion Paper, Institute of Medicine, Washington, DC 2012

Some clinical adages to SDM?

Ask - how do you feel about being involved in making decisions about your treatment?

It's OK if we say I don’t know, let’s look into it, it’s your decision

You and your patient’s perception are not necessarily “right” and likely not the same

THIS HAS VERY LITTLE IF ANYTHING TO DO WITH SHARED-DECISIONS

"Standard of Care"
and follow
Clinical Practice Guidelines

May or may not follow
Clinical Practice Guidelines

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

Guidelines would be awesome if they…

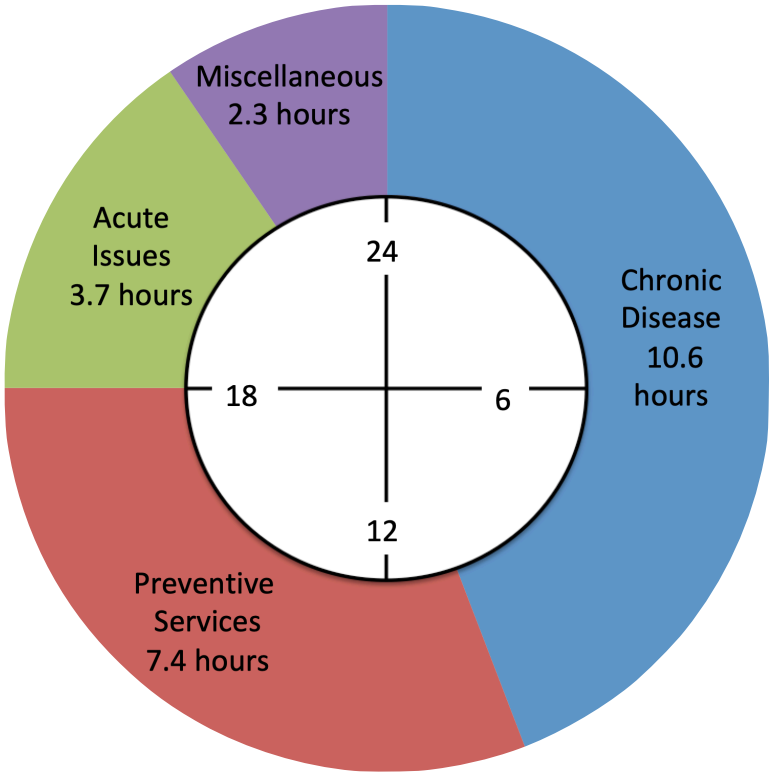
Were developed primarily by, and definitely for, the people that ultimately end up using them

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

A Primary Care Day:

Brought to you by the Good people at Guidelines!



If we follow clinical practice guidelines
11 hours for chronic disease
7 hours for preventive services

We also need
4 hours for acute issues
2 hours miscellaneous

Ann Fam Med. 2005;3:209-14.
Am J Public Health. 2003;93:635-41.
Ann Fam Med 2012;10:396-400.

At a MINIMUM,

YOU

should know the

Best Available Evidence for the top 20 or so things you see in practice on a day-to-day basis

Describing Benefits

The chance of "X"

WITH NO TREATMENT

The chance of "X"

WITH TREATMENT

Languages: English (EN)

The Absolute CVD Risk/Benefit Calculator

Framingham
US Data, 10 Year Risk
Heart attacks + angina/coronary insufficiency + heart failure + strokes + intermittent claudication

QRISK®2-2014
UK Data, 10 Year Risk
Heart attacks + strokes

ACC/AHA ASCVD
US Data, 10 Year Risk
CHD death + nonfatal heart attacks + fatal/nonfatal strokes

PREDICT
New Zealand Data, 5 Year Risk
Heart attacks + angina + heart failure + strokes/TIAs + peripheral vascular disease

---

Age
50 years

Gender
Male ✔ Female

Smoker
Yes ✔ No
CVD risk is reversed after 5-10 years of no smoking

Diabetes
Yes ✔ No

Systolic Blood Pressure
120 mmHg
Enter present blood pressure regardless of treatment
120 mmHg is used for baseline risk

On treatment for BP
Yes ✔ No
Click YES if taking blood pressure medication
Only applies if SBP is greater than 120 mmHg

Total Cholesterol
3 mmol/L
Cholesterol should be prior to drug treatment
3 mmol/L is used for baseline risk.
Click to change to mg/dL.

