MAYO CLINIC

Meaningful Implementation of Shared Decision Making into Routine Clinical Practice

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Disclosures

No financial conflict of interest

KER unit investigators do not receive funding from any for-profit pharmaceutical or manufacturer, nor do they receive any royalties or monetary benefits, directly or indirectly, from the use of the decision aids

Decision aids are available free of charge

High Quality Healthcare

The Institute of Medicine (IOM) has designated patient-centered care, alongside care that is safe, effective, efficient, timely, and equitable, as a key feature of high quality healthcare

Enabling greater involvement of patients in their healthcare decisions, through shared decision making, is an integral component of patient-centered care

The state of affairs

Patients make decisions in the face of avoidable ignorance

Clinicians misdiagnose preferences

Decisions are driven by other concerns

Care depends on where you receive it

Low-quality care

Why Shared Decision Making

Patient centered high value healthcare

Evidence based medicine

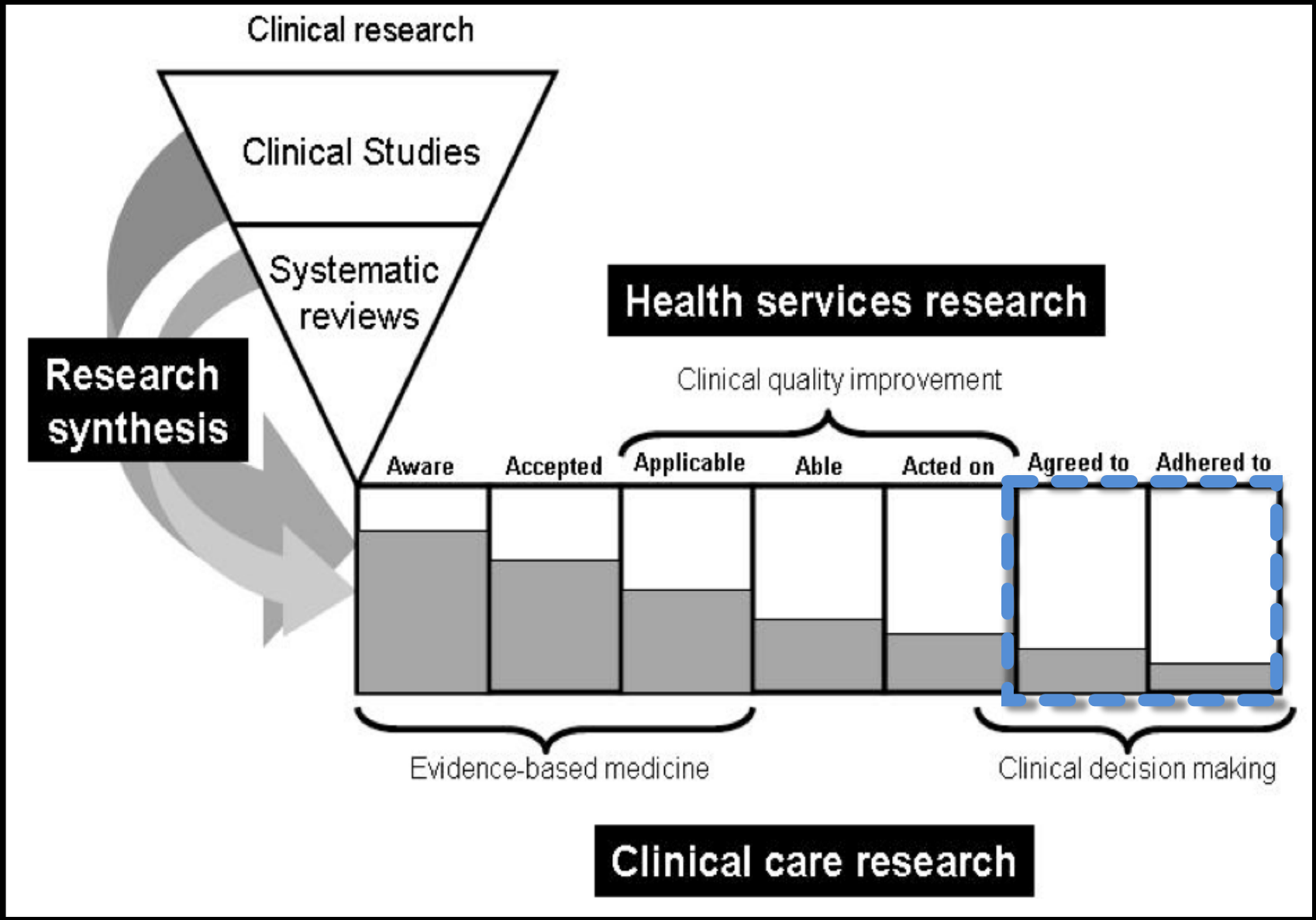
Makes explicit the uncertainty of the evidence

Gives a voice to patients (values/ preferences)

