Patient-centered Translation of Evidence Into Practice

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Disclosures

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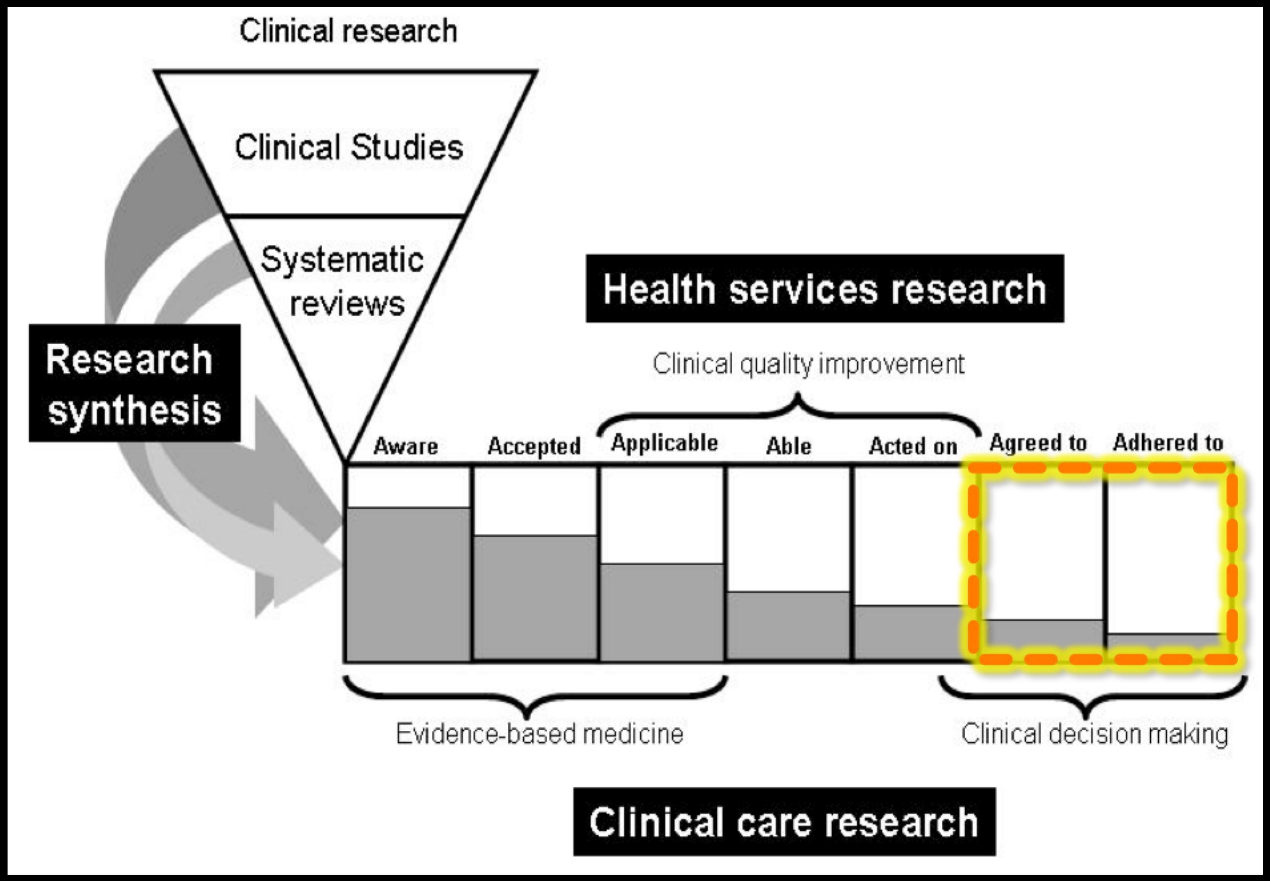
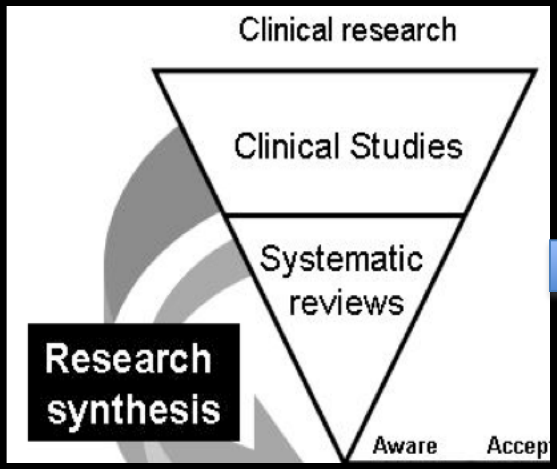
  - NIDDK: R34 DK84009
  - Foundation for Informed Medical Decision Making (FIMDM)
  - American Diabetes Association (ADA)
  - Mayo Clinic Foundation for Medical Education and Research
  - Mayo Clinic CCaTS

EBM ⟶ KT



Glasziou and Haynes ACP JC 2005



Systematic Review: Comparative Effectiveness and Safety of Oral Medications for Type 2 Diabetes Mellitus

Shari Bolen, MD, MPH; Leonard Feldman, MD; Jason Vassy, MD, MPH; Lisa Wilson, BS, ScM; Hsin-Chieh Yeh, PhD; Spyridon Marinopoulos, MD, MBA; Crystal Wiley, MD, MPH; Elizabeth Selvin, PhD; Renee Wilson, MS; Eric B. Bass, MD, MPH; and Frederick L. Brancati, MD, MHS

Background: As newer oral diabetes agents continue to emerge on the market, comparative evidence is urgently required to guide appropriate therapy.

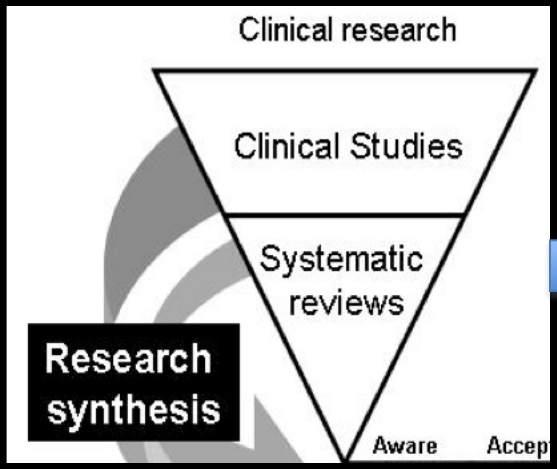
had a beneficial effect on high-density lipoprotein cholesterol levels (mean relative increase, 0.08 to 0.13 mmol/L [3 to 5 mg/dL]) but a harmful effect on low-density lipoprotein (LDL) cholesterol levels (mean relative increase, 0.26 mmol/L [10 mg/dL]) compared with

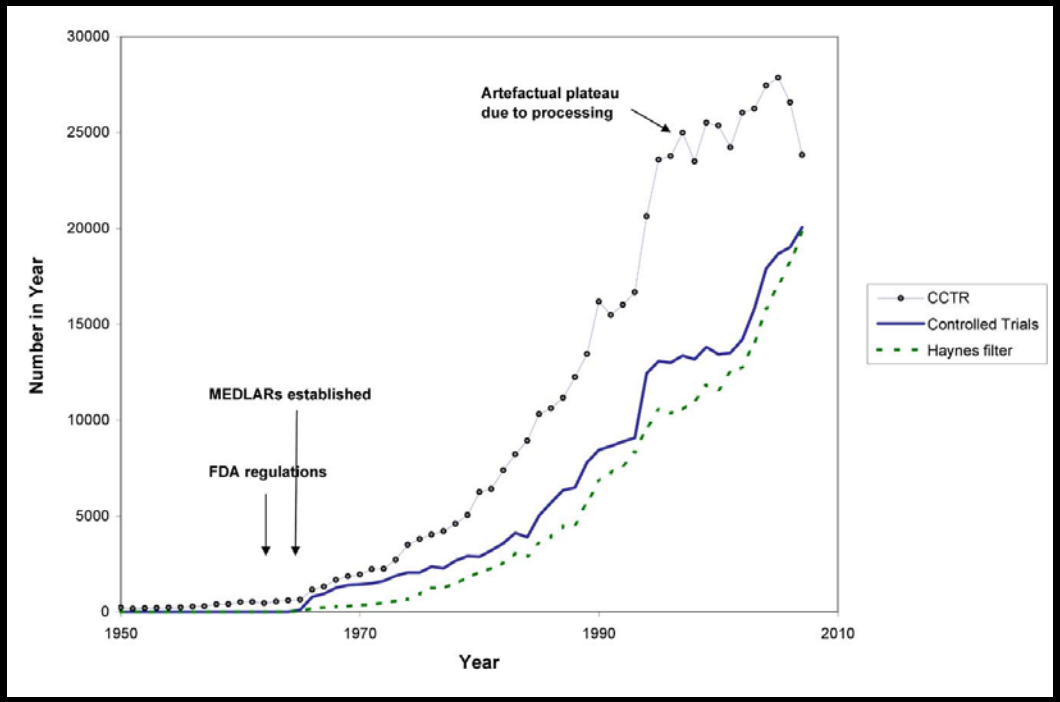
LESS IS MORE

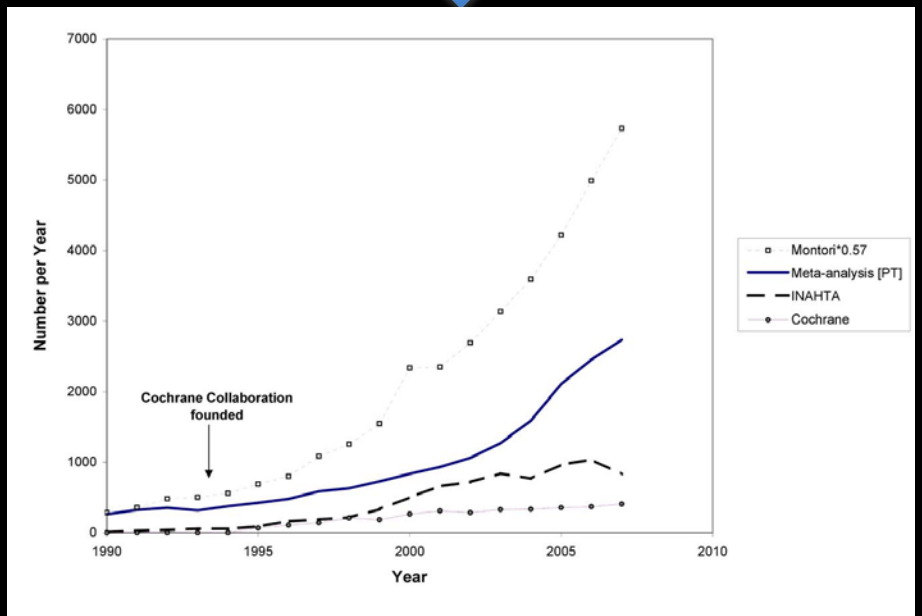
Initial Coronary Stent Implantation With Medical Therapy vs Medical Therapy Alone for Stable Coronary Artery Disease

Meta-analysis of Randomized Controlled Trials

Kathleen Stergiopoulos, MD, PhD; David L. Brown, MD

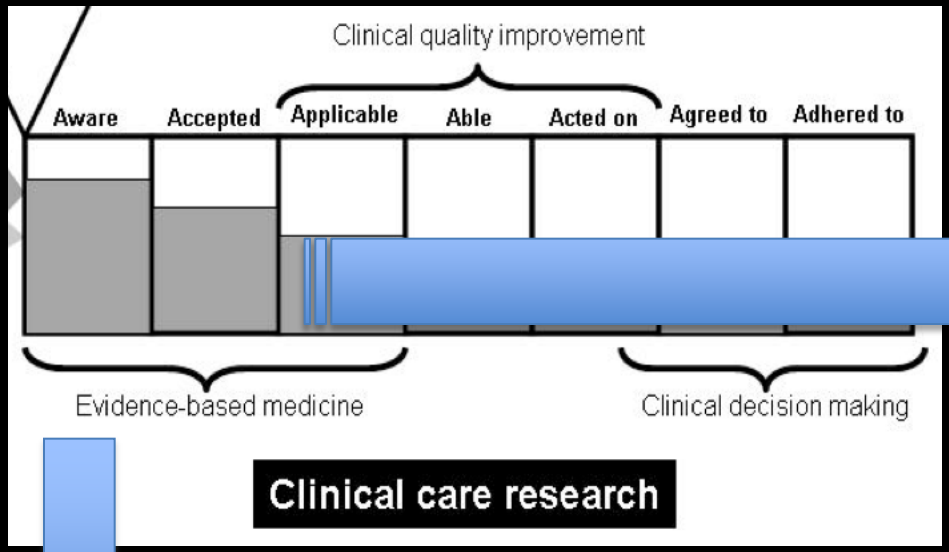


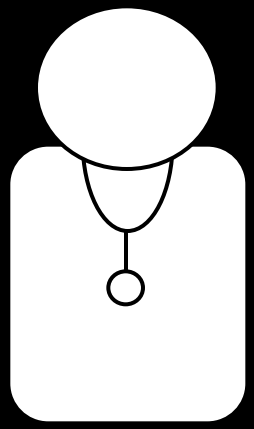




"There are now 75 trials and 11 systematic reviews of trials, per day…"

Bastian et. al, 2010
PLoS Medicine





National Cholesterol Education Program

ATP III Guidelines At-A-Glance Quick Desk Reference

1

Step 1 **Determine lipoprotein levels–obtain complete lipoprotein profile after 9- to 12-hour fast.**

ATP III Classification of LDL, Total, and HDL Cholesterol (mg/dL)

LDL Cholesterol – Primary Target of Therapy	
<100	Optimal
100-129	Near optimal/above optimal

Source: IOM, *Best Care at Lower Costs*

A survey of 627 US primary care clinicians

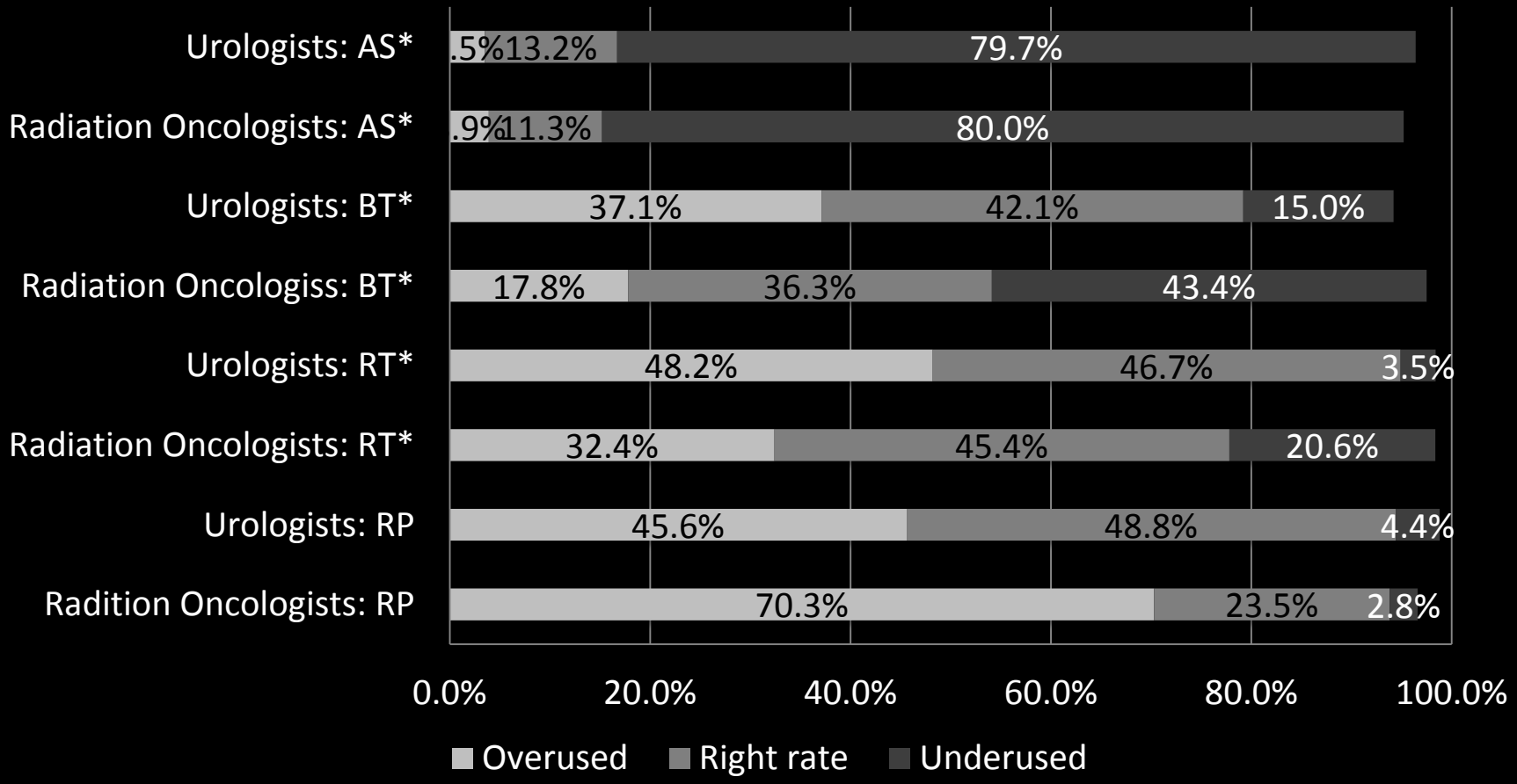
50% of my patients get too much care

50% of primary care docs are too aggressive
60% of specialists are too aggressive

35% practice much more aggressively than what they would like

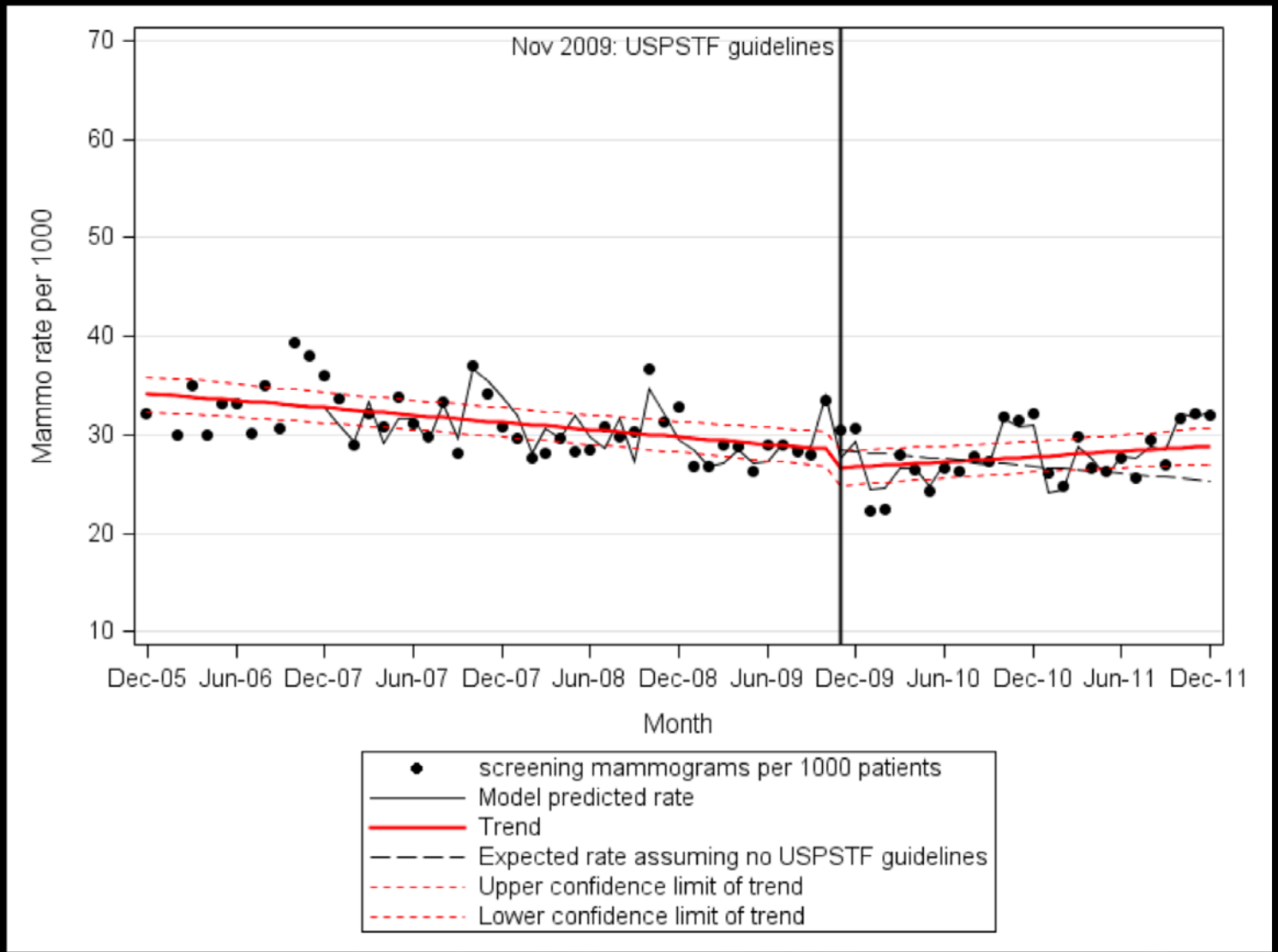
Sirovich BE et al. Arch Intern Med 2011

Treatment of Low Grade Prostate Cancer



Kim SP et al. Prostate Cancer Prostatic Dis 2014

Rates of Mammography Screening Among Younger Women



Wang AT et al. PLOS One 2014

CER Translation Gap

Study	Results	Practice	Translation
ALLHAT	Thiazide diuretics were superior in preventing cardiovascular disease events	ACE-inhibitors	No change
CATIE	Conventional antipsychotics were as effective as atypical antipsychotics for schizophrenia	Atypical Antipsychotics	No change
COMPANION	Compared to optimal medical therapy, both cardiac resynchronization therapy (CRT) and CRT plus defibrillator use improved survival, reduced hospitalization rates, and improved functional status in patients with moderate to severe heart failure	Medical therapy	Minimal change
COURAGE	Optimal medical therapy combined with percutaneous coronary intervention (PCI) had similar survival benefit and angina relief, compared to optimal medical therapy alone	PCI	Minimal/No change
SPORT	Surgery for lumbar spinal stenosis had better outcomes than nonsurgical treatment, according to the cohort study results	Surgical Treatment	No change

Source: Timbie 2012

Why?