HDL Cholesterol
1.3 mmol/L
HDL should be prior to drug treatment

Relative Benefit: 0%

Benefit often has *nothing* to do with the effect on the surrogate marker. At present, you can only select one intervention at a time.

- Physical Activity
- Mediterranean Diet vs Low fat
- Vitamin/Omega-3 supplements
- BP meds (not atenolol/doxazosin)
- Low-mod intensity statins
- High intensity statins
- Fibrates
- Niacin
- Ezetimibe
- Metformin
- Sulfonylureas
- Insulins
- Glitazones
- GLPs
- DPP-4s
- Meglitinides
- SGLT2
- Smoking Cessation
- ASA

Benefit Estimate Details

Risk Time Period

10 years

97.9%	No event
2.1%	Total with an event
0.0%	Number who benefit from treatment
NNT ∞	Number needed to treat
2.1%	Baseline events using baseline factors alone
0.0%	Additional events “caused” by risk factors

As with all risk calculators, calculated risk numbers are +/- 5% at best. More information.

cvdcalculator.com

Comparing Treatment Options for Pain: The C-TOP Tool

Neuropathic Pain | Osteoarthritis Pain (Coming Soon) | Back Pain (Coming Soon)

Medication Options

- **Amitriptyline** (Elavil®)
- **Cannabinoids** (Nabiximols, nabilone, medical marijuana)
- **Duloxetine** (Cymbalta®)
- **Gabapentin** (Neurontin®)
- **High-Dose Opioids** (morphine, oxycodone)
- **Pregabalin** (Lyrica®)
- **All Treatments** (comparison)

Curious about capsaicin, botox, tramadol, carbamazepine, or venlafaxine for neuropathic pain? Click here to learn more.

Meaningful Pain Relief from Amitriptyline

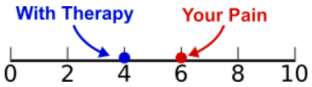
(30% reduction in pain scores)

Amitriptyline Benefit	Placebo Benefit	No Benefit
25% (ranges 13% to 45%)	25%	50%

A typical placebo group response seen in pain studies is **25%** but this can be adjusted in the FAQ section.

Meaningful Pain Relief

An example of a **30% reduction** in pain scores is a decrease from **6** to **4** on a **10** point pain scale



Amitriptyline Harms

Dry mouth	34%	6% (placebo)
Sleepiness	34%	9% (placebo)
Balance problems	20%	3% (placebo)
Stopped due to side effects	16%	7% (placebo)

Other Considerations

- Typically taken at bedtime due to sleepiness effects
- Approximate cost (CAD) for 30-day supply (without dispensing fee): **$1.50 to $3.50**

http://pain-calculator.com

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

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

Durand *et al. BMC Health Services Research* (2015) 15:167
DOI 10.1186/s12913-015-0823-2