Reduce unwarranted variations

Ethical

Right thing to do



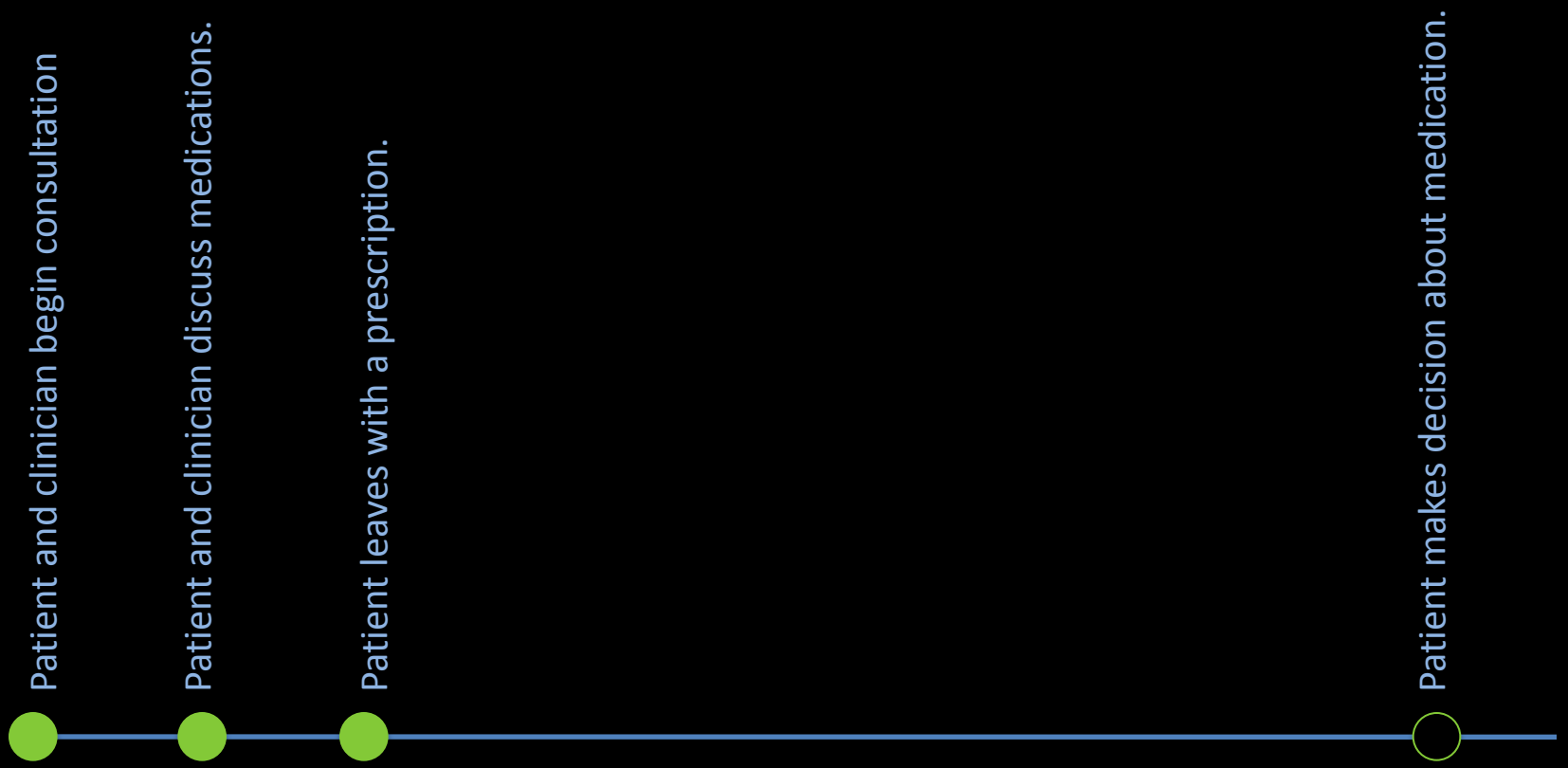
Glasziou and Haynes ACP JC 2005


Patient values and preferences
Context
Research evidence

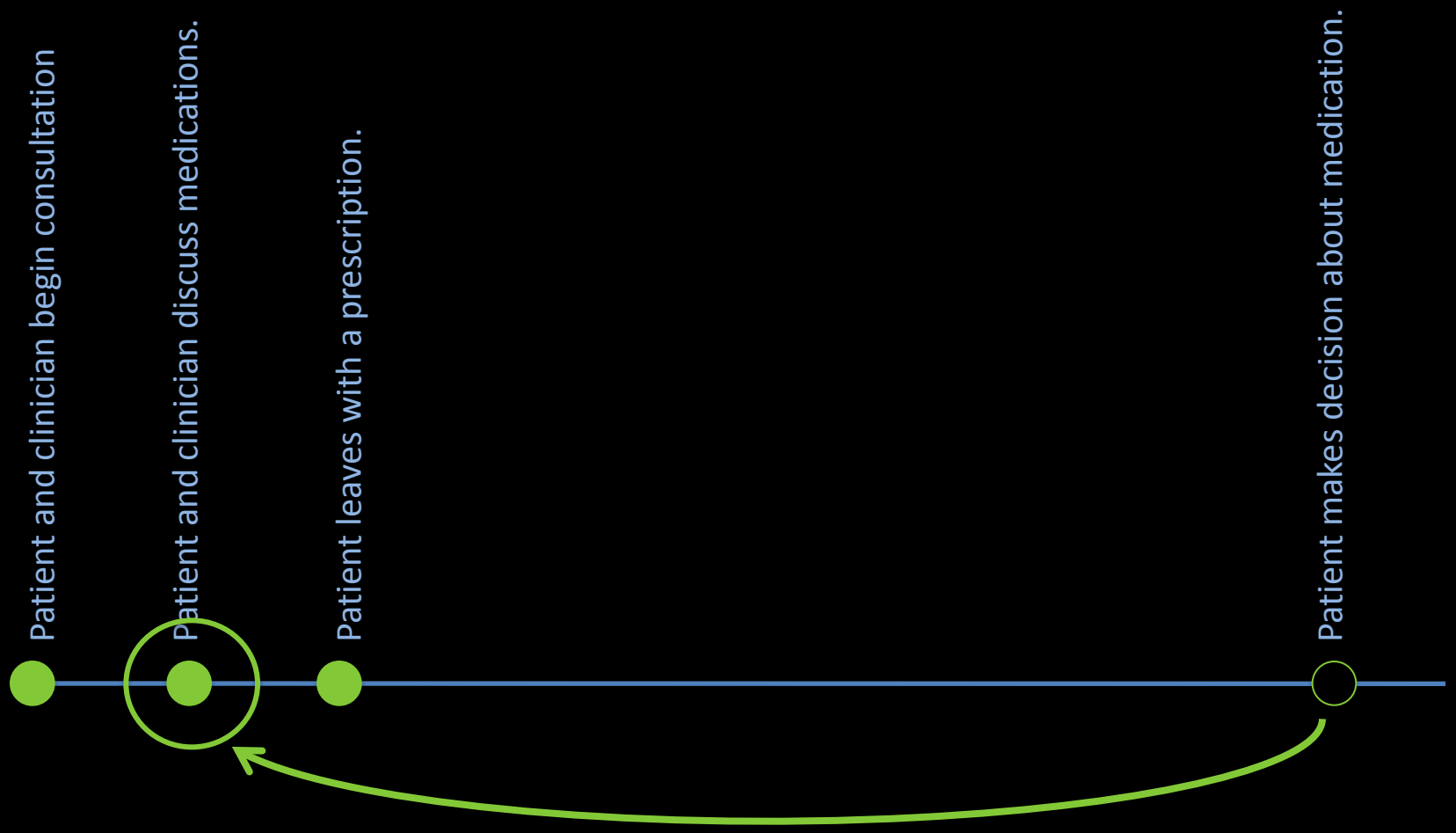
Shared Decision Making

is an approach where clinicians and patients communicate together using the best available evidence when faced with the task of making decisions, where patients are supported to deliberate about the possible attributes and consequences of options, to arrive at informed preferences in making a determination about the best action and which respects patient autonomy, where this is desired, ethical and legal.