Misalignment of financial incentives

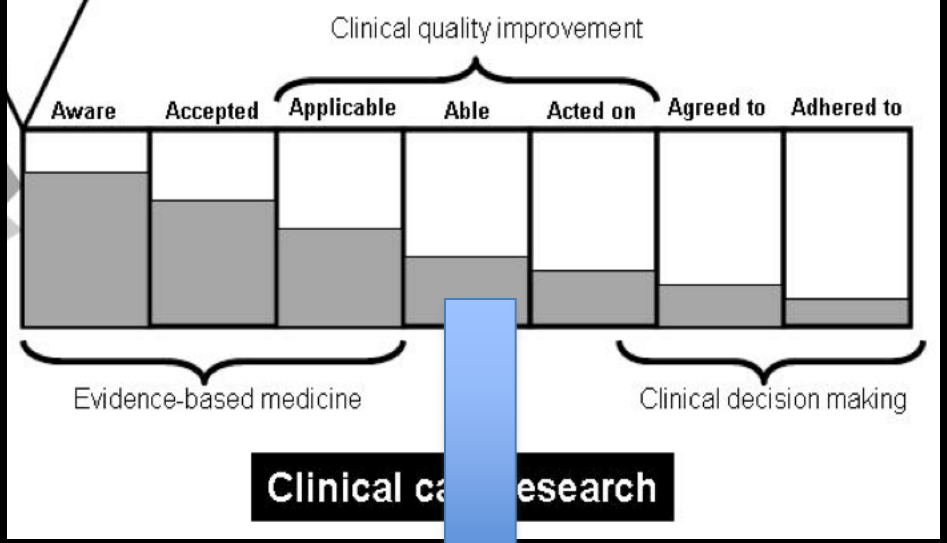
Complexity of research

Biases in interpretation of results

Applicability of the evidence

Limited use of decision support

Source: Timbie 2012; Morrato 2013



Generic Disease Management System

Summary for diseases and preventive services

Patient summary

Refresh data | Print report

Clinic # Go
Name
Birth date Age Male Female
Prim. Phys.
Has DM1 DM2 CAD Asth. Depr Hypertension Myeloma Gammopathy

Last blood pressure	99/56	Date	02/10/2011
Last height		cm Date	
Last weight	48.3	kg Date	02/10/2011
Last BMI		Date	
PHQ-9 score		Date	
Last Asthma Action Plan			
Current tobacco use		Last CVI	
Last advance directive			
Last MAGE screening			
Last echo			11/09/2006
Last ECG			07/15/2009
Last nuclearstudy			
ERA Score	11		
Ejection Fraction	25%		

Labs for past 5 years

History | Graph

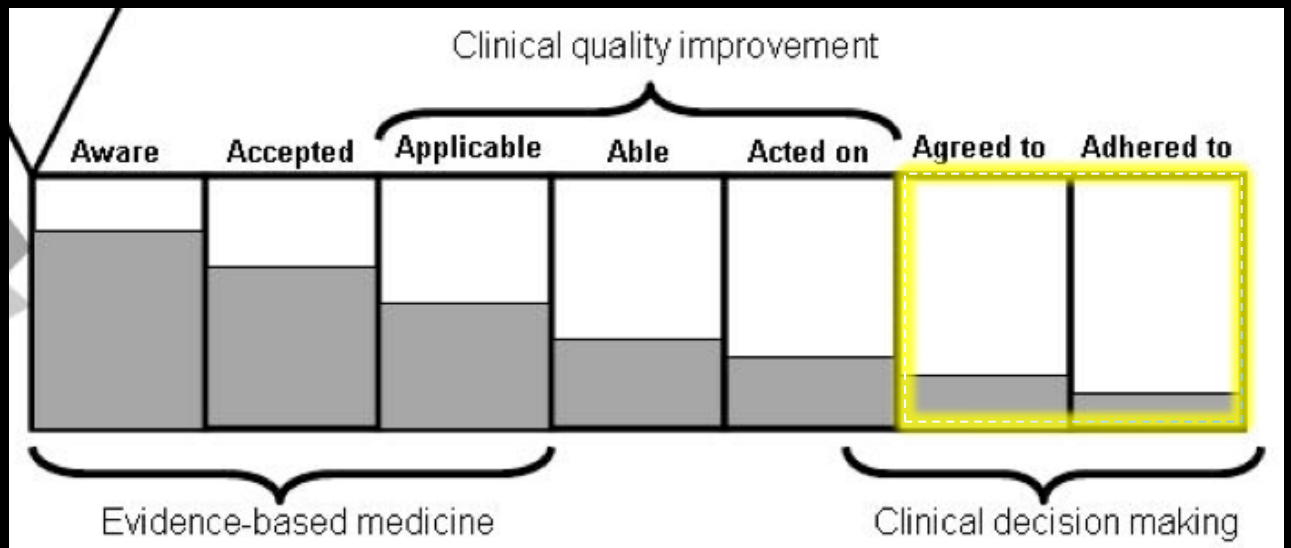
	Normal value	Most recent value		mm/dd/yyyy
Hemoglobin	12.0-15.5	15.4 g/dL		07/15/2009
Sodium	136-145	141 mmol/L		07/15/2009
Potassium	3.6-5.2	3.9 mmol/L		02/10/2011
Glucose	70-100	156	* mg/dL	02/10/2011
HbA1c	4.0-6.0	8.3	* %	02/10/2011
AST (SGOT)	8-43	21 U/L		03/23/2010
ALT (SGPT)				
Creatinine	0.6-1.1	1.0 mg/dL		09/23/2009
eGFR				
Total cholesterol		286	* mg/dL	03/23/2010
Triglycerides		275	* mg/dL	03/23/2010
HDL cholesterol		39	* mg/dL	03/23/2010
LDL cholesterol		191	* mg/dL	03/23/2010
hsCRP				
Lipoprotein(a)				
INR	0.9-1.2	2.7	*	12/30/2010
Uric acid				
TSH	0.3-5.0	1.5 mIU/L		11/13/2008
Random Microalb.	<25	26	* mg/g	09/23/2009

Recommended actions

- Colon cancer screening due.
- LDL should be < 100.
- Eye exam due.
- HbA1c should be < 8.
- Creatinine due.
- Microalbumin due.
- Lipid panel due.
- INR due.

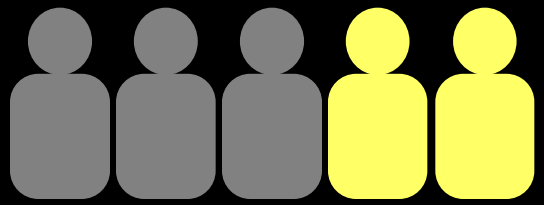
Rec. actions next 90 days

- HbA1c due by May 10, 2011 & recommended every 3 months if HbA1c >= 8.



Clinical care research

Key problem:
Do not follow advice

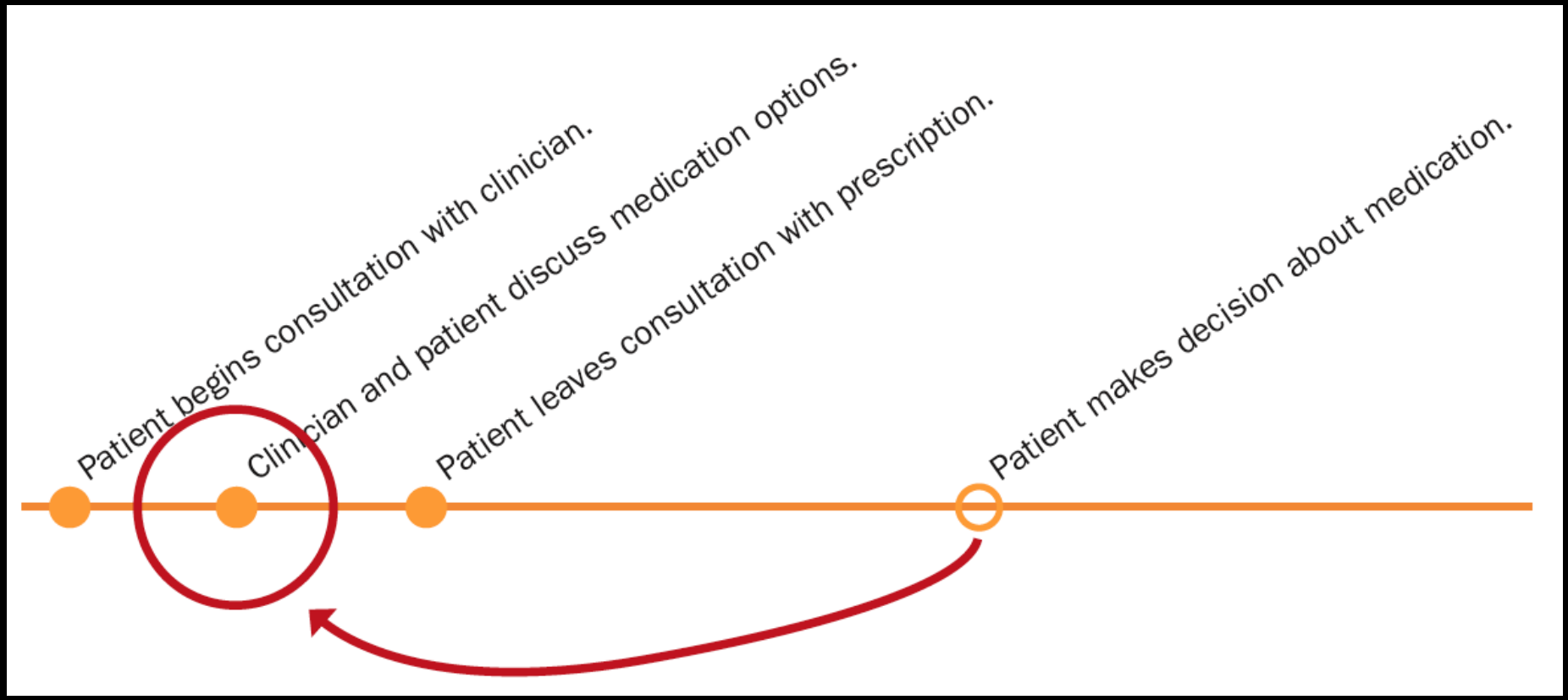


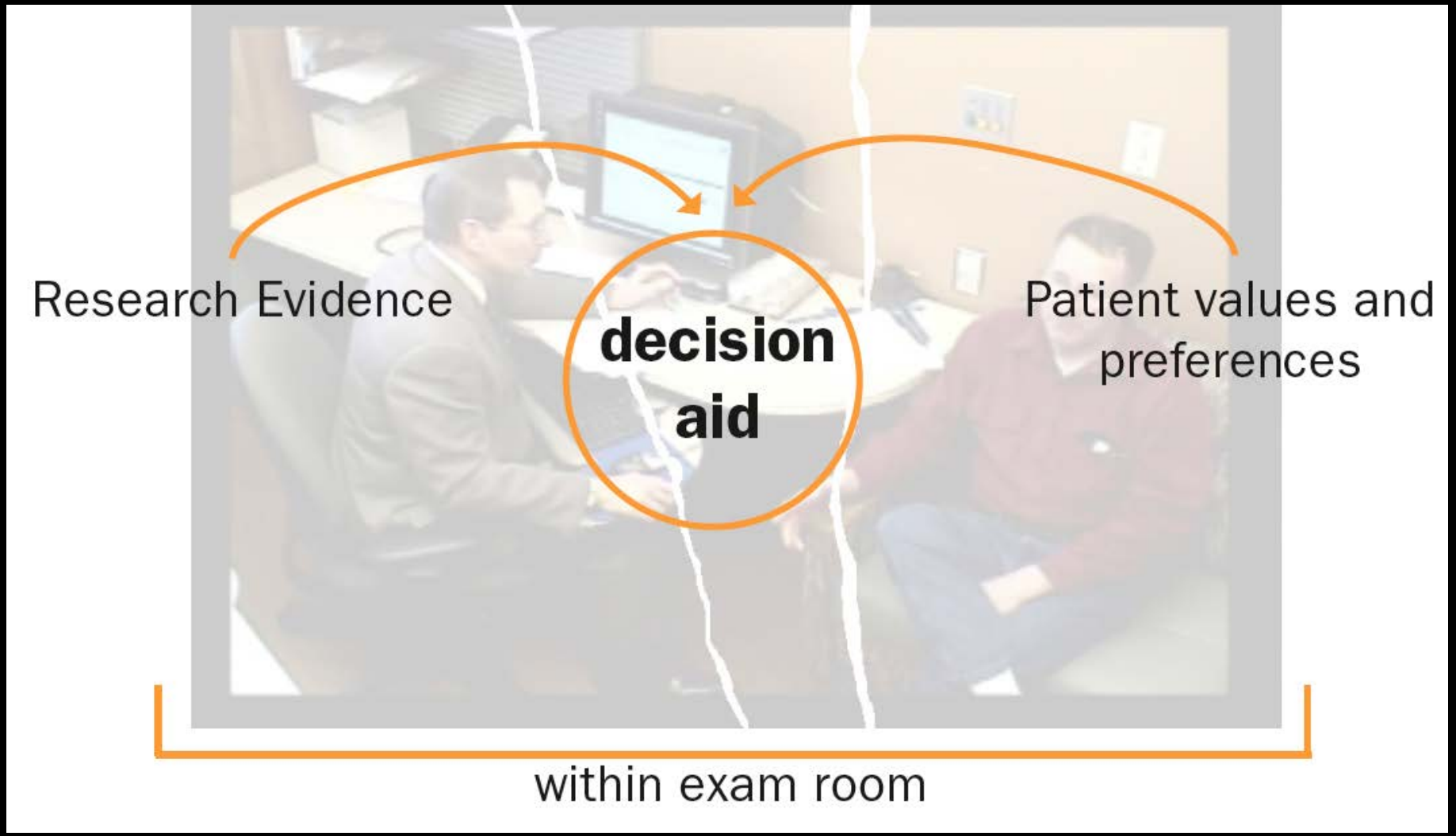
Wasted or misallocated healthcare resources:
US$ 290b (100b in avoidable hospitalizations)

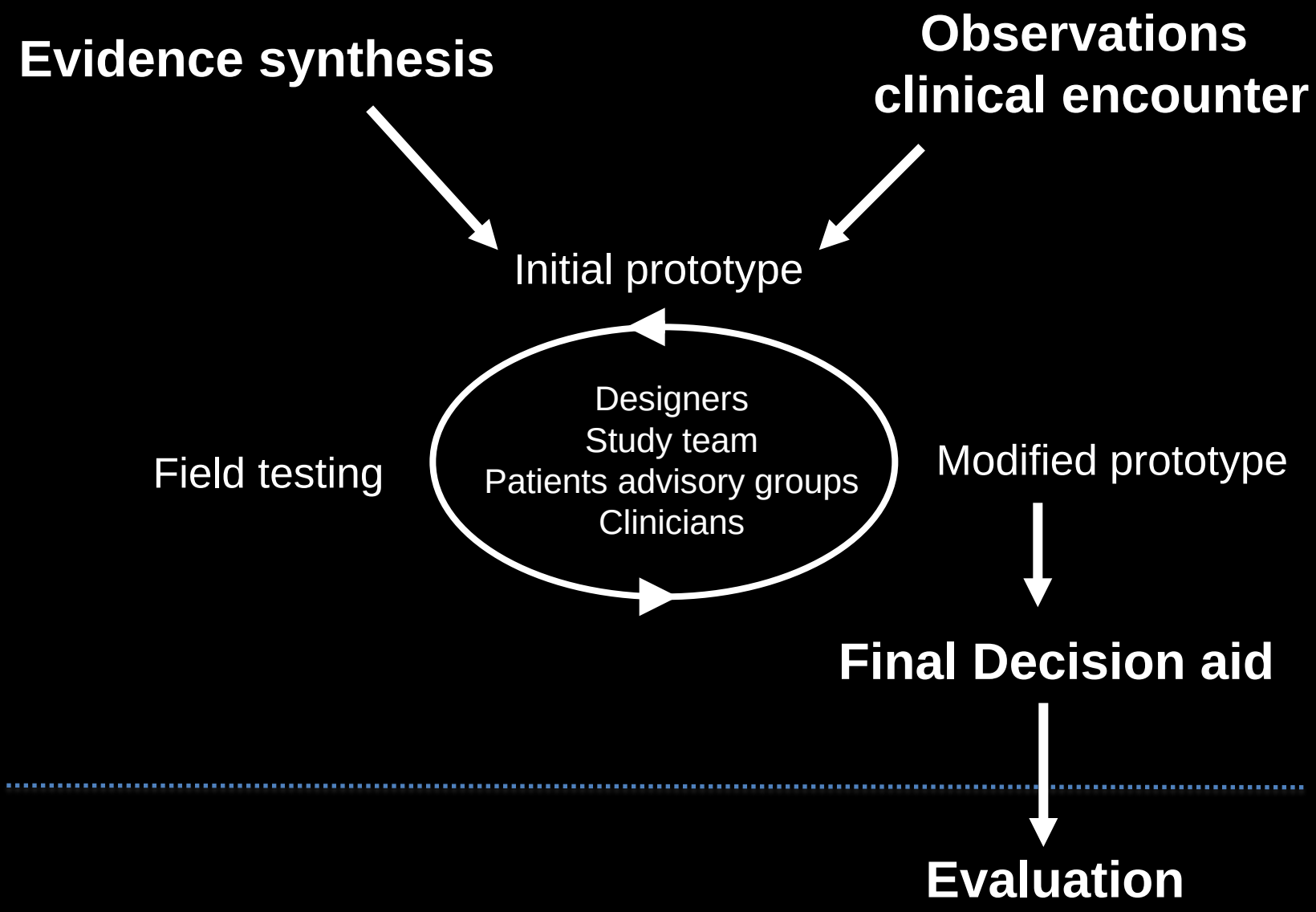
Poor health despite cost and side effects

Complicated patient-clinician relationship

Cutler and Everett NEJM 2010 10.1056/NEJMp1002305

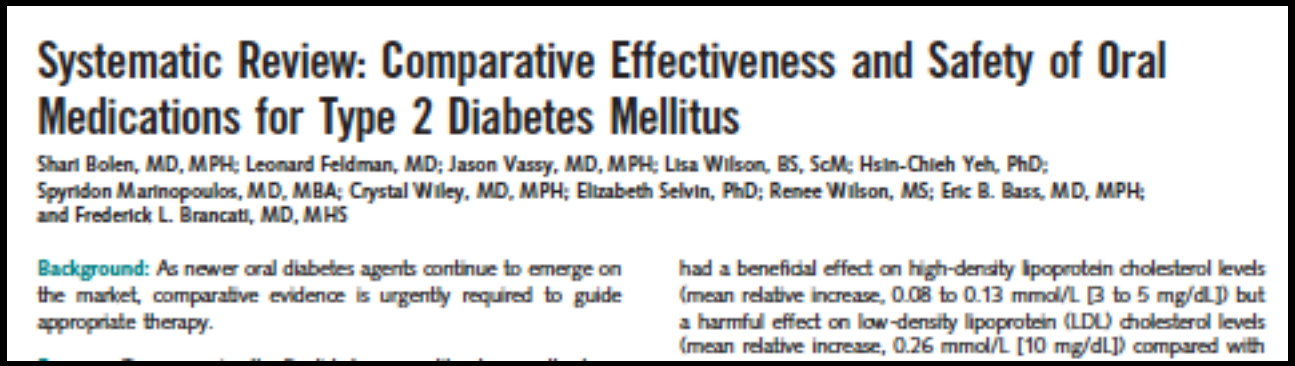

Patient begins consultation with clinician.
Clinician and patient discuss medication options.
Patient leaves consultation with prescription.
Patient makes decision about medication.