BMC
Health Services Research

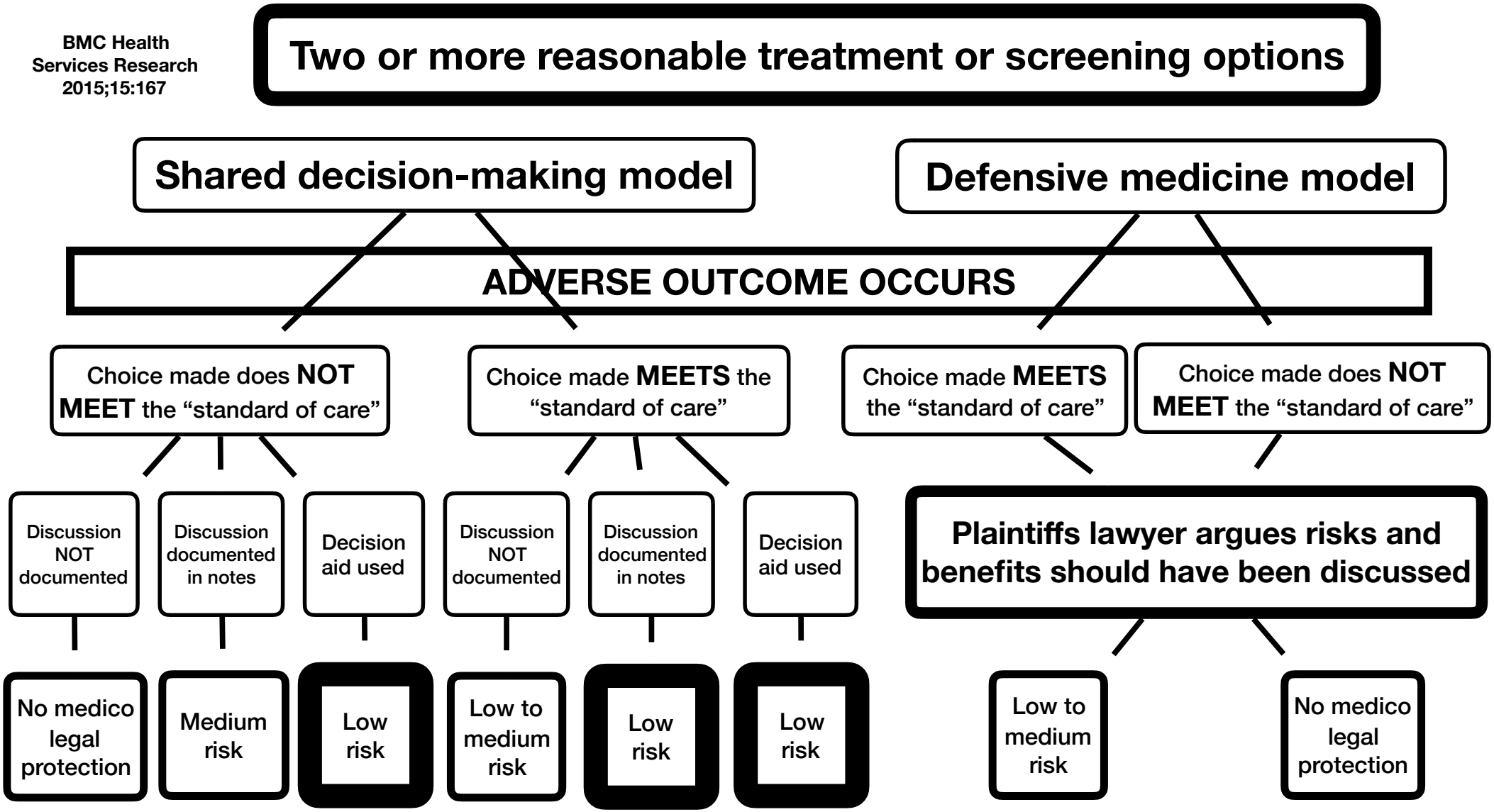
RESEARCH ARTICLE Open Access

Can shared decision-making reduce medical malpractice litigation? A systematic review

Marie-Anne Durand[1,2*], Benjamin Moulton[3,4,5], Elizabeth Cockle[2], Mala Mann[6] and Glyn Elwyn[1,7]

"There is insufficient evidence to determine whether or not shared decision-making and the use of decision support interventions can reduce medical malpractice litigation. Further investigation is required."

BMC Health Services Research 2015;15:167



Defensive model (guidelines/standard of care)

NEVER get to a low litigation risk

Reducing litigation risk

2 THINGS to DO

Shared decision-making model

1) Use a decision aid

2) Document decision