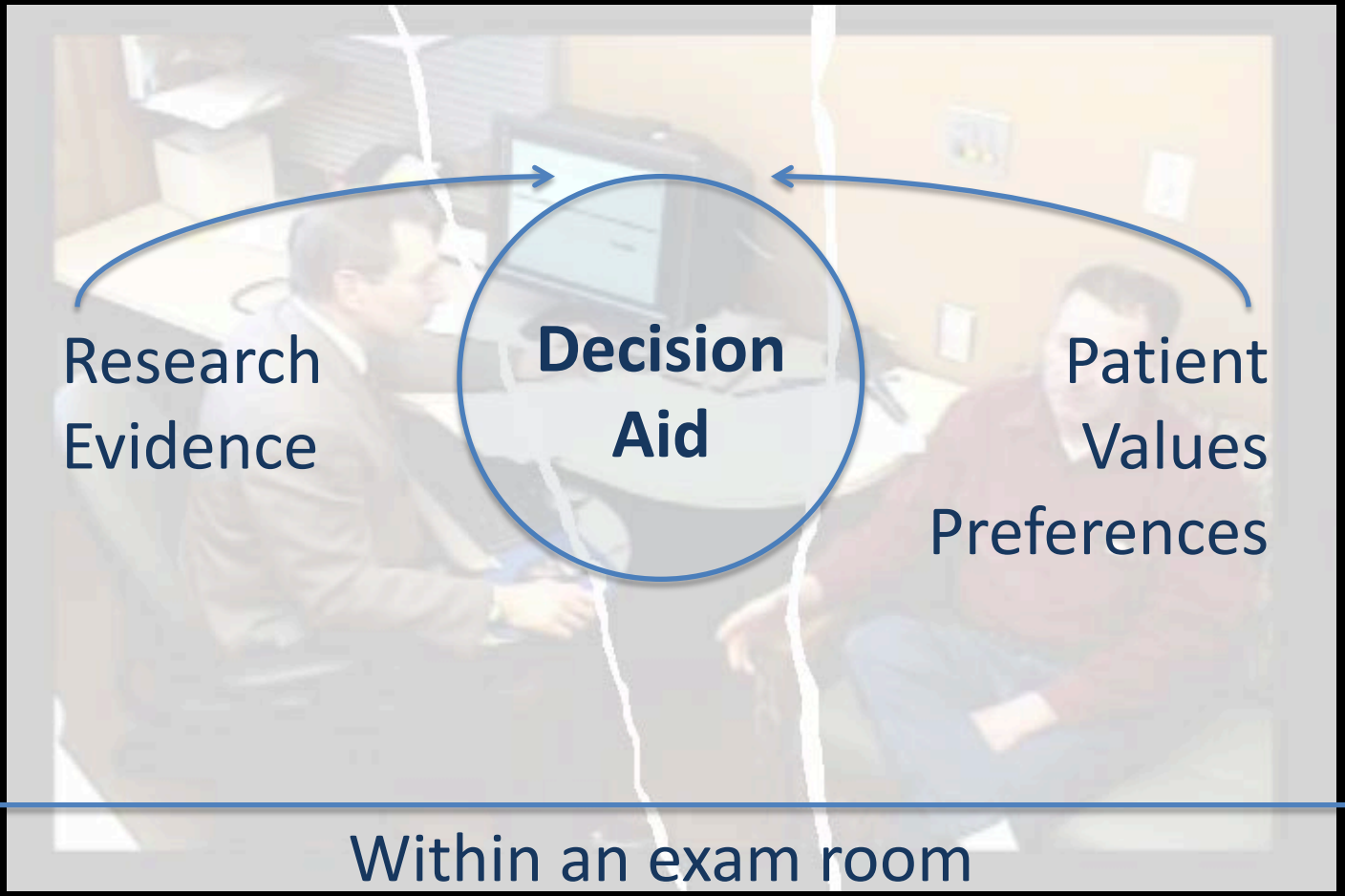
Current state of decision making

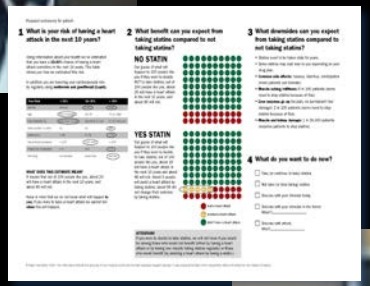


Shared decision making



Shared decision making





1 What is your risk of having a heart attack in the next 10 years?

2 What benefit can you expect from taking statins compared to not taking statins?

NO STATIN

YES STATIN

3 What downsides can you expect from taking statins compared to not taking statins?