Research Evidence
decision aid
Patient values and preferences
within exam room


Evidence synthesis
Observations
clinical encounter
Initial prototype
Designers
Study team
Patients advisory groups
Clinicians
Field testing
Modified prototype
Final Decision aid
Evaluation

Diabetes Cards

- Nature of diabetes medication discussions
- Summarizing the research evidence



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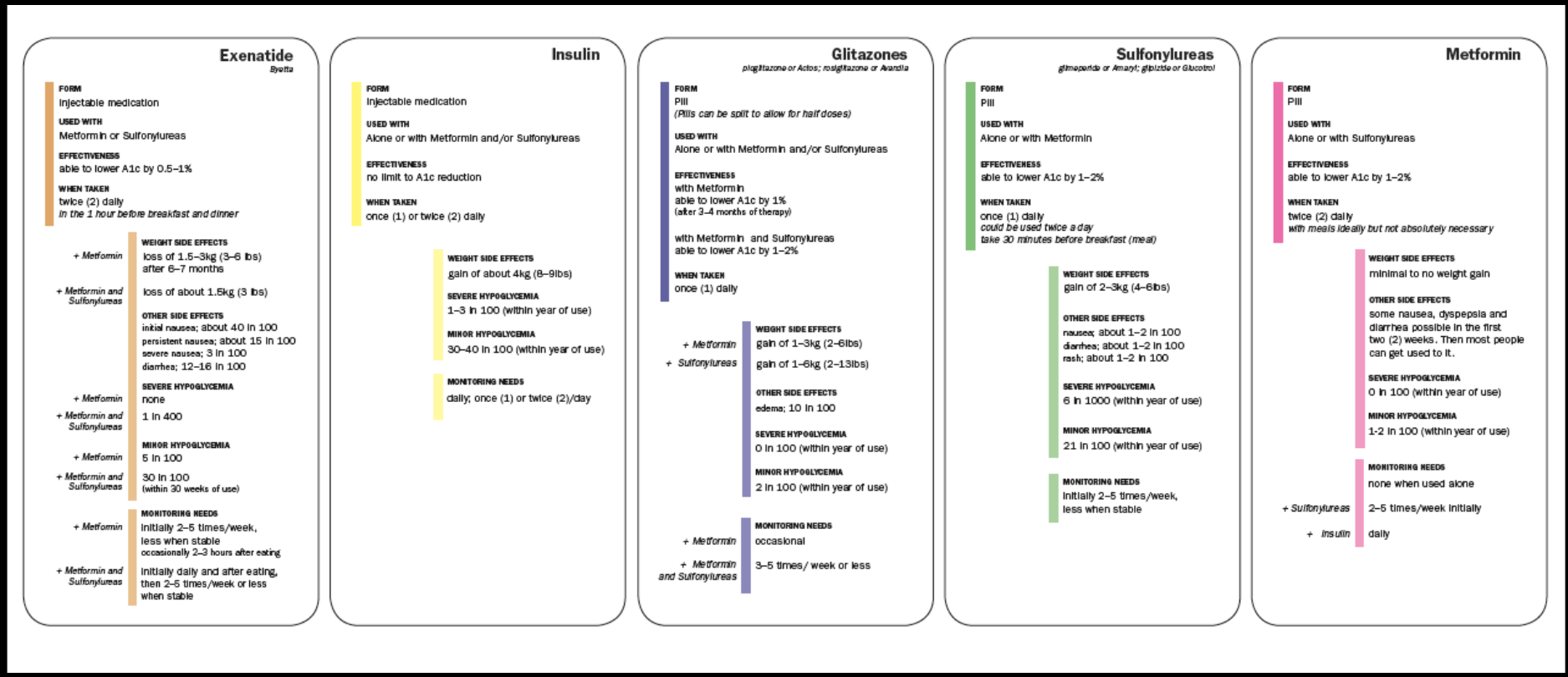
- Iterative process – *Choice Architecture*

Research Evidence
+
Practice Review

decision aid

Diabetes Advisory Group
+
Live Clinical Setting



Exenatide
Byetta

FORM
Injectable medication

USED WITH
Metformin or Sulfonylureas

EFFECTIVENESS
able to lower A1c by 0.5–1%

WHEN TAKEN
twice (2) daily
in the 1 hour before breakfast and dinner

WEIGHT SIDE EFFECTS
+ Metformin: loss of 1.5–3kg (3–6 lbs) after 6–7 months
+ Metformin and Sulfonylureas: loss of about 1.5kg (3 lbs)

OTHER SIDE EFFECTS
initial nausea; about 40 in 100
persistent nausea; about 15 in 100
severe nausea; 3 in 100
diarrhea; 12–16 in 100

SEVERE HYPOGLYCEMIA
+ Metformin: none
+ Metformin and Sulfonylureas: 1 in 400

MINOR HYPOGLYCEMIA
+ Metformin: 5 in 100
+ Metformin and Sulfonylureas: 30 in 100 (within 30 weeks of use)

MONITORING NEEDS
+ Metformin: initially 2–5 times/week, less when stable
occasionally 2–3 hours after eating
+ Metformin and Sulfonylureas: initially daily and after eating, then 2–5 times/week or less when stable

Insulin

FORM
Injectable medication

USED WITH
Alone or with Metformin and/or Sulfonylureas

EFFECTIVENESS
no limit to A1c reduction

WHEN TAKEN
once (1) or twice (2) daily

WEIGHT SIDE EFFECTS
gain of about 4kg (8–9lbs)

SEVERE HYPOGLYCEMIA
1–3 in 100 (within year of use)

MINOR HYPOGLYCEMIA
30–40 in 100 (within year of use)

MONITORING NEEDS
daily; once (1) or twice (2)/day

Glitazones
pioglitazone or Actos; rosiglitazone or Avandia

FORM
Pill
(Pills can be split to allow for half doses)

USED WITH
Alone or with Metformin and/or Sulfonylureas

EFFECTIVENESS
with Metformin
able to lower A1c by 1%
(after 3–4 months of therapy)

with Metformin and Sulfonylureas
able to lower A1c by 1–2%

WHEN TAKEN
once (1) daily

WEIGHT SIDE EFFECTS
+ Metformin: gain of 1–3kg (2–6lbs)
+ Sulfonylureas: gain of 1–6kg (2–13lbs)

OTHER SIDE EFFECTS
edema; 10 in 100

SEVERE HYPOGLYCEMIA
0 in 100 (within year of use)

MINOR HYPOGLYCEMIA
2 in 100 (within year of use)

MONITORING NEEDS
+ Metformin: occasional
+ Metformin and Sulfonylureas: 3–5 times/ week or less

Sulfonylureas
glimepiride or Amaryl; glipizide or Glucotrol

FORM
Pill

USED WITH
Alone or with Metformin

EFFECTIVENESS
able to lower A1c by 1–2%

WHEN TAKEN
once (1) daily
could be used twice a day
take 30 minutes before breakfast (meal)

WEIGHT SIDE EFFECTS
gain of 2–3kg (4–6lbs)

OTHER SIDE EFFECTS
nausea; about 1–2 in 100
diarrhea; about 1–2 in 100
rash; about 1–2 in 100

SEVERE HYPOGLYCEMIA
6 in 1000 (within year of use)

MINOR HYPOGLYCEMIA
21 in 100 (within year of use)

MONITORING NEEDS
initially 2–5 times/week, less when stable

Metformin

FORM
Pill

USED WITH
Alone or with Sulfonylureas

EFFECTIVENESS
able to lower A1c by 1–2%

WHEN TAKEN
twice (2) daily
with meals ideally but not absolutely necessary

WEIGHT SIDE EFFECTS
minimal to no weight gain

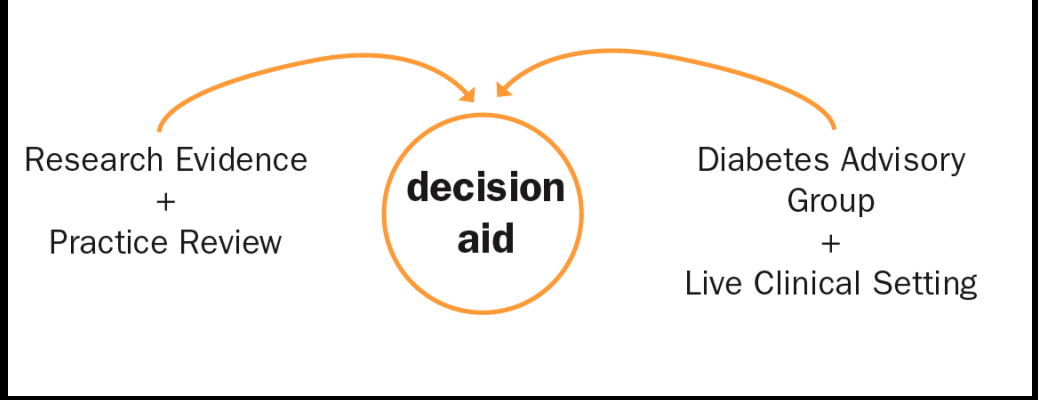
OTHER SIDE EFFECTS
some nausea, dyspepsia and diarrhea possible in the first two (2) weeks. Then most people can get used to it.

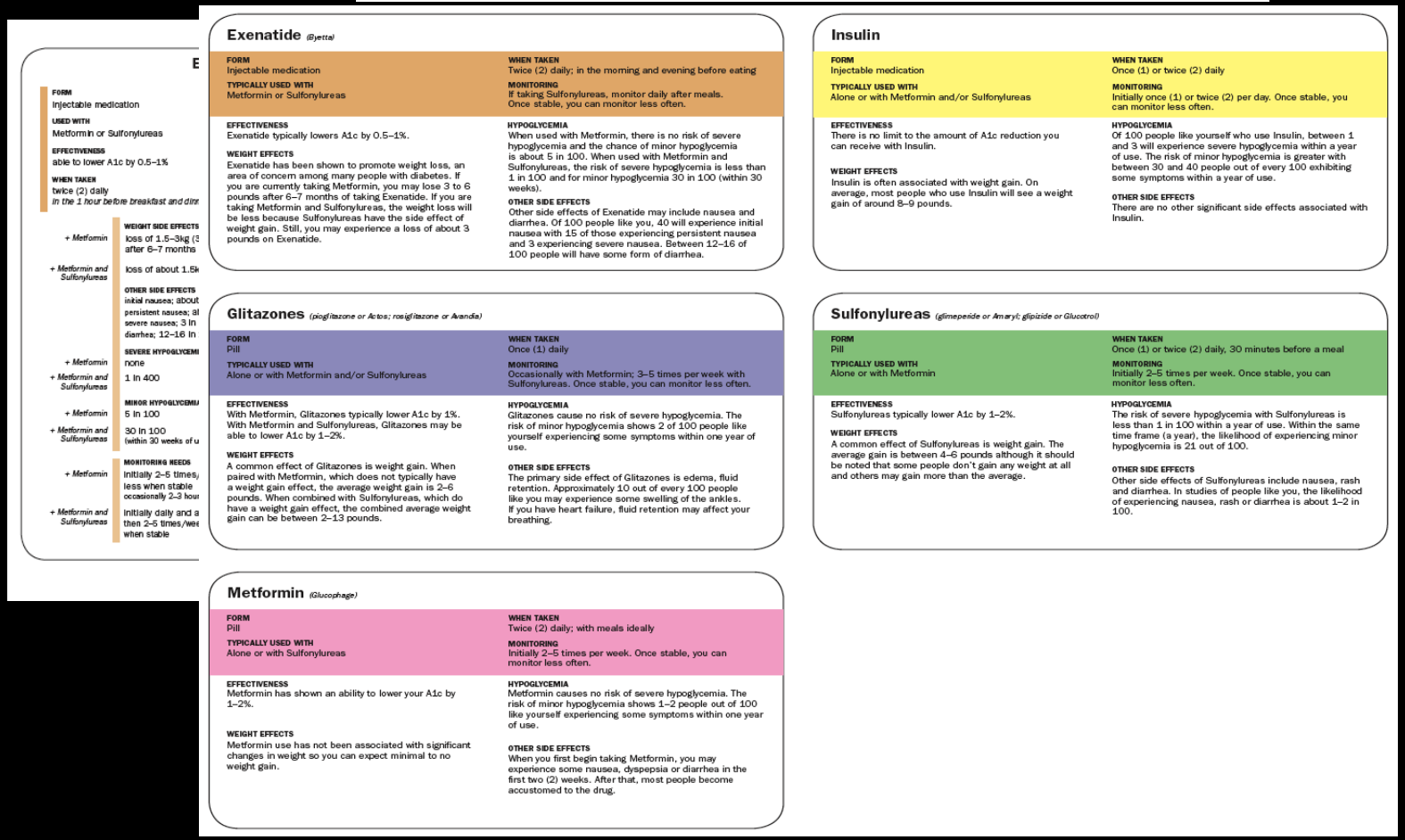
SEVERE HYPOGLYCEMIA
0 in 100 (within year of use)

MINOR HYPOGLYCEMIA
1-2 in 100 (within year of use)

MONITORING NEEDS
none when used alone
+ Sulfonylureas: 2–5 times/week initially
+ Insulin: daily

"Baseball Cards"





E

FORM
Injectable medication

USED WITH
Metformin or Sulfonylureas

EFFECTIVENESS
able to lower A1c by 0.5–1%

WHEN TAKEN
twice (2) daily
in the 1 hour before breakfast and din

+ Metformin	WEIGHT SIDE EFFECTS loss of 1.5–3kg (3 after 6–7 months
+ Metformin and Sulfonylureas	loss of about 1.5k
	OTHER SIDE EFFECTS initial nausea; about persistent nausea; al severe nausea; 3 in diarrhea; 12–16 in
+ Metformin	SEVERE HYPOGLYCEMI none
+ Metformin and Sulfonylureas	1 in 400
+ Metformin	MINOR HYPOGLYCEMIA 5 in 100
+ Metformin and Sulfonylureas	30 in 100 (within 30 weeks of u
+ Metformin	MONITORING NEEDS initially 2–5 times/ less when stable occasionally 2–3 hou
+ Metformin and Sulfonylureas	initially daily and a then 2–5 times/wee when stable

Exenatide *(Byetta)*

FORM
Injectable medication

TYPICALLY USED WITH
Metformin or Sulfonylureas

EFFECTIVENESS
Exenatide typically lowers A1c by 0.5–1%.

WEIGHT EFFECTS
Exenatide has been shown to promote weight loss, an area of concern among many people with diabetes. If you are currently taking Metformin, you may lose 3 to 6 pounds after 6–7 months of taking Exenatide. If you are taking Metformin and Sulfonylureas, the weight loss will be less because Sulfonylureas have the side effect of weight gain. Still, you may experience a loss of about 3 pounds on Exenatide.

WHEN TAKEN
Twice (2) daily; in the morning and evening before eating

MONITORING
If taking Sulfonylureas, monitor daily after meals. Once stable, you can monitor less often.

HYPOGLYCEMIA
When used with Metformin, there is no risk of severe hypoglycemia and the chance of minor hypoglycemia is about 5 in 100. When used with Metformin and Sulfonylureas, the risk of severe hypoglycemia is less than 1 in 100 and for minor hypoglycemia 30 in 100 (within 30 weeks).

OTHER SIDE EFFECTS
Other side effects of Exenatide may include nausea and diarrhea. Of 100 people like you, 40 will experience initial nausea with 15 of those experiencing persistent nausea and 3 experiencing severe nausea. Between 12–16 of 100 people will have some form of diarrhea.

Glitazones *(pioglitazone or Actos; rosiglitazone or Avandia)*

FORM
Pill

TYPICALLY USED WITH
Alone or with Metformin and/or Sulfonylureas

EFFECTIVENESS
With Metformin, Glitazones typically lower A1c by 1%. With Metformin and Sulfonylureas, Glitazones may be able to lower A1c by 1–2%.

WEIGHT EFFECTS
A common effect of Glitazones is weight gain. When paired with Metformin, which does not typically have a weight gain effect, the average weight gain is 2–6 pounds. When combined with Sulfonylureas, which do have a weight gain effect, the combined average weight gain can be between 2–13 pounds.

WHEN TAKEN
Once (1) daily

MONITORING
Occasionally with Metformin; 3–5 times per week with Sulfonylureas. Once stable, you can monitor less often.

HYPOGLYCEMIA
Glitazones cause no risk of severe hypoglycemia. The risk of minor hypoglycemia shows 2 of 100 people like yourself experiencing some symptoms within one year of use.

OTHER SIDE EFFECTS
The primary side effect of Glitazones is edema, fluid retention. Approximately 10 out of every 100 people like you may experience some swelling of the ankles. If you have heart failure, fluid retention may affect your breathing.

Metformin *(Glucophage)*

FORM
Pill

TYPICALLY USED WITH
Alone or with Sulfonylureas

EFFECTIVENESS
Metformin has shown an ability to lower your A1c by 1–2%.

WEIGHT EFFECTS
Metformin use has not been associated with significant changes in weight so you can expect minimal to no weight gain.

WHEN TAKEN
Twice (2) daily; with meals ideally

MONITORING
Initially 2–5 times per week. Once stable, you can monitor less often.

HYPOGLYCEMIA
Metformin causes no risk of severe hypoglycemia. The risk of minor hypoglycemia shows 1–2 people out of 100 like yourself experiencing some symptoms within one year of use.

OTHER SIDE EFFECTS
When you first begin taking Metformin, you may experience some nausea, dyspepsia or diarrhea in the first two (2) weeks. After that, most people become accustomed to the drug.

Insulin

FORM
Injectable medication

TYPICALLY USED WITH
Alone or with Metformin and/or Sulfonylureas

EFFECTIVENESS
There is no limit to the amount of A1c reduction you can receive with Insulin.

WEIGHT EFFECTS
Insulin is often associated with weight gain. On average, most people who use Insulin will see a weight gain of around 8–9 pounds.

WHEN TAKEN
Once (1) or twice (2) daily

MONITORING
Initially once (1) or twice (2) per day. Once stable, you can monitor less often.

HYPOGLYCEMIA
Of 100 people like yourself who use Insulin, between 1 and 3 will experience severe hypoglycemia within a year of use. The risk of minor hypoglycemia is greater with between 30 and 40 people out of every 100 exhibiting some symptoms within a year of use.

OTHER SIDE EFFECTS
There are no other significant side effects associated with Insulin.

Sulfonylureas *(glimeperide or Amaryl; glipizide or Glucotrol)*

FORM
Pill

TYPICALLY USED WITH
Alone or with Metformin

EFFECTIVENESS
Sulfonylureas typically lower A1c by 1–2%.

WEIGHT EFFECTS
A common effect of Sulfonylureas is weight gain. The average gain is between 4–6 pounds although it should be noted that some people don't gain any weight at all and others may gain more than the average.

WHEN TAKEN
Once (1) or twice (2) daily, 30 minutes before a meal

MONITORING
Initially 2–5 times per week. Once stable, you can monitor less often.

HYPOGLYCEMIA
The risk of severe hypoglycemia with Sulfonylureas is less than 1 in 100 within a year of use. Within the same time frame (a year), the likelihood of experiencing minor hypoglycemia is 21 out of 100.