4 What do you want to do now?

Our Decision Aids are
focused on facilitating a conversation between
clinicians and patients
and thus
designed as tools intended for use
during the clinical encounter

Conversation not information

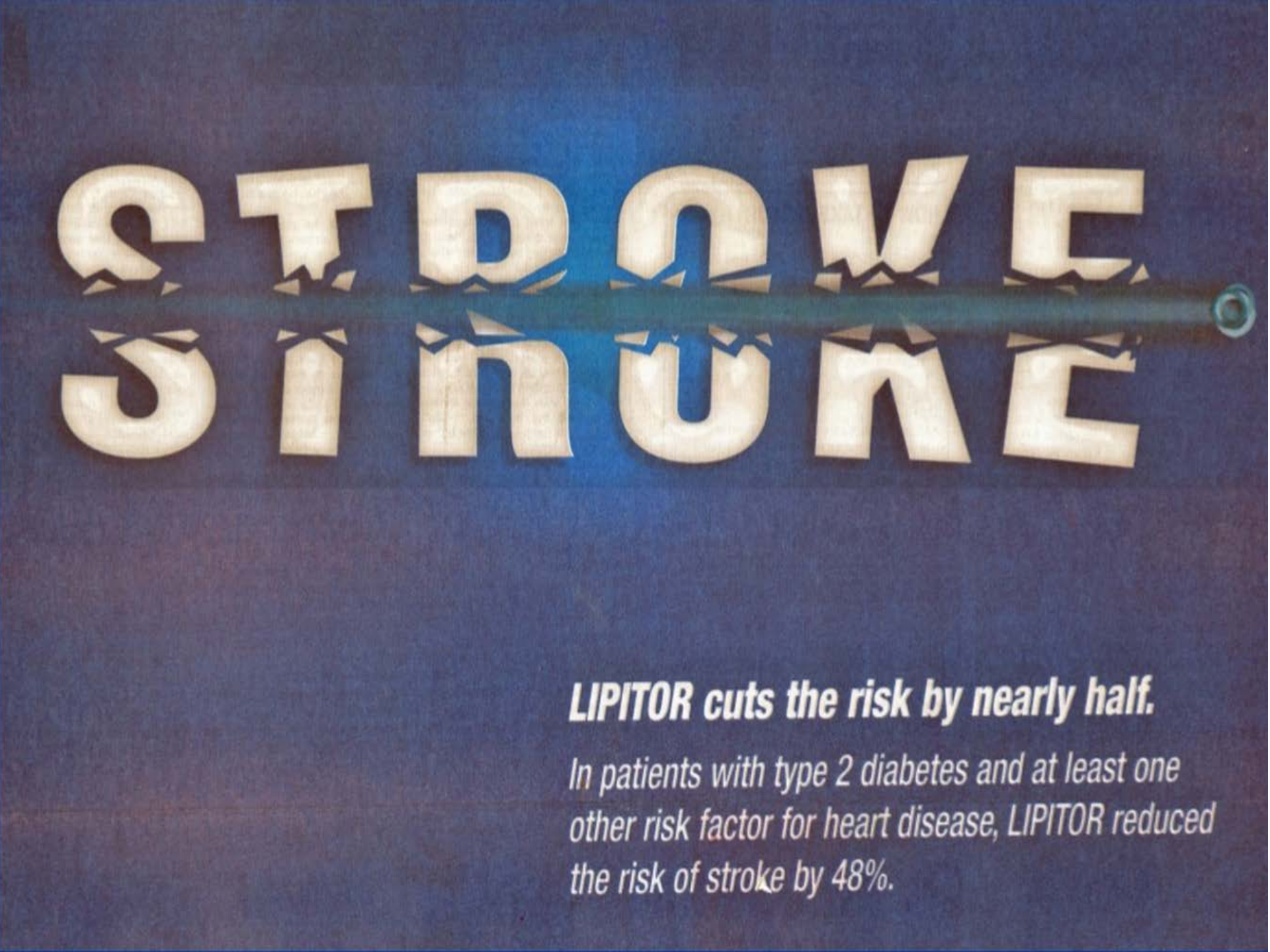
We design to support the interaction of people not the transfer of information