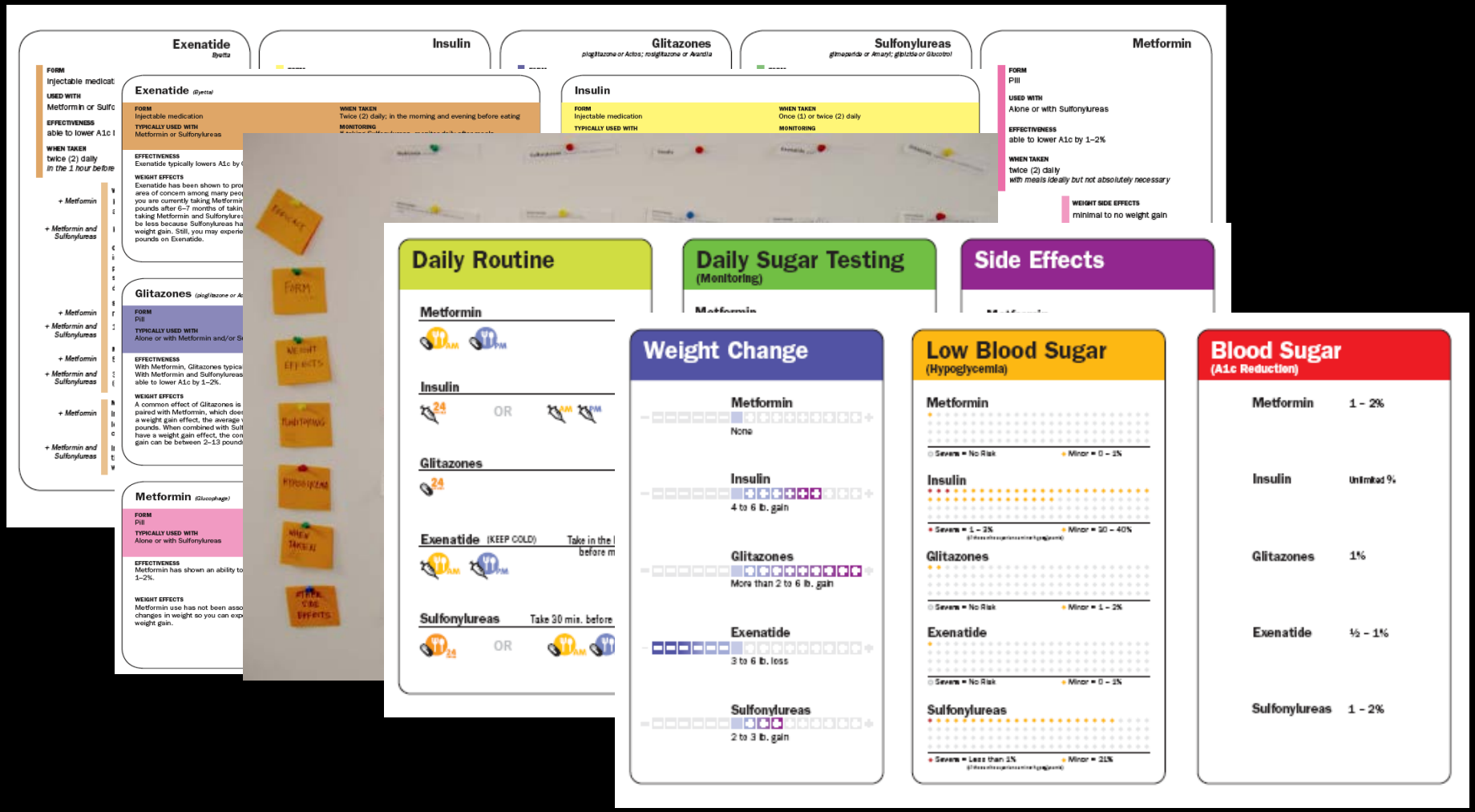
OTHER SIDE EFFECTS
Other side effects of Sulfonylureas include nausea, rash and diarrhea. In studies of people like you, the likelihood of experiencing nausea, rash or diarrhea is about 1–2 in 100.

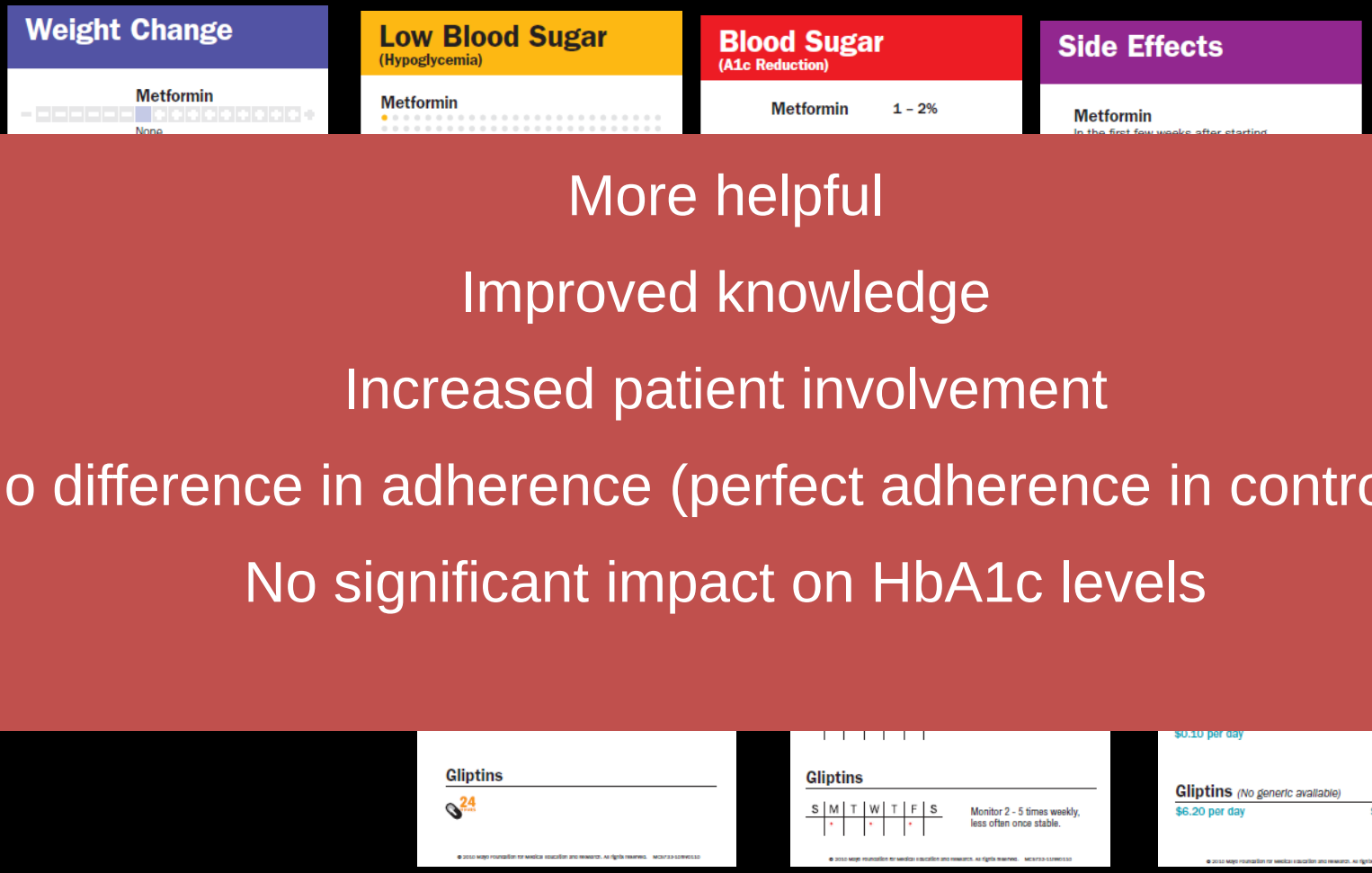
"Narrative Cards"

Research Evidence
+
Practice Review

decision aid

Diabetes Advisory Group
+
Live Clinical Setting





More helpful

Improved knowledge

Increased patient involvement

No difference in adherence (perfect adherence in control gr)

No significant impact on HbA1c levels

Mullan RJ et al. Archives of Internal Medicine 2009

National Cholesterol Education Program

ATP III Guidelines At-A-Glance Quick Desk Reference

Step 1

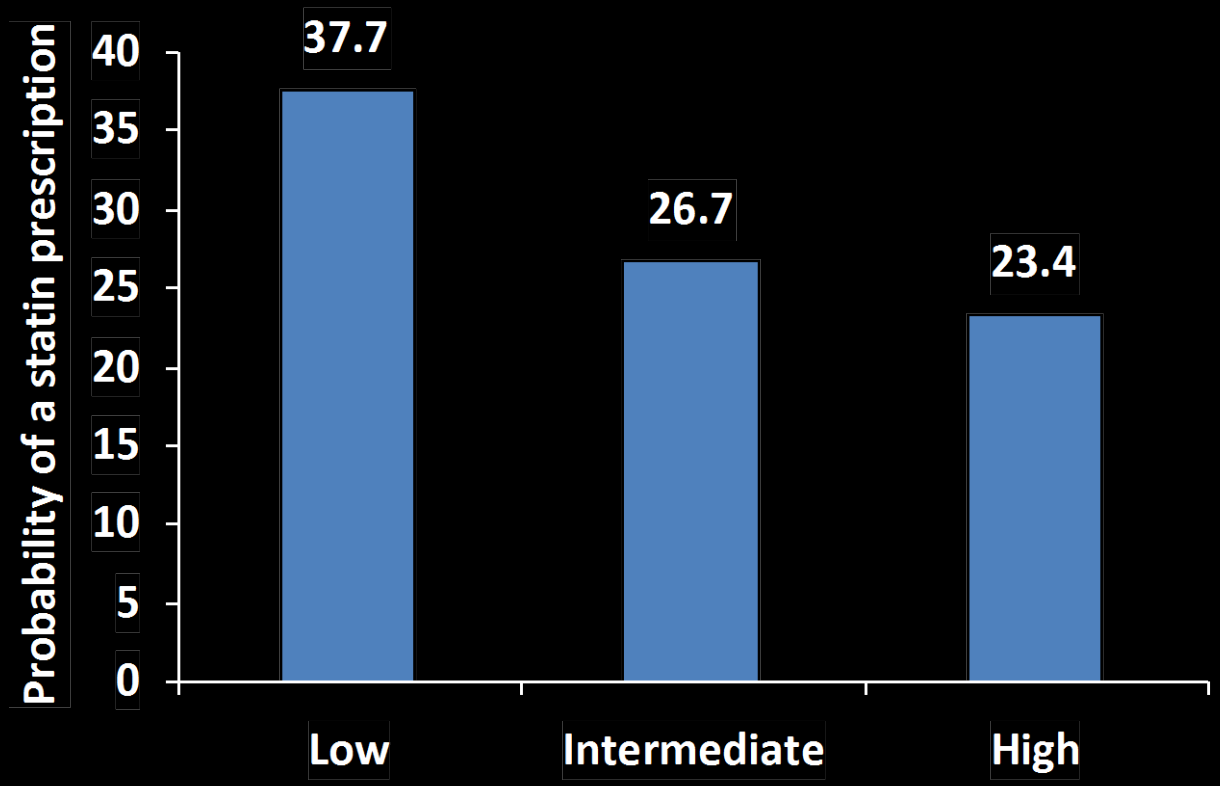
1

Determine lipoprotein levels–obtain complete lipoprotein profile after 9- to 12-hour fast.

ATP III Classification of LDL, Total, and HDL Cholesterol (mg/dL)

LDL Cholesterol – Primary Target of Therapy	
<100	Optimal
100-129	Near optimal/above optimal
130-159	Borderline high
160-189	High

Risk-Treatment Paradox



Ko, Mamdani and Alter JAMA 2004

ACC/AHA Cholesterol Guidelines

2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

Endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American Pharmacists Association, American Society for Preventive Cardiology, Association of Black Cardiologists, Preventive Cardiovascular Nurses Association, and WomenHeart: The National Coalition for Women with Heart Disease

EXPERT PANEL MEMBERS

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Alice H. Lichtenstein, DSc, FAHA, *Vice Chair*

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David Gordon, MD*
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Karol Watson, MD, PhD, FACC, FAHA
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ACC/AHA Cholesterol Guidelines

VIEWPOINT

More Than a Billion People Taking Statins? Potential Implications of the New Cardiovascular Guidelines

John P. A. Ioannidis, MD, DSc
Departments of Medicine and Health Research and Policy, Stanford University School of Medicine, and Department of Statistics, Stanford University School of Humanities and Sciences, Stanford, California.

The American College of Cardiology/American Heart Association (ACC/AHA) guidelines on assessment of cardiovascular risk[1] and on treatment of blood cholesterol, which included recommendations for primary prevention with statins,[2] came under intense criticism immediately with their release. Main concerns focused on flawed methods (problems with the risk calculation),[3] ethics (conflicts of interest),[4] and inferences (too many people offered treatment).

The ACC and the AHA are among the most experienced organizations in medicine that develop guidelines. Their processes are meticulous, including transparent reporting of conflicts. The work behind the guidelines' development was monumental. References to randomized trials and systematic reviews were continuous (the word "evidence" appears 346 times in the cardiovascular risk assessment report and 522 times in the treatment report alone). Panelists were highly qualified. Statins have been extensively evaluated in numerous randomized clinical trials. The guidelines focused on hard clinical outcomes such as myocardial infarction and stroke. Remaining caveats were explicitly protein cholesterol levels and for whom statins demonstrate even better effectiveness.

Risk profiles and the importance of risk factors may well differ in other populations, and the ACC/AHA guidelines are very careful in avoiding such extrapolations.[1] However, unavoidably, extrapolations will happen. Prior experience shows that previous efforts such as the Framingham risk score and the Third Adult Treatment Panel (ATP III) guidelines were adapted and adopted widely around the world. Authoritative guidelines of this sort carry such prestige that they influence global treatment and marketing. Moreover, several statins are available as generic products and are relatively inexpensive, contributing to further pressure to "statinize" the planet even in countries with modest health care budgets.

The core of the ACC/AHA guidelines depends on a new risk score that was explicitly developed for the sake of informing US-oriented recommendations. Problems with this score have been noted,[3] and even its developers largely acknowledged them up front.[1] Based on the evidence of overprediction derived even in the original validation of the risk calculator and subsequent inde-

ACC/AHA Cholesterol Guidelines

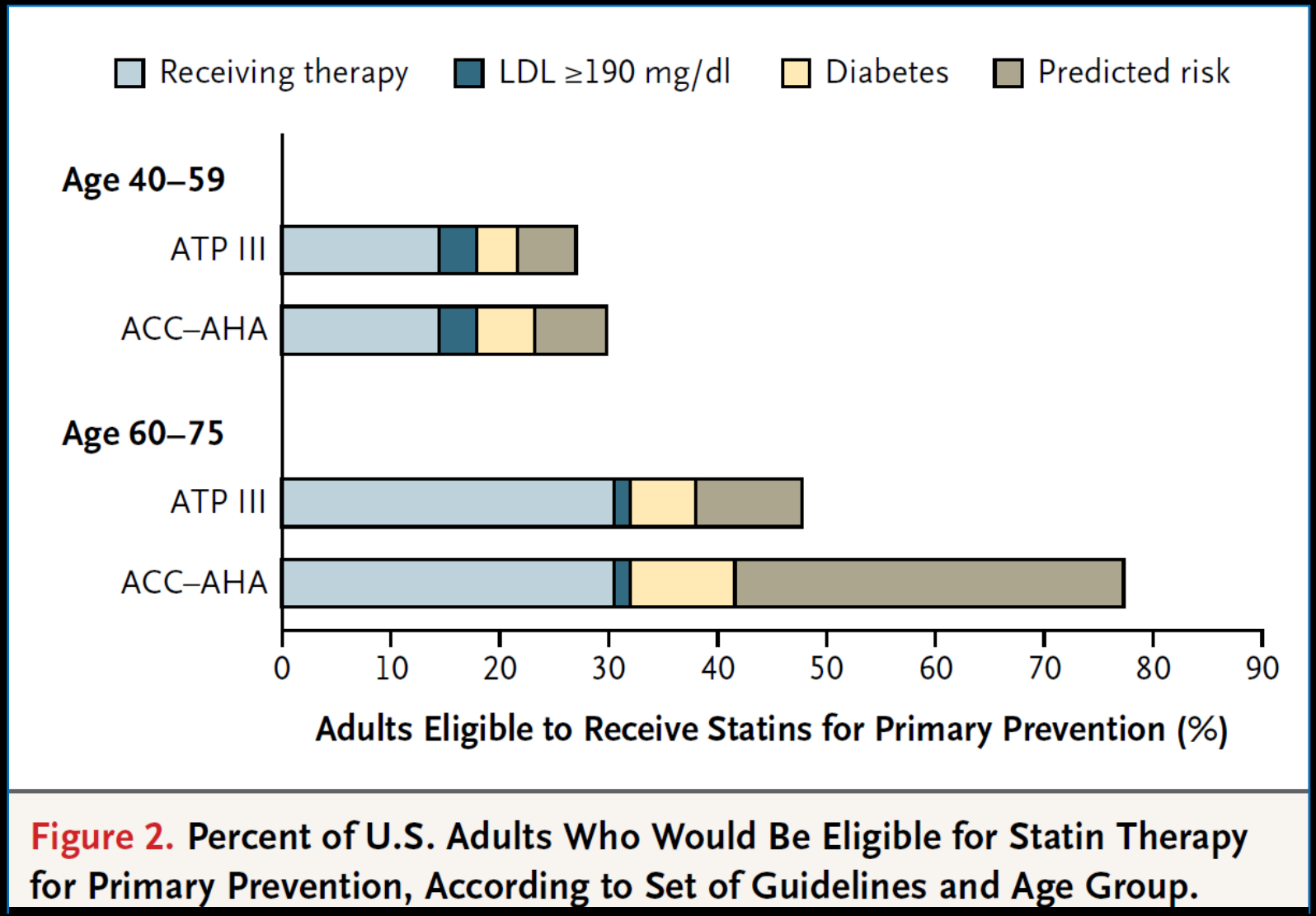


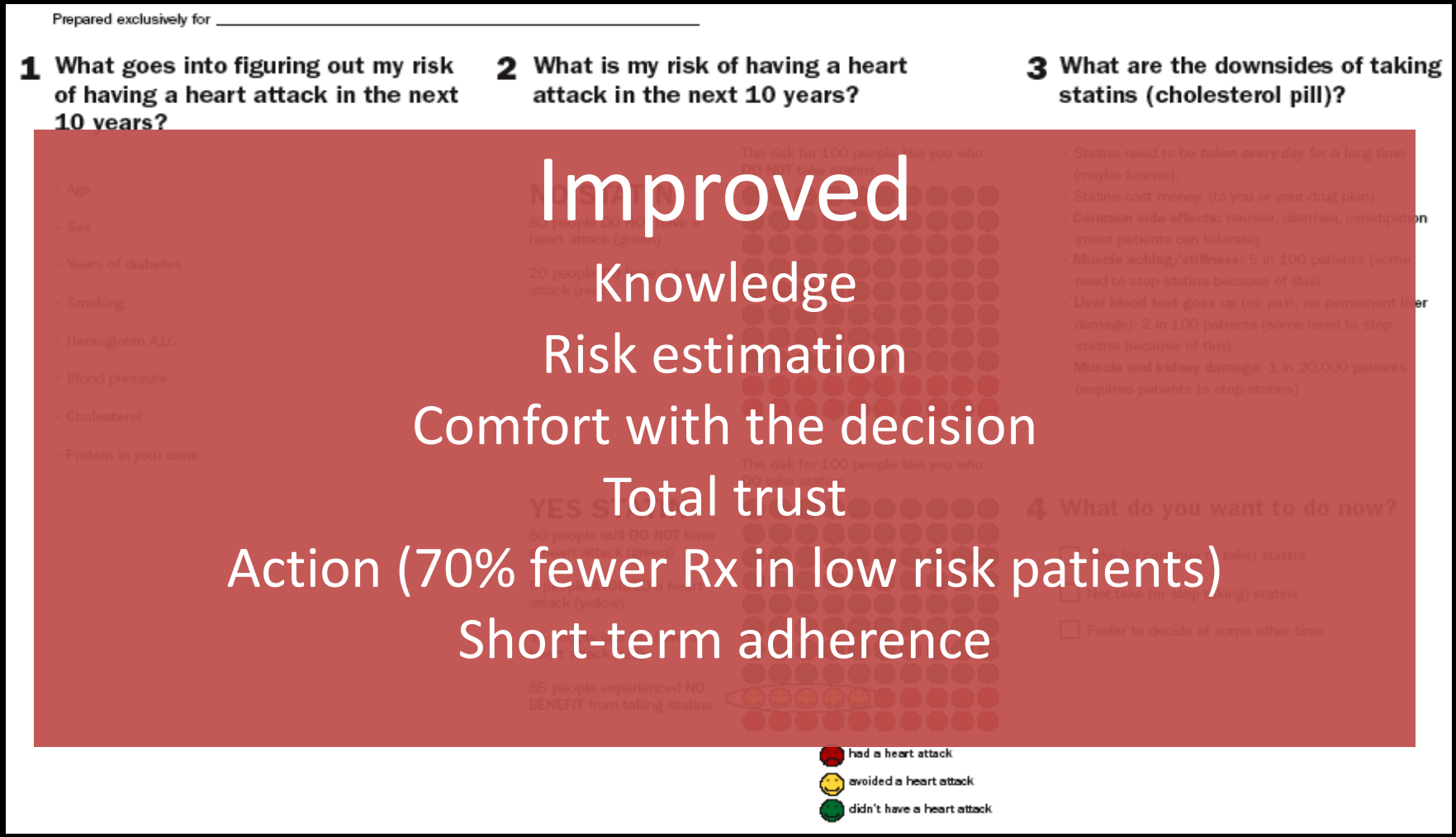
Figure 2. Percent of U.S. Adults Who Would Be Eligible for Statin Therapy for Primary Prevention, According to Set of Guidelines and Age Group.

Pencina MJ. NEJM. 2014; March 19 online

SHOULD I TAKE STATINS?

A decision making tool

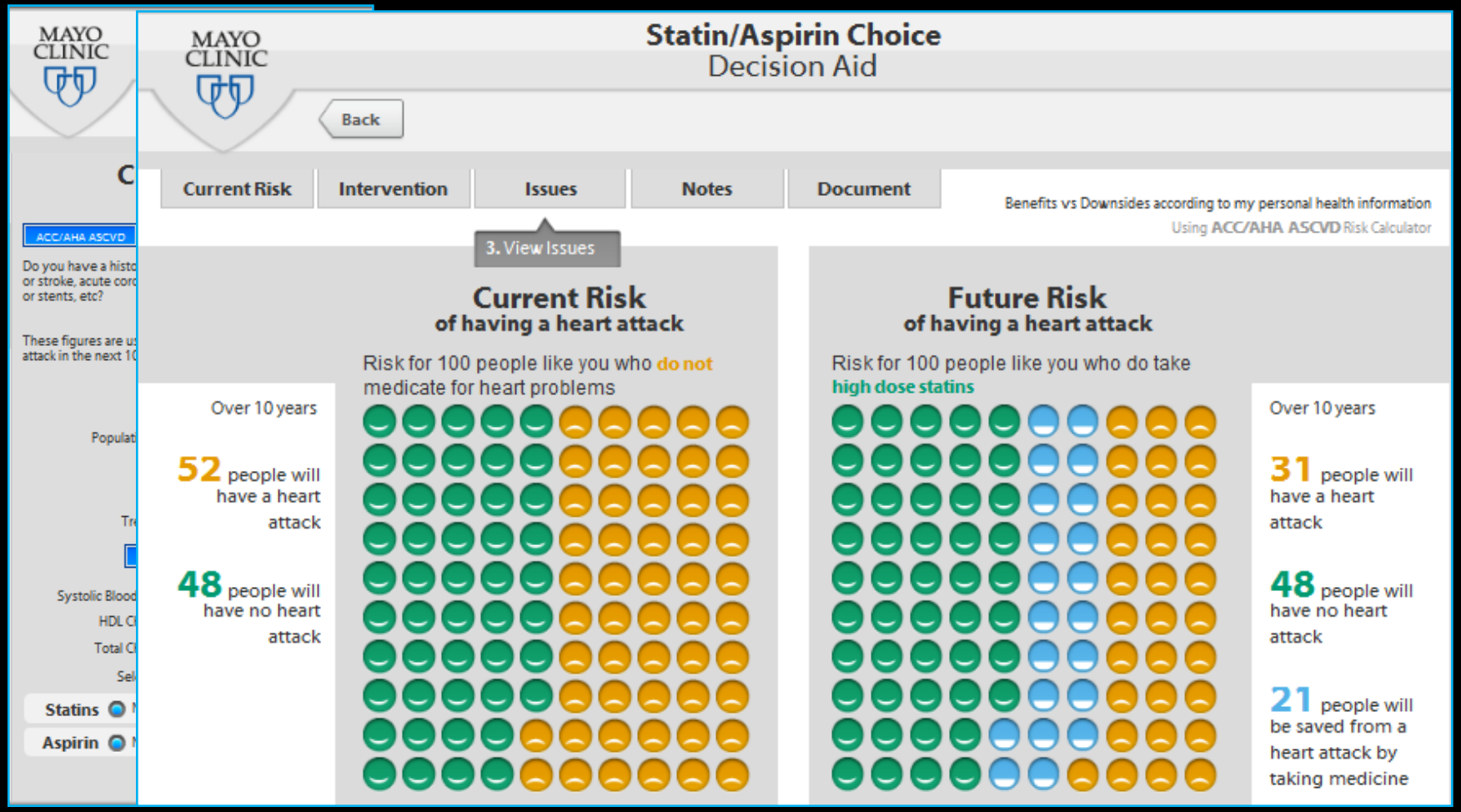
High Risk (>30%)



Weymiller et al. Arch Intern Med 2007

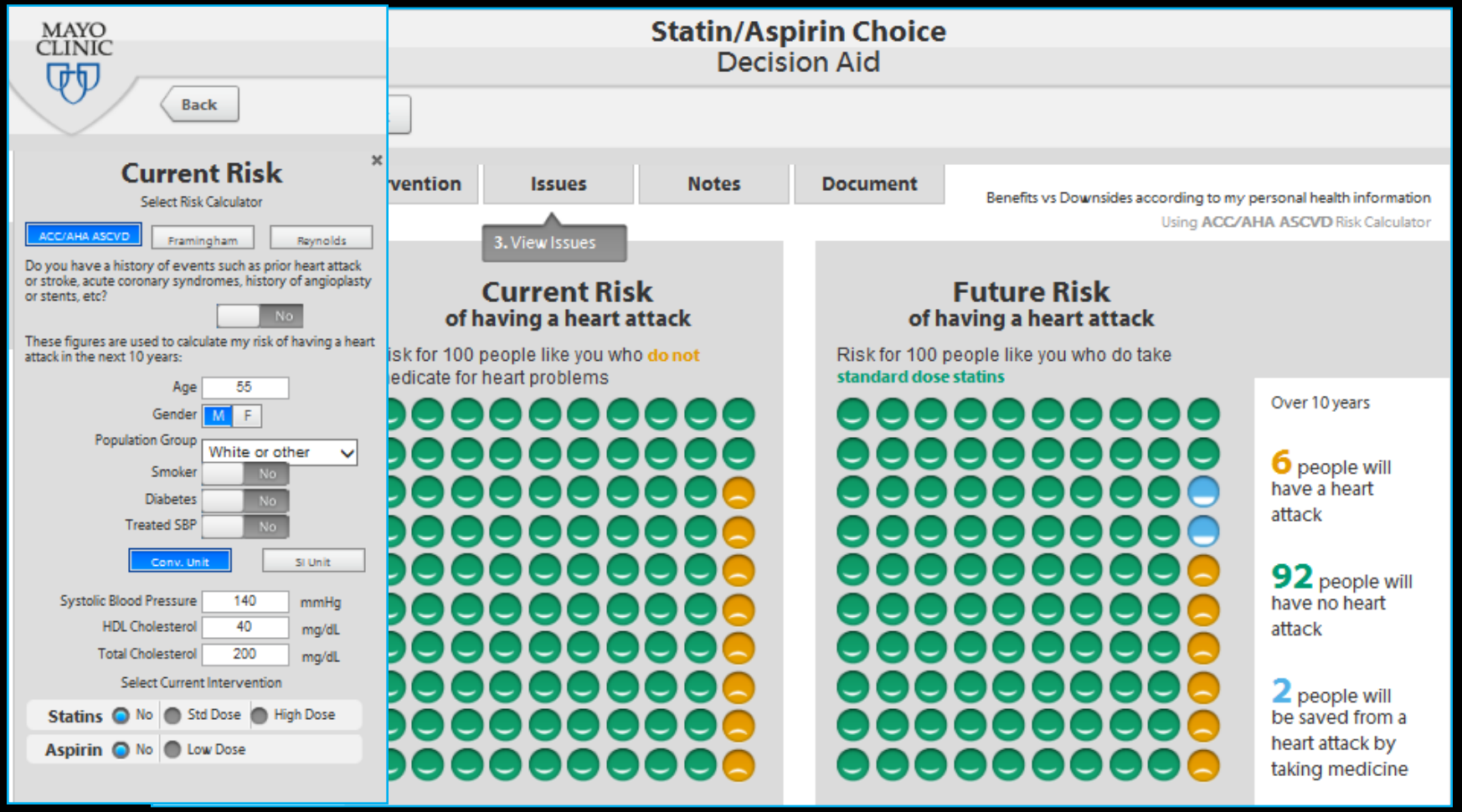
Web

Statin Choice



Web

Statin Choice



MAYO CLINIC

Statin/Aspirin Choice
Decision Aid

Back

Share

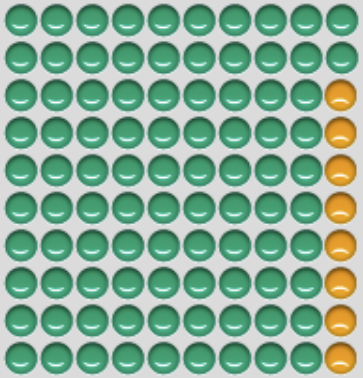
Current Risk | Intervention | Issues | Notes | Document

Benefits vs Downsides according to my personal health information

Using **ACC/AHA ASCVD** Risk Calculator

Current Risk of having a heart attack

Risk for 100 people like you who do not medicate for heart problems



Over 10 years
8 people will have a heart attack
92 people will have no heart attack

Cost

Standard dose statins
about $4/month

Daily Routine

Standard dose statins
One pill once a day

Other Benefits

Standard dose statins
The use of statins reduces your stroke risk by about one fifth.

Side Effects

Standard dose statins

Common side effects
nausea, diarrhea, constipation
(most patients can tolerate);

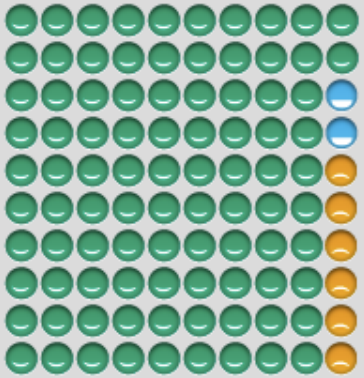
Muscle aching/stiffness
5 in 100 patients
(some need to stop statins because of this);

Liver blood test goes up
(no pain, no permanent liver damage):
2 in 100 patients
(some need to stop statins because of this);

Muscle and kidney damage
1 in 20,000 patients
(requires patients to stop statins).

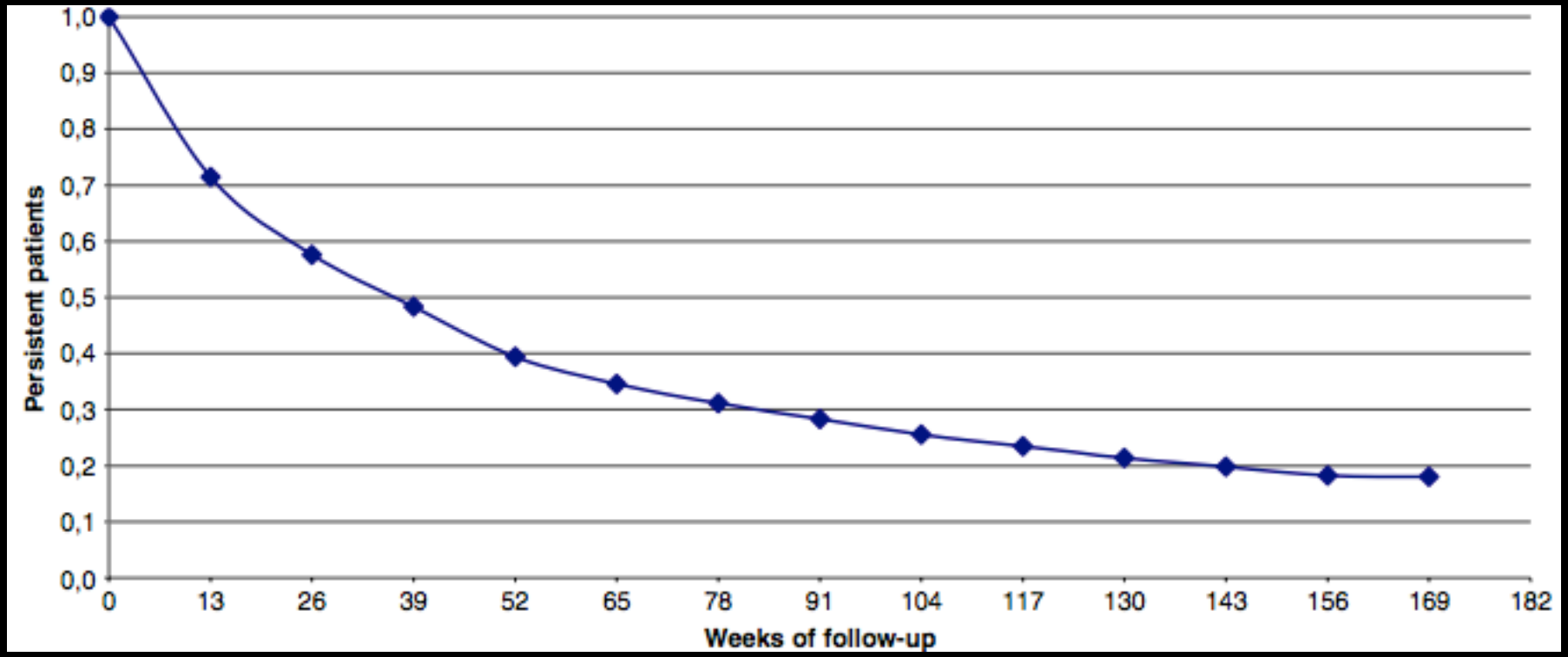
Future Risk of having a heart attack

Risk for 100 people like you who do take standard dose statins



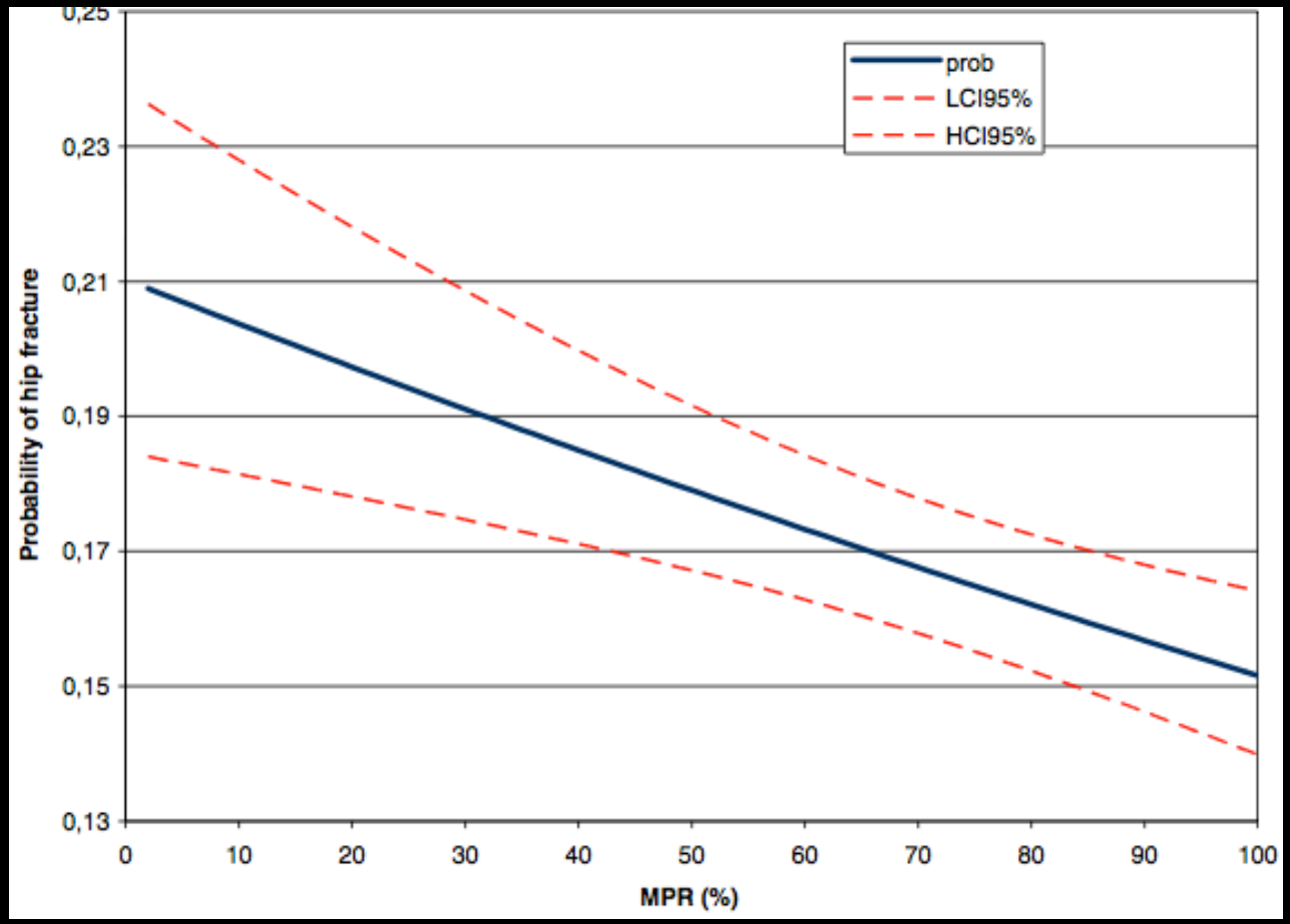
Over 10 years
6 people will have a heart attack
92 people will have no heart attack
2 people will be saved from a heart attack by taking medicine