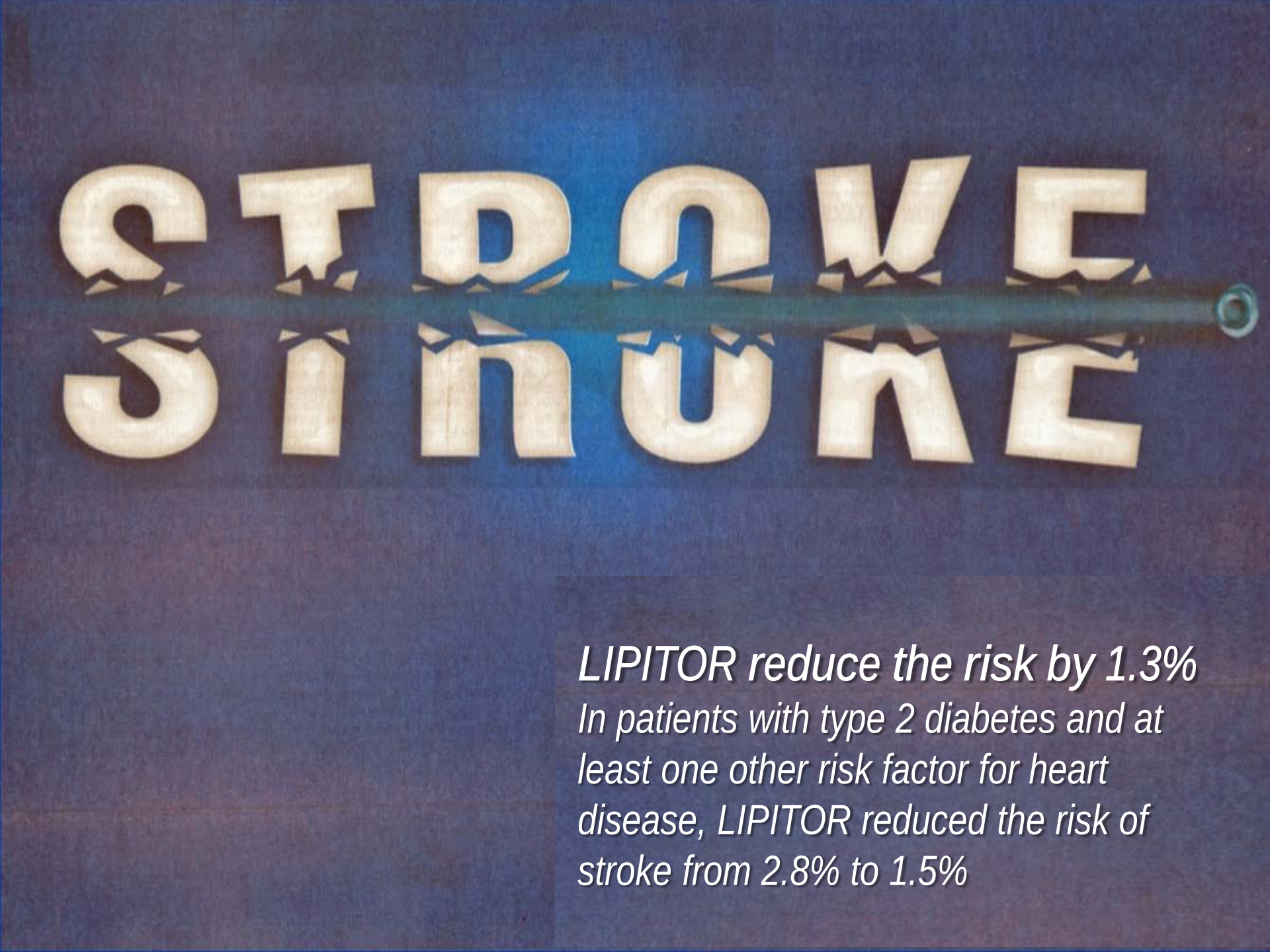
Designed for context

How that is done depends on the challenges of the medical and personal situation

Development is a partnership

The voice and experience of clinicians, patients and caregivers is the impetus of development


STROKE
STROKE
LIPITOR cuts the risk by nearly half.
In patients with type 2 diabetes and at least one other risk factor for heart disease, LIPITOR reduced the risk of stroke by 48%.