Adherence after Initiating Bisphosphonates

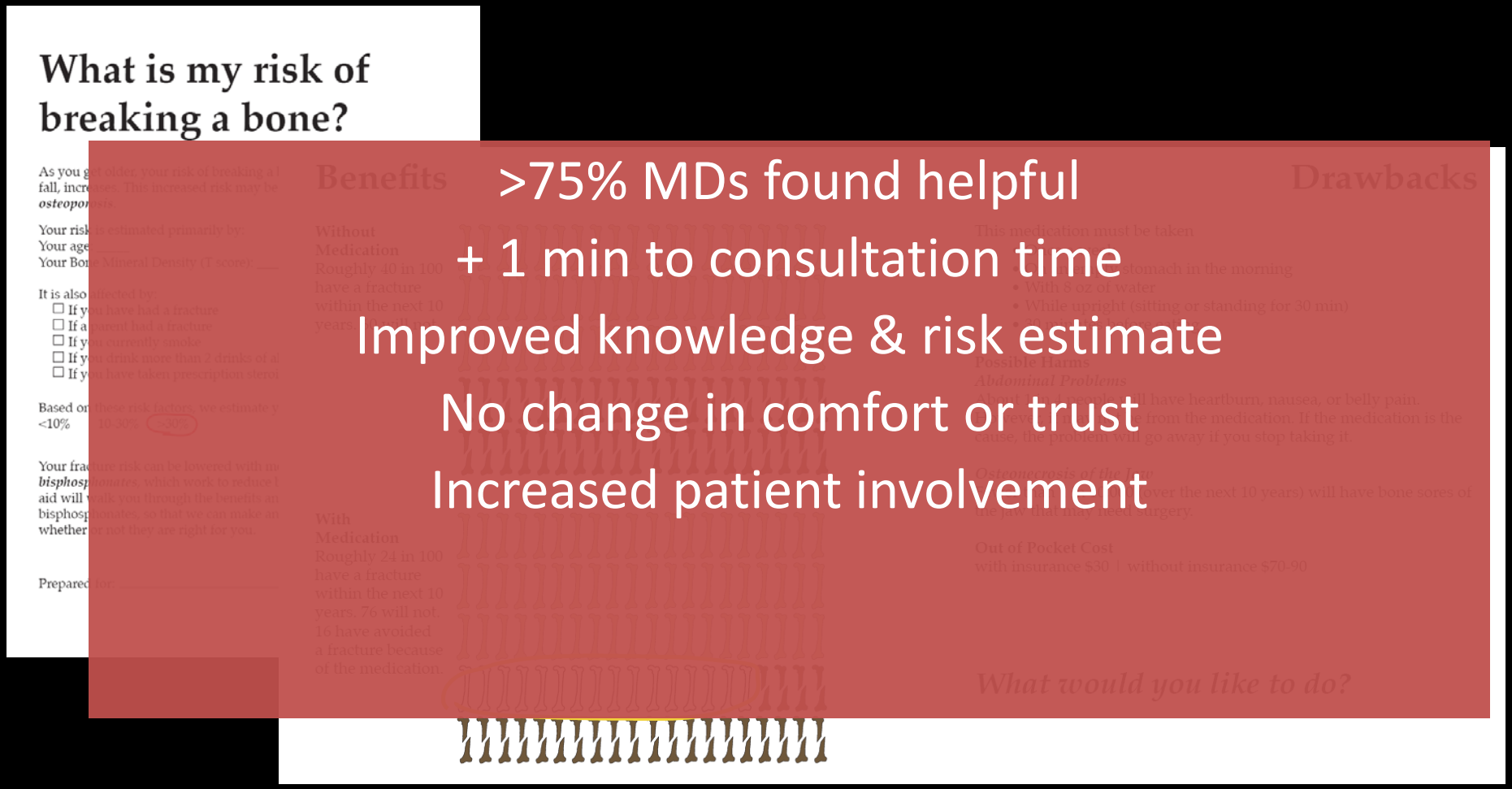


Source: Rabenda et. al Osteoporosis 2008

Association Between Adherence and Risk of Fracture



Osteoporosis Choice



>75% MDs found helpful

\+ 1 min to consultation time

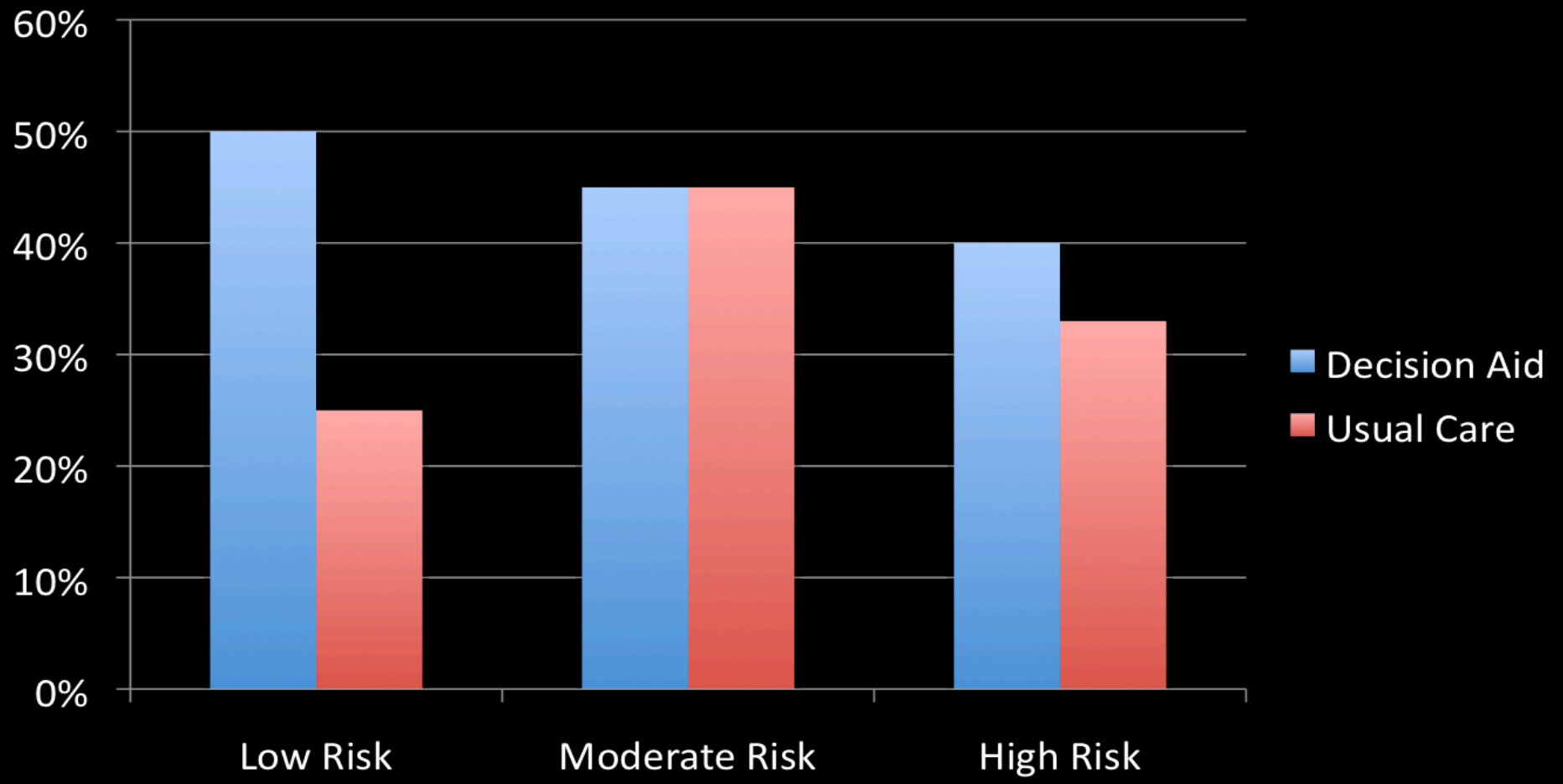
Improved knowledge & risk estimate

No change in comfort or trust

Increased patient involvement

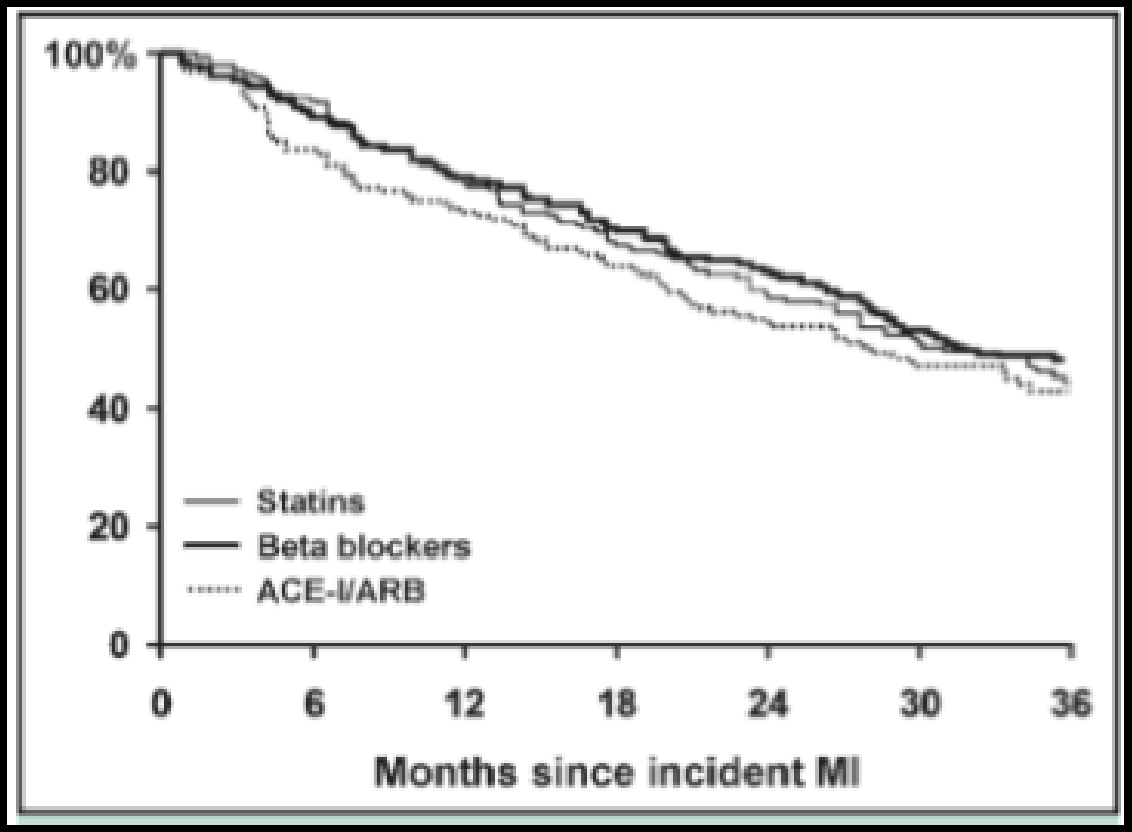
Montori VM et al. Am J Med 2011

Decision to Start Bisphosphonate



	Total, n (%)	Accept treatment, n (%)	Reject treatment, n (%)	Representative quote
A. Verbalized against treatment				
1. Concern about side effects	7 (39)	5 (71)	2 (18)	"The jaw thing frightens me."
2. Distrust of medications	6 (33)	0 (0)	6 (55)	"I won't take pills so don't ask."
3. Patient knowledge against treatment				
a. Family member with no osteoporosis complication	3 (17)	0 (0)	3 (27)	"My mother was 96 before she broke a bone."
b. History of adverse effect (personal or other)	3 (17)	2 (29)	1 (9)	"I think my mother took this and it made her legs and feet swell"
c. Health good without other treatments	1 (6)	0 (0)	1 (9)	"In general my health's pretty dam good overall, so why mess with a good thing?"
4. Low value of potential benefits				
a. Too old to benefit	3 (17)	1 (14)	2 (18)	"I don't want to live that long"
b. Limited knowledge of osteoporosis	2 (11)	0 (0)	2 (18)	"If I felt bad...[I would consider treatment]"
c. Medications will not produce benefit	2 (11)	1 (14)	1 (9)	"It won't make it get better?"
5. Cost of medication	2 (11)	1 (14)	1 (9)	"If it's not too expensive."
B. Verbalized in favor of treatment				
1. High value of benefits	3 (17)	2 (29)	1 (9)	"Ok, because I don't want to go back to a nursing home"
2. Patient knowledge in favor of treatment				
a. Family member with poor outcome	3 (17)	3 (43)	0 (0)	"My mother fell and broke her hip. That was the end of it"
b. Personal research and insight	2 (11)	2 (29)	0 (0)	

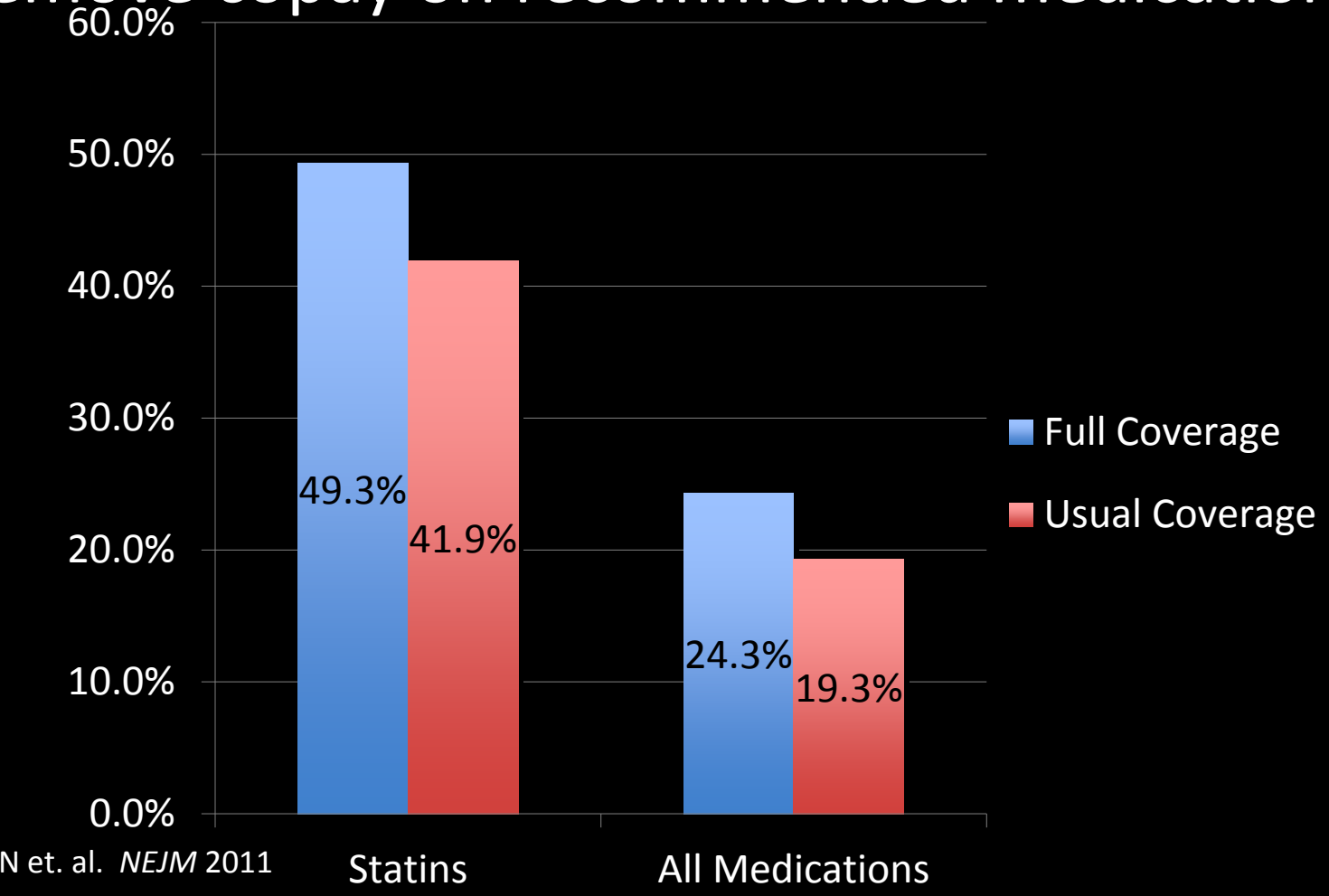
Recommended "Medication Bundle" after an AMI



Shah ND, et al. *Am J Med* 2009

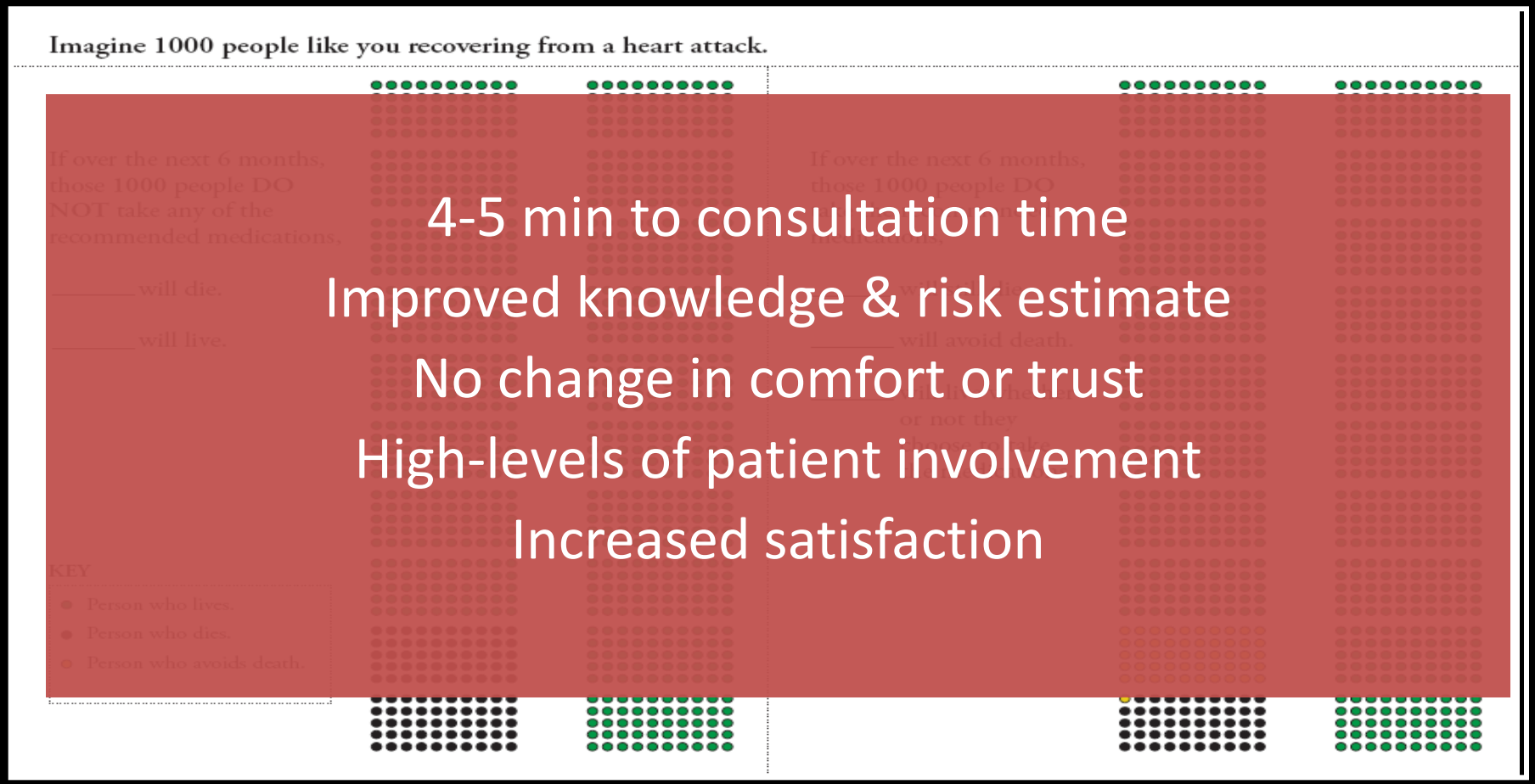
Structural Intervention

Remove copay on recommended medications



Choudhry N et. al. *NEJM* 2011

Knowledge Transfer



4-5 min to consultation time

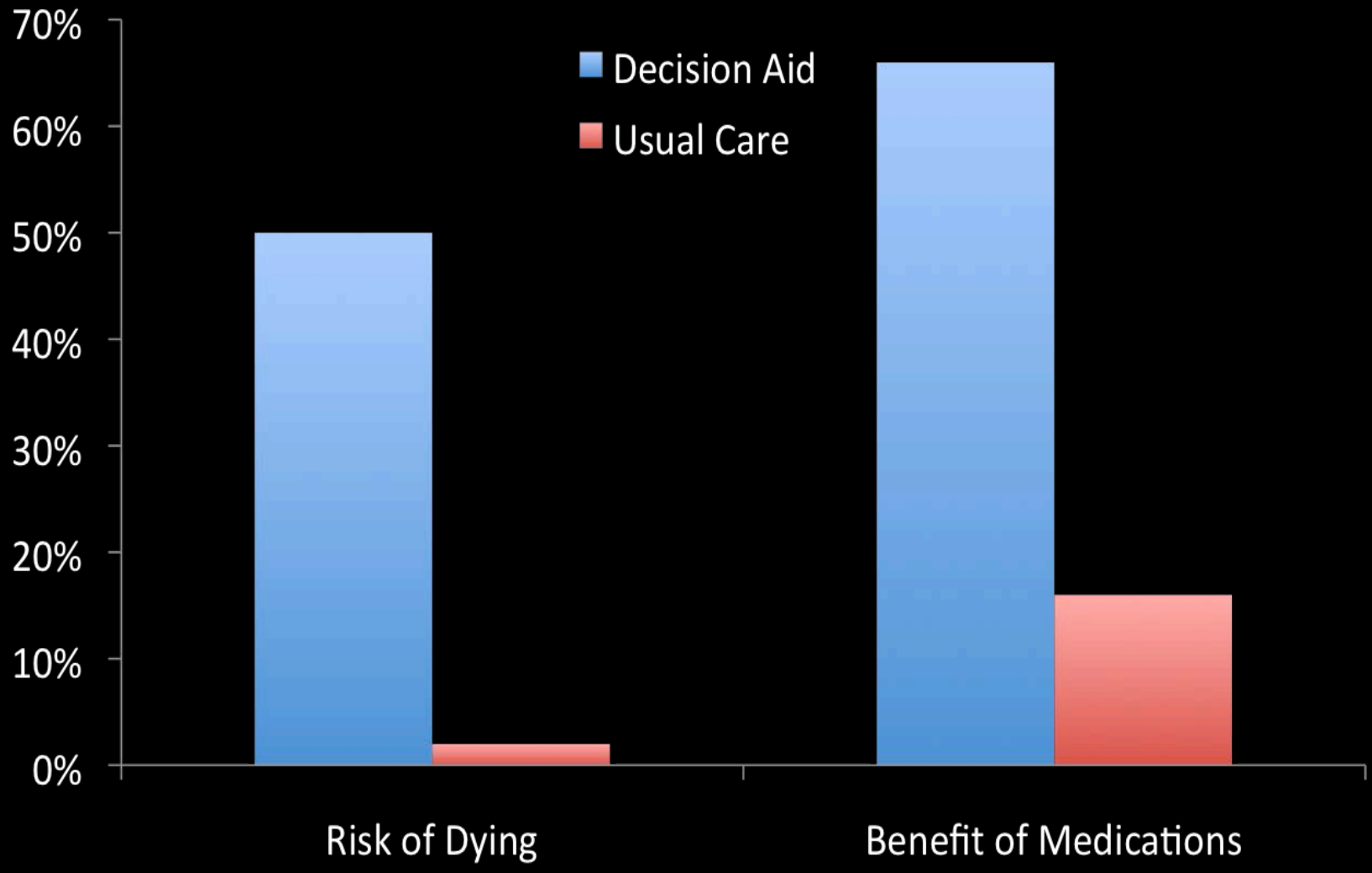
Improved knowledge & risk estimate

No change in comfort or trust

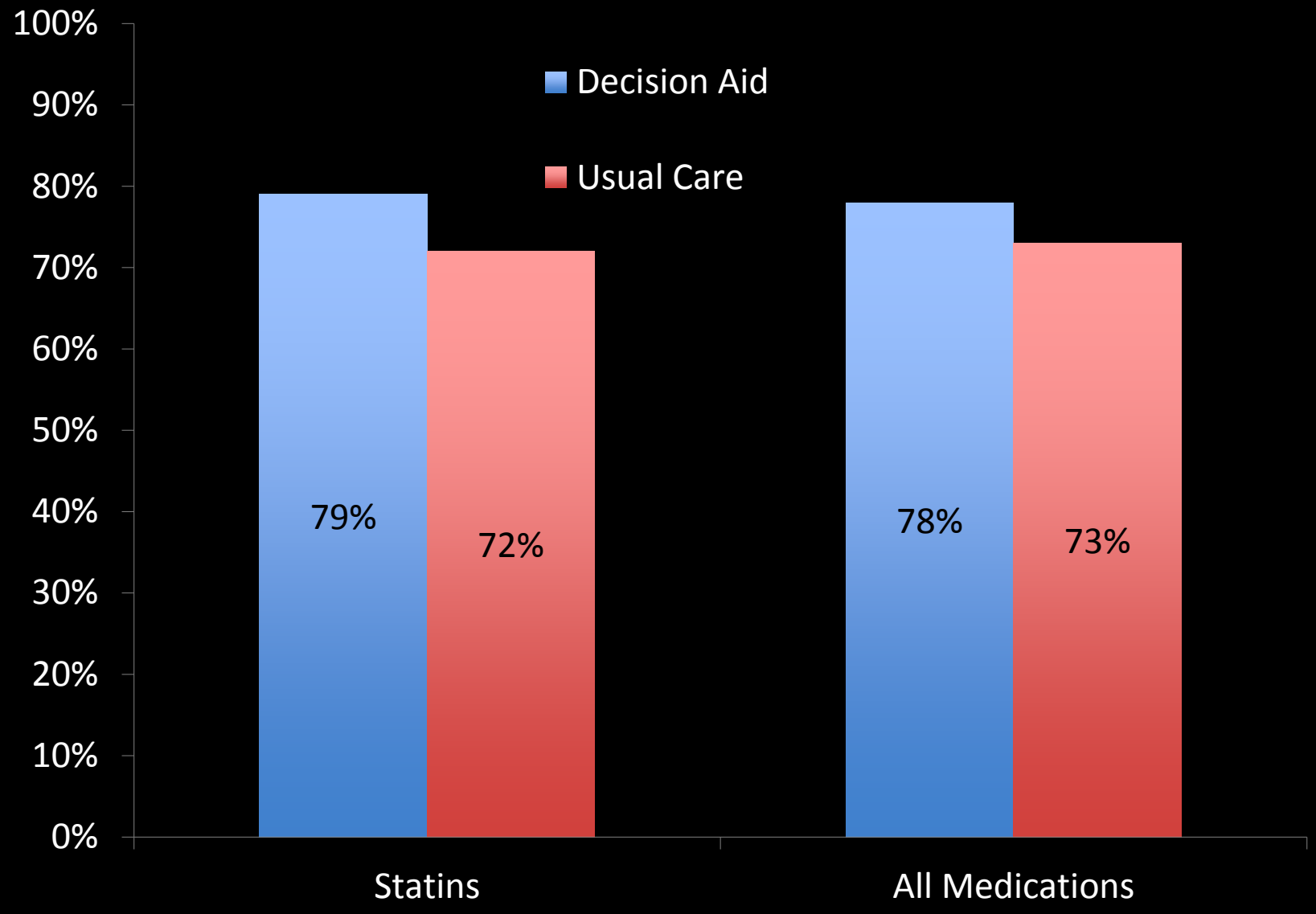
High-levels of patient involvement

Increased satisfaction

Knowledge of Risks and Benefits



Adherence to Medications



A Case Study

A 63 y.o. woman presents to the ED with pain in the neck going to her left arm. Intermittent sharp twinges of pain in her chest.

No ischemic changes on ECG; serial cardiac troponins were negative

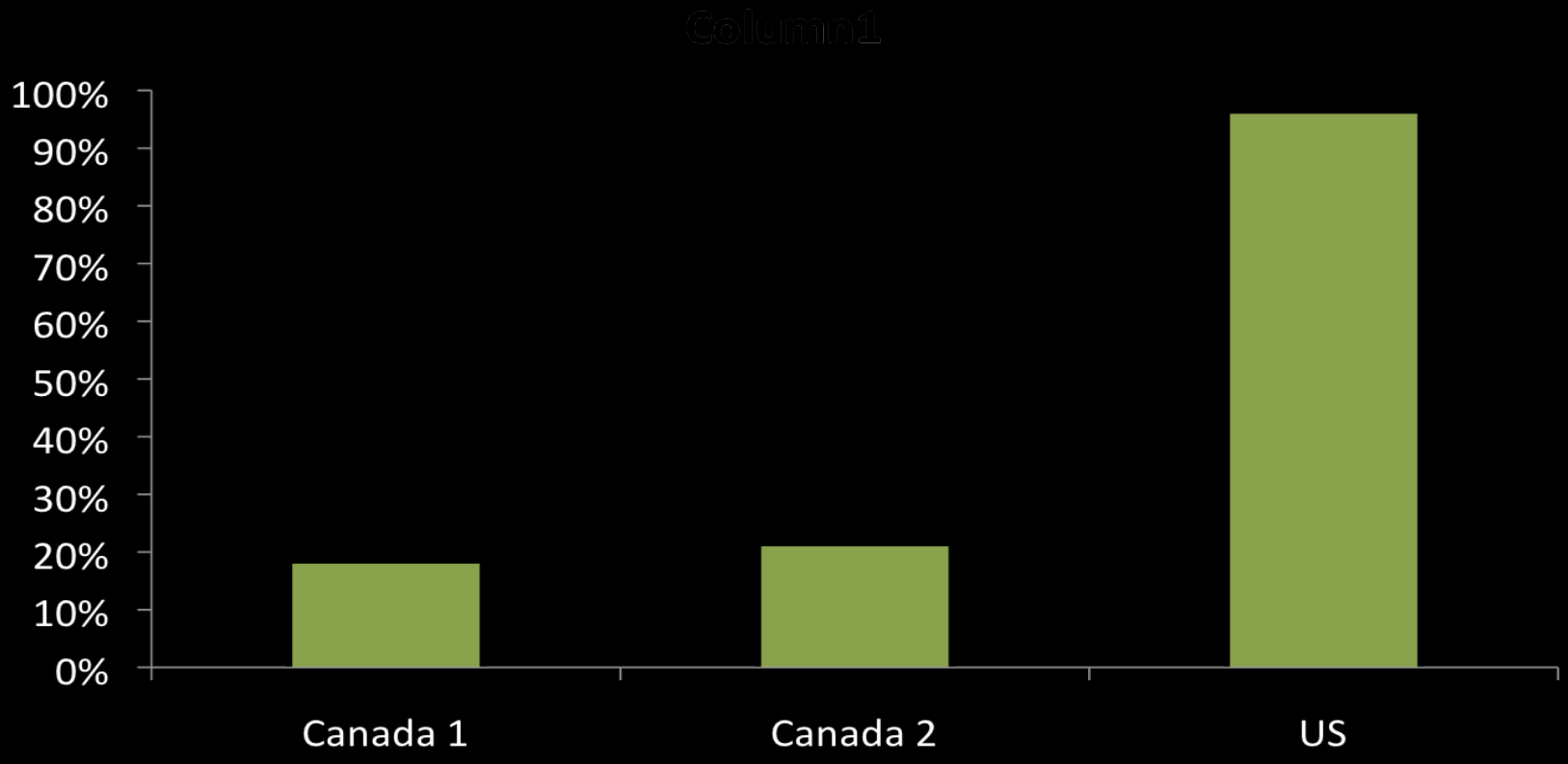
PMH: Hypertension, Migraines, Breast cancer

Former smoker

Overall risk of ACS in the next 45-days: <3%

What would you want to do if you were her?

Hospital or ED Observation Unit Admission



What's Next?

Prepared for: _____

1 Your Chest Pain Diagnosis

Our initial evaluation has NOT shown any evidence of a heart attack. This conclusion is based on a blood test (to look for troponins — enzymes that are released when the heart muscle is damaged) and an electrocardiogram (to check that your heart is getting enough oxygen and blood). Over the next five hours, two additional blood tests (troponins) will be taken to definitively rule out a heart attack.

However, even if these tests do confirm our diagnosis, your chest pain may indicate possible warning signs of a FUTURE heart attack.

2 Further Tests

A STRESS TEST EVALUATION may more precisely determine if your heart is functioning correctly by viewing blood flow to your heart while at rest and under stress.

Examining your risk will help you to determine whether you would like to have a stress test now or would like assistance in making a clinic appointment.[4]

3 Your Personal Risk Evaluation

Your risk of having a heart attack or of having a pre-heart attack diagnosis within the next 45 days can be determined by comparing you to people with similar factors[3] who also came to the Emergency Department with chest pain.

Of every **100** people with factors like yours who came to the emergency department with chest pain...

3 had a heart attack or a pre-heart attack diagnosis within 45 days of their emergency department visit,

97 did not.

4 Would You Like to Have a Stress Test Now or Make an Appointment?

- ❑ I would like to be admitted to the observation unit to have an urgent cardiac stress test. I realize that this could add to the cost of my evaluation and lengthen my emergency stay.
- ❑ I would like to be seen by a Mayo Clinic heart doctor within 24-72 hours and would like assistance in scheduling this appointment.
- ❑ I would like to schedule an appointment on my own to consult with my primary care physician.
- ❑ I would like my emergency department doctor to make this decision for me.

[3] • Age
• Gender
• Race
• If chest pain is made worse when manual pressure is applied to the chest area
• If there is a history of coronary artery disease
• If the chest pain causes perspiration
• Findings on electrocardiograms (electronic tracings of the heart)
• Initial cardiac troponin T result

[4] Stress test options include nuclear stress testing, ultrasound stress testing, and exercise ECG (electrocardiogram) stress testing. Nuclear stress testing includes exposure to radiation which has been shown to be related to increased cancer risk over a lifetime. Your doctor can help you explore which option may be best for you.

Hess et. al *Circ CQO* 2012

Summary of Findings: *Chest Pain Choice*

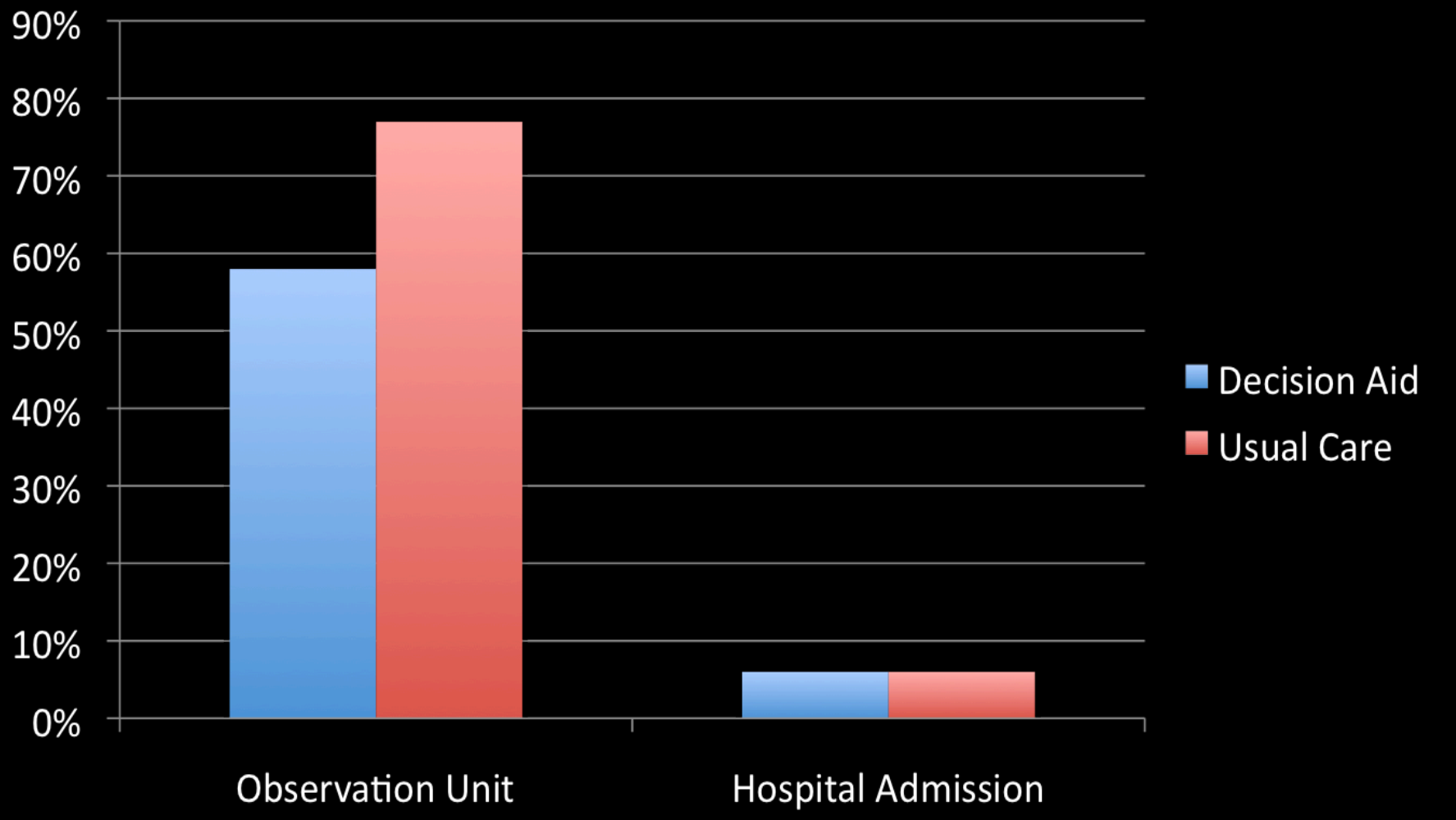
Improved knowledge

Comfort with the decision

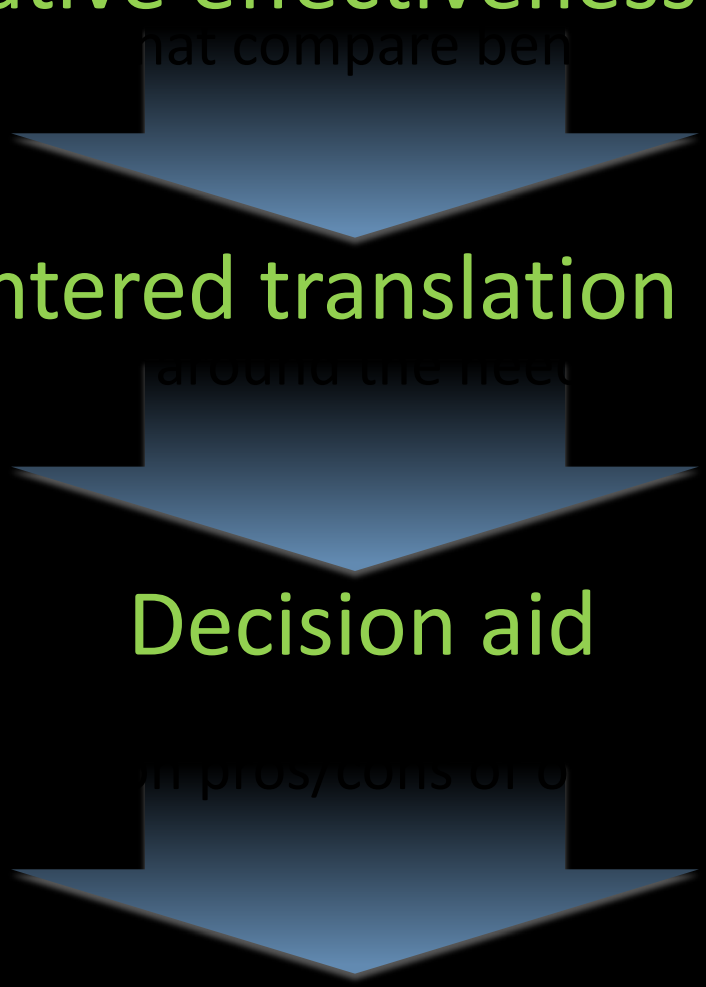
Greater level of engagement

High levels of satisfaction

Management Decisions




CURRENTLY ON
EXIT 58A-B
95
1
Zoloft
9
Prozac
Paxil
LAST EXIT
BEFORE TOLL
Buspar
Wellbutrin
Celexa
Xanax


Comparative effectiveness research
Patient centered translation into action
Decision aid
Shared decision making

Effective Health Care Program

Comparative Effectiveness Review
Number 46

Second-Generation Antidepressants in the Pharmacologic Treatment of Adult Depression:

An Update of the 2007 Comparative Effectiveness Review

AHRQ
Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • www.ahrq.gov

Evidence Table 1. Randomi

Study Characteristics	Research Interventi
Author, Year	Research

Table E. S
effectiven

Figure 14. Odds ratios of response rates comparing SSRIs and SNRIs with SNRIs and SSNRIs

Favors first drug Favors second drug

SSRI vs. SSNRI

0.38 (0.10, 3.07)
0.74 (0.56, 0.98)
1.14 (0.87, 1.46)
0.46 (0.13, 2.87)
0.93 (0.72, 1.22)
0.93 (0.70, 1.20)
0.43 (0.11, 3.45)
0.81 (0.56, 1.22)
1.27 (0.89, 1.76)
0.51 (0.14, 3.25)
1.07 (0.73, 1.51)
1.04 (0.72, 1.44)
0.48 (0.12, 4.14)
0.99 (0.57, 1.59)
1.48 (0.91, 2.27)
0.57 (0.16, 3.65)
1.24 (0.76, 1.89)
1.21 (0.73, 1.89)
0.49 (0.13, 3.91)
0.93 (0.67, 1.33)
1.46 (1.16, 1.83)
0.58 (0.17, 3.67)
1.18 (0.86, 1.63)
1.17 (0.88, 1.53)
1.13 (0.80, 1.55)
1.25 (0.92, 1.75)
1.32 (0.78, 2.09)
1.12 (0.78, 1.67)
0.84 (0.50, 1.50)
0.96 (0.59, 1.65)

1 2 5

w conclusions about treating depression in
xisting low energy. Results from head-to-
ot available.

Antidepressant Medicines*

Brand Name	Generic Available?	Drug Name
Wellbutrin®; Wellbutrin SR®, Wellbutrin XL®		
Celexa®		
Pristiq®		
Cymbalta®		

What did research find about specific antidepressants?