LIPITOR reduce the risk by 1.3%

In patients with type 2 diabetes and at least one other risk factor for heart disease, LIPITOR reduced the risk of stroke from 2.8% to 1.5%

~~Communicating risk to patients~~

Employ risk in service of good communication and shared action

Sharing information
Estimates of the likelihood of benefits and harms

You are at high risk of an acute myocardial infarction
If you want to avoid a myocardial infarction you should use a statin

Adapted from Lin/Montori

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Sharing information
Estimates of the likelihood of benefits and harms

You are at high risk of an acute myocardial infarction
If you want to avoid a myocardial infarction you should use a statin

Your risk of an acute myocardial infarction is 20%
Using a statin can reduce that risk by 25%

Adapted from Lin/Montori

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Your risk of a heart attack is 20%
Using a cholesterol medicine, a statin, can reduce that risk by 25%

Adapted from Lin/Montori

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Your risk of an acute myocardial infarction is 20%
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Your risk of a heart attack is 20%
Using a cholesterol medicine, a statin, can reduce that risk by 25%

Out of 100 people like you
20 will have a heart attack over the next 10 years
Using a cholesterol medicine call statin
can reduce that risk from 20 in 100 to 15 in 100

Adapted from Lin/Montori

Sharing information
Estimates of the likelihood of benefits and harms

Weymiller et al. 2007; http://shareddecisions.mayoclinic.org

Risk communication methods

RESEARCH AND REPORTING METHODS | Annals of Internal Medicine

Evidence-Based Risk Communication

A Systematic Review

Daniella A. Zipkin, MD; Craig A. Umscheid, MD, MS; Nancy L. Keating, MD, MPH; Elizabeth Allen, MD; KoKo Aung, MD, MPH; Rebecca Beyth, MD, MSc; Scott Kaatz, DO, MSc; Devin M. Mann, MD, MS; Jeremy B. Sussman, MD, MS; Deborah Korenstein, MD; Connie Schardt, MLS; Avishek Nagi, MS; Richard Sloane, MPH; and David A. Feldstein, MD

Background: Effective communication of risks and benefits to patients is critical for shared decision making.

Purpose: To review the comparative effectiveness of methods of communicating probabilistic information to patients that maximize their cognitive and behavioral outcomes.

Data Sources: PubMed (1966 to March 2014) and CINAHL, EMBASE, and the Cochrane Central Register of Controlled Trials (1966 to December 2011) using several keywords and structured terms.

Study Selection: Prospective or cross-sectional studies that recruited patients or healthy volunteers and compared any method of communicating probabilistic information with another method.

Data Extraction: Two independent reviewers extracted study characteristics and assessed risk of bias.

Data Synthesis: Eighty-four articles, representing 91 unique studies, evaluated various methods of numerical and visual risk display across several risk scenarios and with diverse outcome measures. Studies showed that visual aids (icon arrays and bar graphs) improved patients' understanding and satisfaction. Presentations including absolute risk reductions were better than those including relative risk reductions for maximizing accuracy and seemed less likely than presentations with relative risk reductions to influence decisions to accept therapy. The presentation of numbers needed to treat reduced understanding. Comparative effects of presentations of frequencies (such as 1 in 5) versus event rates (percentages, such as 20%) were inconclusive.

Limitation: Most studies were small and highly variable in terms of setting, context, and methods of administering interventions.

Conclusion: Visual aids and absolute risk formats can improve patients' understanding of probabilistic information, whereas numbers needed to treat can lessen their understanding. Due to study heterogeneity, the superiority of any single method for conveying probabilistic information is not established, but there are several good options to help clinicians communicate with patients.

Primary Funding Source: None.

Ann Intern Med. 2014;161:270-280. doi:10.7326/M14-0295 www.annals.org

For author affiliations, see end of text.

Risk communication methods

Confusing & biased		Clear & Unbiased
Relative risks (RR)	vs.	Absolute risks (AR)
Gain (loss) frame	vs.	Balanced framing
Verbal labels	vs.	Numeric (visual) labels

Adapted from Lin/Montori

Risk communication methods

Confusing & biased		Clear & Unbiased
Relative risks	vs.	**Absolute risks**
Gain (loss) frame	vs.	Balanced framing
Verbal labels	vs.	Numeric/visual labels

Adapted from Lin/Montori

Relative risk vs. Absolute risk
Communicating effectiveness – Which is better?

Mammography reduces the risk of dying from breast cancer in the next 10 years by 25%

Mammography reduces the risk of dying from breast cancer in the next 10 years from 4/1000 to 3/1000

If 1000 women have mammography, one will be saved from dying from breast cancer in the next 10 years

Adapted from Lin/Montori

Relative risk vs. Absolute risk

Communicating effectiveness – Which is better?

Risk for Disease		Absolute Diff	Relative Diff
Group A	**Group B**	**[A-B]**	**[B/A]**
20% (2/10)	10% (1/10)	10%	50%
2% (2/100)	1% (1/100)	1%	50%
0.2% (2/1000)	0.1% (1/1000)	0.1%	50%

If RR for benefits & AR for harms
Additional bias (benefit will seem bigger)

Adapted from Lin/Montori

Risk communication methods

Confusing & biased		Clear & Unbiased
Relative risks (RR)	vs.	Absolute risks (AR)
Gain (loss) frame	vs.	**Balanced framing**
Verbal labels	vs.	Numeric (visual) labels

Adapted from Lin/Montori

Gain (loss) vs. Balanced framing

Gain framing emphasizes the advantages of compliance

"If **you have** regular mammograms, you **increase the chance** of detecting breast cancer at an earlier, more treatable stage."

Loss framing emphasizes costs of NOT performing a behavior

" If **you don't have** regular mammograms, you **reduce your chances** of detecting breast cancer at an early, more treatable stage."