Research has found some specific information about the benefits of a few medicines:

ed feeling better
emeron® took about
ntidepressants
s.
as regular Prozac®

exor®, Effexor XR®)
her antidepressants.
ed it because of side

ms related

ments in their
ut the same amount

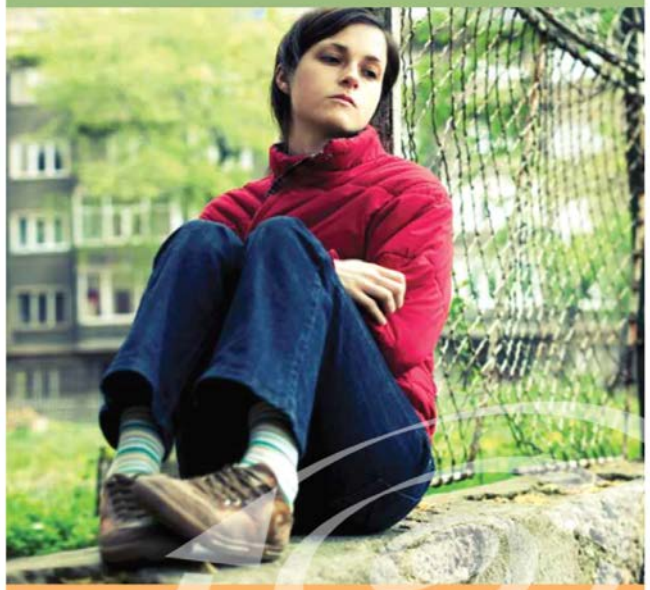
balta®) both helped
the same amount.
Fluoxetine (Prozac®),
d sertraline (Zoloft®)
ount, but there is not

5

Effective Health Care Program

Medicines for Treating Depression

A Review of the Research for Adults



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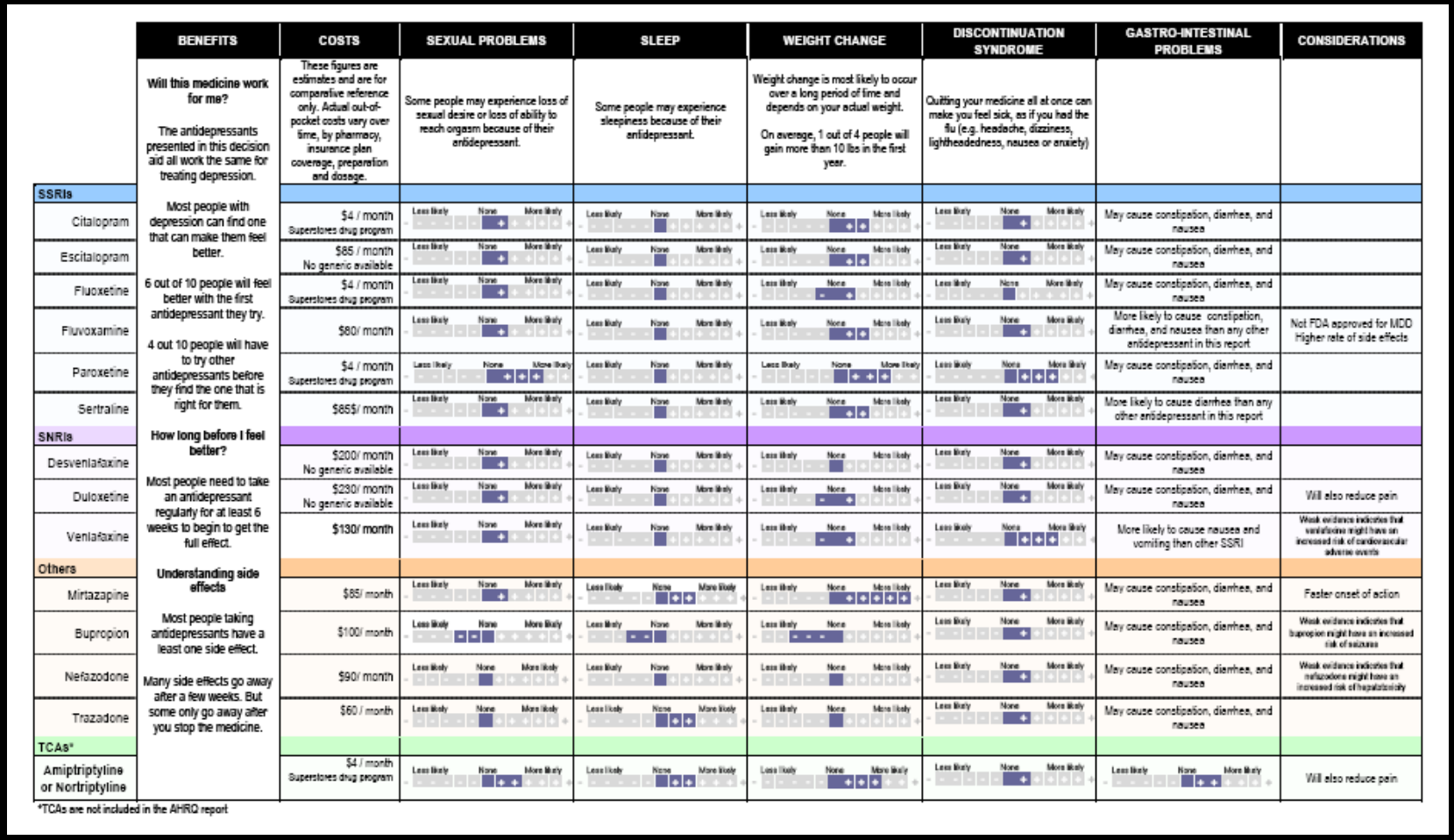
Evidence Synthesis



	BENEFITS	COSTS	SEXUAL PROBLEMS	SLEEP	WEIGHT CHANGE	DISCONTINUATION SYNDROME	GASTRO-INTESTINAL PROBLEMS	CONSIDERATIONS
	Will this medicine work for me? The antidepressants presented in this decision aid all work the same for treating depression. Most people with depression can find one that can make them feel better. 6 out of 10 people will feel better with the first antidepressant they try. 4 out 10 people will have to try other antidepressants before they find the one that is right for them. **How long before I feel better?** Most people need to take an antidepressant regularly for at least 6 weeks to begin to get the full effect. **Understanding side effects** Most people taking antidepressants have a least one side effect. Many side effects go away after a few weeks. But some only go away after you stop the medicine.	These figures are estimates and are for comparative reference only. Actual out-of-pocket costs vary over time, by pharmacy, insurance plan coverage, preparation and dosage.	Some people may experience loss of sexual desire or loss of ability to reach orgasm because of their antidepressant.	Some people may experience sleepiness because of their antidepressant.	Weight change is most likely to occur over a long period of time and depends on your actual weight. On average, 1 out of 4 people will gain more than 10 lbs in the first year.	Quitting your medicine all at once can make you feel sick, as if you had the flu (e.g. headache, dizziness, lightheadedness, nausea or anxiety)		
SSRIs								
Citalopram		$4 / month Superstores drug program	Less likely None More likely	Less likely None More likely	Less likely None More likely	Less likely None More likely	May cause constipation, diarrhea, and nausea	
Escitalopram		$85 / month No generic available	Less likely None More likely	Less likely None More likely	Less likely None More likely	Less likely None More likely	May cause constipation, diarrhea, and nausea	
Fluoxetine		$4 / month Superstores drug program	Less likely None More likely	Less likely None More likely	Less likely None More likely	Less likely None More likely	May cause constipation, diarrhea, and nausea	
Fluvoxamine		$80/ month	Less likely None More likely	Less likely None More likely	Less likely None More likely	Less likely None More likely	More likely to cause constipation, diarrhea, and nausea than any other antidepressant in this report	Not FDA approved for MDD Higher rate of side effects
Paroxetine		$4 / month Superstores drug program	Less likely None More likely	Less likely None More likely	Less likely None More likely	Less likely None More likely	May cause constipation, diarrhea, and nausea	
Sertraline		85/ month	Less likely None More likely	Less likely None More likely	Less likely None More likely	Less likely None More likely	More likely to cause diarrhea than any other antidepressant in this report	
SNRIs								
Desvenlafaxine		$200/ month No generic available	Less likely None More likely	Less likely None More likely	Less likely None More likely	Less likely None More likely	May cause constipation, diarrhea, and nausea	
Duloxetine		$230/ month No generic available	Less likely None More likely	Less likely None More likely	Less likely None More likely	Less likely None More likely	May cause constipation, diarrhea, and nausea	Will also reduce pain
Venlafaxine		$130/ month	Less likely None More likely	Less likely None More likely	Less likely None More likely	Less likely None More likely	More likely to cause nausea and vomiting than other SSRI	Weak evidence indication that venlafaxine might have an increased risk of cardiovascular adverse events
Others								
Mirtazapine		$85/ month	Less likely None More likely	Less likely None More likely	Less likely None More likely	Less likely None More likely	May cause constipation, diarrhea, and nausea	Faster onset of action
Bupropion		$100/ month	Less likely None More likely	Less likely None More likely	Less likely None More likely	Less likely None More likely	May cause constipation, diarrhea, and nausea	Weak evidence indication that bupropion might have an increased risk of seizures
Nefazodone		$90/ month	Less likely None More likely	Less likely None More likely	Less likely None More likely	Less likely None More likely	May cause constipation, diarrhea, and nausea	Weak evidence indication that nefazodone might have an increased risk of hepatotoxicity
Trazadone		$60 / month	Less likely None More likely	Less likely None More likely	Less likely None More likely	Less likely None More likely	May cause constipation, diarrhea, and nausea	
TCAs*								
Amiptriptyline or Nortriptyline		$4 / month Superstores drug program	Less likely None More likely	Less likely None More likely	Less likely None More likely	Less likely None More likely	Less likely None More likely	Will also reduce pain

*TCAs are not included in the AHRQ report

Stakeholders meetings

24 participants /12 organizations

(Health systems, patients, clinicians, buyers)

Clinical observations

2 primary care practices

(Patients, family physicians, care managers)

Focus groups/ Discussion

Family physicians, care managers

Patients Advisory Groups

Keep in Mind

Sexual Issues

Sleep

Cost

Weight Change

Stopping Approach

What You Should Know

Will this medicine work for me?

- The antidepressants presented in this decision aid all work the same for treating depression.
- Most people with depression can find one that can make them feel better.
- 6 out of 10 people will feel better with the first antidepressant they try and the rest will have to try other antidepressants before they find the one that is right for them.

How long before I feel better?

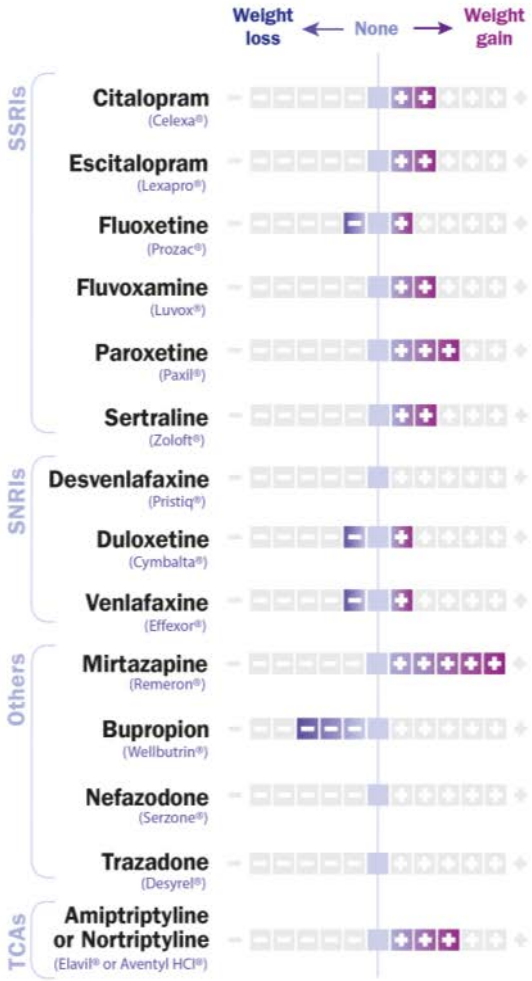
- Most people need to take an antidepressant regularly for at least 6 weeks to begin to get the full effect.

Understanding side effects

- Most people taking antidepressants have at least one side effect.
- Many side effects go away after a few weeks, but some only go away after you stop the medicine.

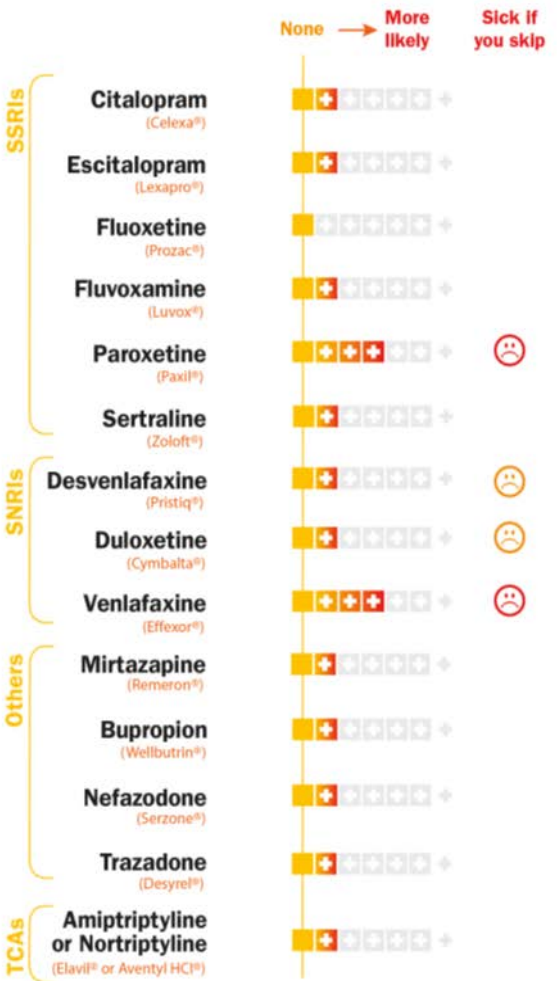
Weight Change

Weight change is most likely to occur over a long period of time and depends on your actual weight.



Stopping Approach

Quitting your medicine all at once can make you feel sick, as if you had the flu (e.g. headache, dizziness, light-headedness, nausea or anxiety).



Comfortable

Knowledgeable

Satisfied

(feel better)

Comfortable

Satisfied

Use tool/like it

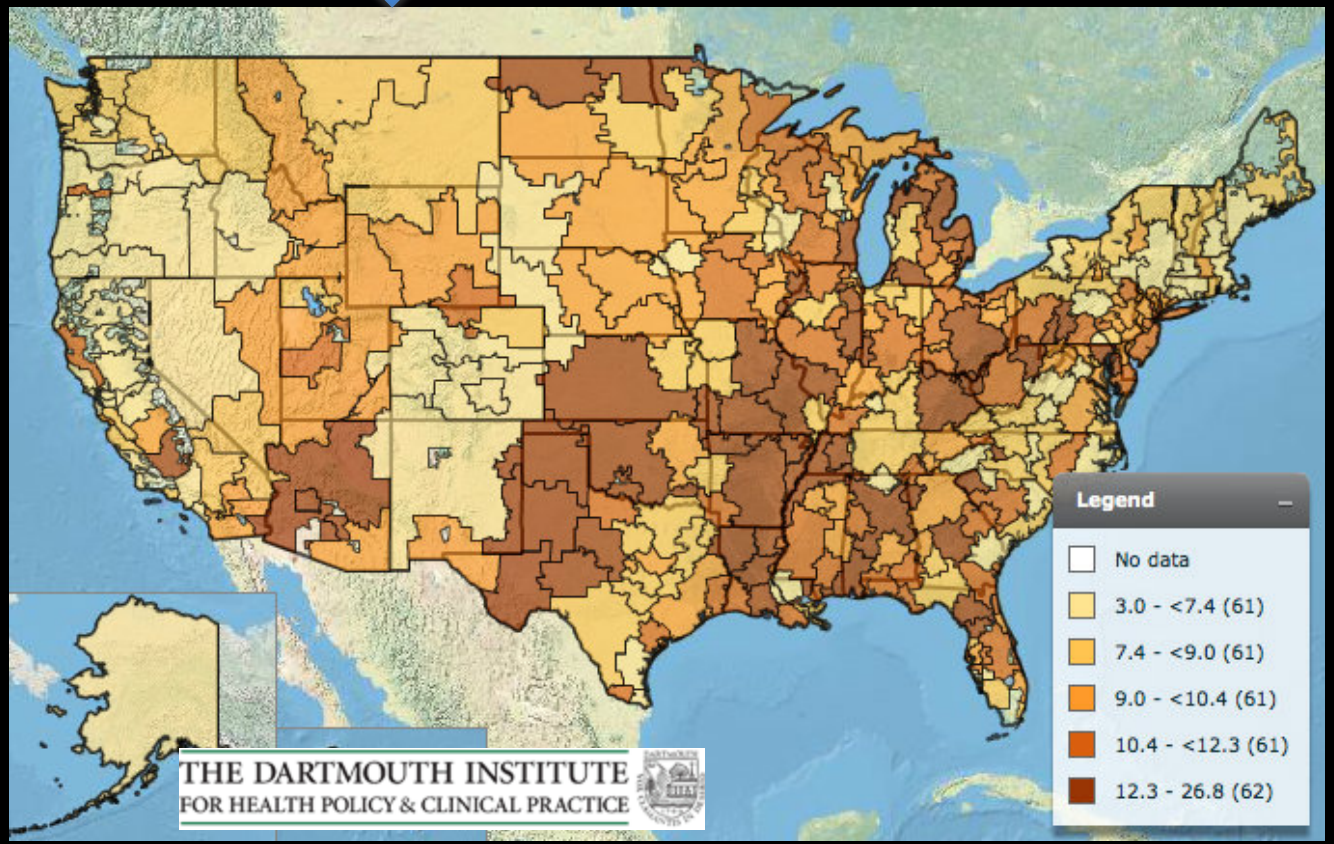
Engaged in decision making process

LESS IS MORE

Initial Coronary Stent Implantation With Medical Therapy vs Medical Therapy Alone for Stable Coronary Artery Disease

Meta-analysis of Randomized Controlled Trials

Kathleen Stergiopoulos, MD, PhD; David L. Brown, MD



PCI Choice

Coronary artery disease is a CHRONIC disease.

If you don't choose to have a stent placed now, it's possible that you could still have one later.

MEDICINES

In 15 people like you:
THREE will need a stent within one year, 12 will not.

MEDICINES + STENTS

In 15 people like you:
ONE will need another stent within one year, 14 will not.

Based upon this shared information...

What is most important to *you*?

MEDICINES

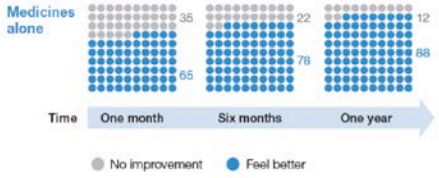
MEDICINES + STENTS

Did you know...

Use of stents for stable coronary artery disease will **NOT** lower your risk of heart attack or death when compared to using medicines alone.

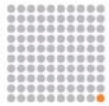
Benefits

Improvement of symptoms in 100 people like you after treatment:

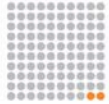


Risks

During stent procedure

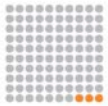


In 100 people like you:
ONE will have a heart attack, stroke or other major complication, 99 will not.



In 100 people like you:
TWO will have bleeding or damage to a blood vessel, 98 will not.

Bleeding and clotting within one year



In 100 people like you:
THREE will have a bleeding event from the additional blood thinner needed with a stent, 97 will not.

In 100 people like you:
TWO will develop a clot that forms in the stent leading to a heart attack, 98 will not.

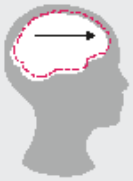
Head CT Choice

Based on the medical history and physical exam of your child, we believe **your child's head injury is "minor."** Your child should recover over time, with rest and close follow-up with your physician.

It's very rare, but sometimes there are more serious injuries such as bleeding in or around the brain.

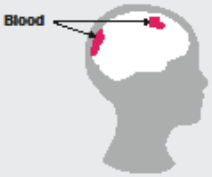
What is the risk that your child will have these types of injuries to his/her brain?

Concussion



- Cannot be seen on a CT scan.
- Recovery is almost always complete.
- Symptoms should resolve in several days to a few months.

Brain Injury



- Occurs when the head injury is severe enough to cause bleeding in or around the brain.
- May require medical intervention such as a stay in the hospital or surgical procedure.
- Diagnosed with imaging, such as a CT scan

In 100 children with minor head injury similar to your child:

1 will have brain injury and **99 will not**

Kuppermann et al., Lancet, 2009

To find out if there was any bleeding in the brain with this injury, we can:

 **Do a HEAD CT SCAN** **or**  **Do ACTIVE OBSERVATION**

ACTIVE OBSERVATION

You should monitor your child for signs that she/he is getting worse in the next 24 hours (as described below).

If your child's symptoms are no worse after 24 hours, then there was no serious bleeding in or around the brain.

It is very unlikely to develop, but if your child develops new or worsening symptoms such as these, bring him/her back to the Emergency Department as soon as possible.

Severely worsening headache (despite resting)

Unsteady or cannot walk

Difficulty talking or recognizing people

Lack of alertness (if they are becoming less and less alert within the next day)

Vomiting (enough episodes to interfere with intake)

Your child can maintain regular activities including sleep.
If your clinician has diagnosed a concussion, there will be further restrictions on activity.

Which issues are most important to you when choosing what to do next?

	SPEED OF DIAGNOSIS	RADIATION	SEDATION	COST	BURDEN	WAIT IN ED
HEAD CT SCAN 	Now	Yes	Possible	Added cost for the scan	May find irrelevant things that lead to more tests	More time needed to do CT scan and get results
ACTIVE OBSERVATION 	Delayed	No	No	No added cost	Potential return to ED if symptoms worsen	Less time in the ED

After discussing this together, we want to:

- ☐ Do a Head CT Scan
- ☐ Do Active Observation
- ☐ Let the Emergency Department doctor decide what to do next

You will have the opportunity to revisit this decision with the clinician while you are in the Emergency Department.

Experience

Work	Setting	Evaluation
Statin Choice	**Primary + specialty care**	**Feasible, effective, implemented in EHR, web-based, multicenter trial**
DM2 Med Choice	**Primary care**	**Feasible, effective, multicenter trial, web-based**
Aspirin Choice	Primary care (group)	Not evaluated
Depression Choice	**Primary care**	**Ongoing trial**
Genomic Choice	Experimental	Design phase
Osteoporosis Choice	**Primary care**	**Feasible, effective, EHR**
ICD Choice	Specialty care	Design phase
Smoking choice	**Primary care**	**Feasible, effective, single center trial**
Chest Pain Choice	**Emergency**	**Feasible, effective, *multicenter trial***
AMI Choice	**Hospital ward**	**Feasible, effective, *multicenter trial***
Hypertension	**e-primary care**	**Design phase**
Rosiglitazone	General	Not evaluated
Prostate cancer screening and early treatment	General (tablet)	Design phase
PCI vs. medical therapy	**Specialty care**	**Feasible, effective, *multicenter trial***
Mammography < 40	Primary care	Design phase
Pediatric Head CT	**Emergency Department**	**Trial**

Lessons learnt

User-centered design happens in the field, takes multiple iterations and expertise

Challenges with evidence synthesis and changing evidence

Testing decision aids in usual clinical settings is tough: decision moments are unpredictable

Repeated use for chronic decisions has been difficult to study in efficacy trials

Lessons learnt

Decision aids have increased knowledge and patient involvement in the decision consistently

The impact on improving adherence to medications is mixed

Clinicians and patients have reported high-levels of satisfaction (in trial settings); however *culture* is important

http://shareddecisions.mayoclinic.org