Adapted from Lin/Montori

Risk communication methods

Confusing & biased		Clear & Unbiased
Relative risks (RR)	vs.	Absolute risks (AR)
Gain (loss) frame	vs.	Balanced framing
Verbal labels	**vs.**	**Numeric (visual) labels**

Adapted from Lin/Montori

Verbal vs. numeric (visual) labels

Verbal label

"Your likelihood of having a child with Down syndrome is **high**. There is a **small possibility** that problem will not be detected by the test. Amniocentesis may be recommended in the event of a positive test but this procedure carries a **high risk** of spontaneous abortion."

Numeric label

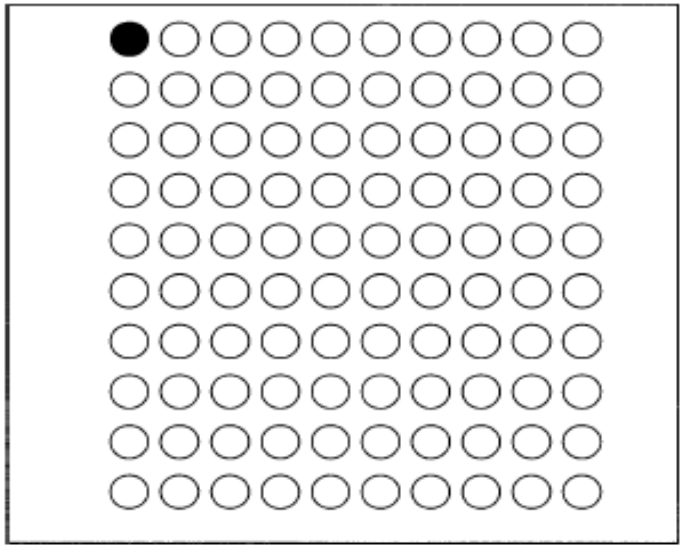
"Of 1000 pregnant women who are 40 yrs old, 10 will have children with Down syndrome. Of those 10 who had Down syndrome, 9 would test positive and 1 would test negative. Of 990 women whose children do not have Down syndrome, 394 would test positive and 596 would test negative."

Adapted from Lin/Montori

Verbal vs. numeric (visual) labels

Visual label

Figure 3
Likelihood of having a Down syndrome baby for a forty-year-old woman



Each circle represents one forty-year-old woman carrying a baby. An empty circle indicates that the baby does not have Down syndrome. A filled circle indicates that the baby does have Down syndrome. This pictograph represents a 1 in 100 chance of having a Down syndrome baby.

Helping Patients Understand Risk Information

Risk of what? Over what time frame?

How big is the risk?

Does the risk information apply to you?

How big is the change in risk?

Does the change in risk reasonably apply to you?

Gigerenzer, - Reckoning risks

Schwartz 2007

Take home message

- **Use frequencies not percentage**

  "Out of every 10 pts who take Prozac, 3 experience sexual problems"

- **Use absolute risks**

  "Mammography screening reduces the risk of dying from breast cancer by about 1 in 1,000: from about 4 in 1,000 to 3 in 1,000."

- **Use balanced framing**

  "If we look at 100 women like you who have this surgery, 97 will survive and 3 will die"

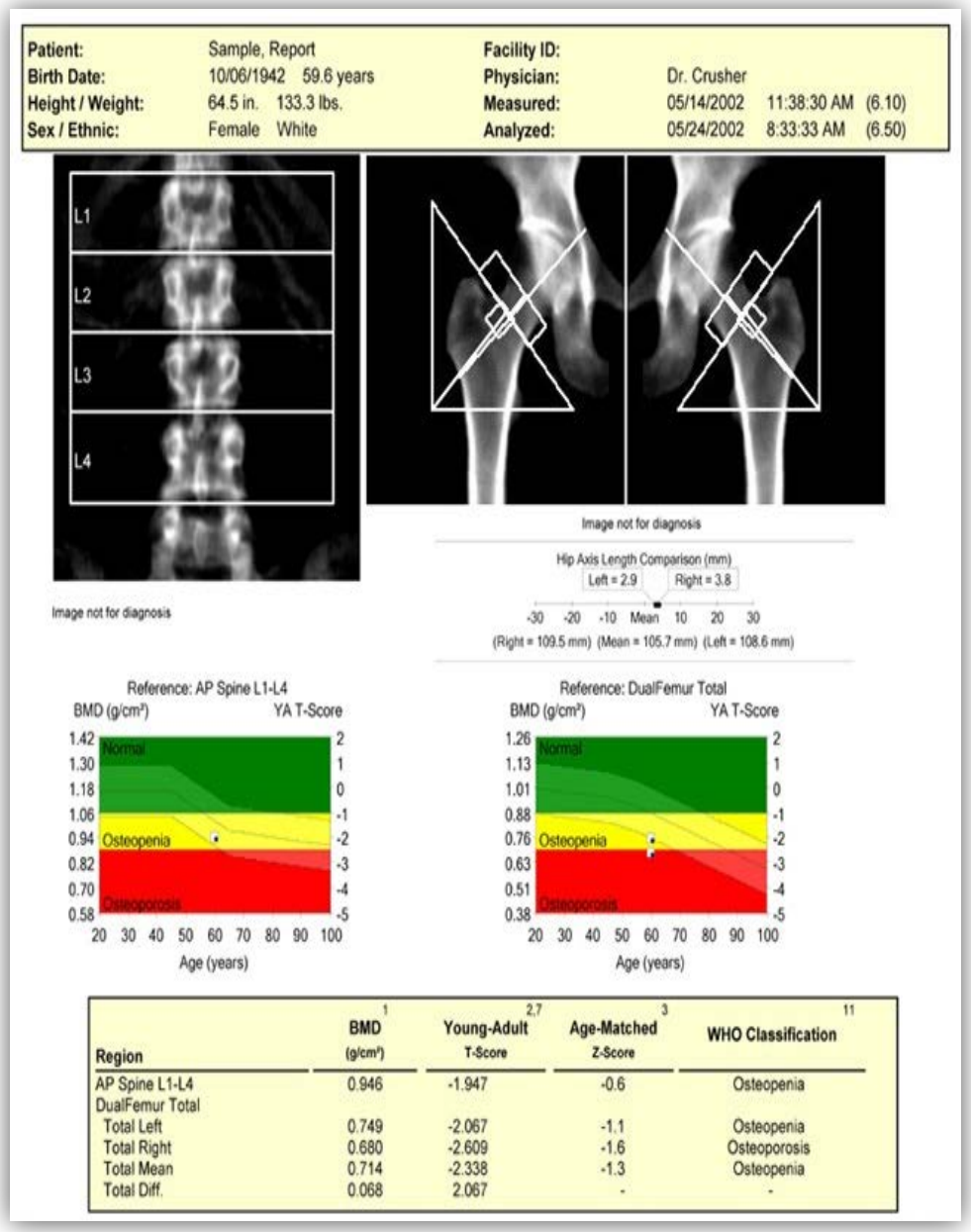
- **Use graphics, pictures to depict risk/benefit information**

  "Pts have better comprehension when presentation format requires less cognitive burden."

~~Communicating risk to patients~~

Employ risk in service of good communication and shared action

The case of osteoporosis



Debrief

What are some of the challenges?

What could have been helpful?

(Now you try it)

osteoporosisdecisionaid.mayoclinic.org/index.php/osteo/index

Current Risk | Intervention | Issues | Notes | Document

Benefits vs Downsides according to my personal health information

3. View Issues

Current Risk of having a fracture

Risk of 100 people like you who do not medicate for bone problems.

Osteo

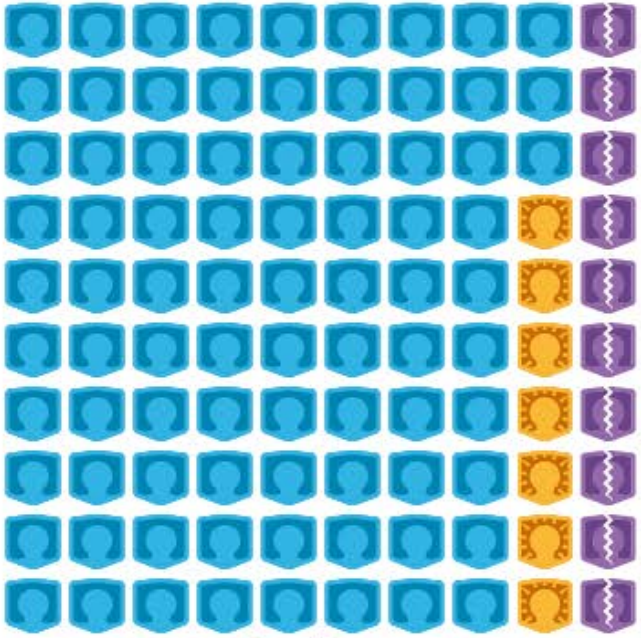
Over 10 years

83 will not break a bone

17 will break a bone

Future Risk of having a fracture

Risk of 100 people like you who do take Bisphosphonates.



Over 10 years

83 will not break a bone

7 will avoid breaking a bone

10 will break a bone

osteoporosisdecisionaid.mayoclinic.org/index.php/osteo/index

Current Risk | Intervention | Issues | Notes | Document

Benefits vs Downsides according to my personal health information

Current Risk of having a fracture

Risk for 100 people like you who **do not** medicate for bone problems.

Over 10 years

83 will not break a bone

17 will break a bone

Cost

With insurance **$30**/year

Without insurance **$70-90**/year

Daily Routine

This medication must be taken:

Once a week

On an empty stomach in the morning

With 8 oz of water

While upright (sitting or standing for 30 min)

30 minutes before eating or taking other medicines.

Expect to take this medicine for 5 years.

Side Effects

Abdominal Problems
About 1 in 4 people will have heartburn, nausea, or belly pain. However, it may not be from the medication. If the medication is the cause, the problem will go away if you stop taking it.

Osteonecrosis of the Jaw
Fewer than 1 in 10,000 (over the next 10 years) will have bone sores of the jaw that may need surgery.

Bone breaks because of the medicine
About 1 in 10,000 people who have used the medicine for more than 5 years will break a bone in their leg because of the medicine.

Future Risk of having a fracture

Risk for 100 people like you who do take Bisphosphonates.

Over 10 years

83 will not break a bone

7 will avoid breaking a bone

10 will break a bone

Debrief

what were some of your struggles?
What would have been helpful?

Opportunities for SDM in practice

When pros and cons are closely balanced

When pros>cons only if patients adhere

When pros and cons are not well known

What if patients ask?

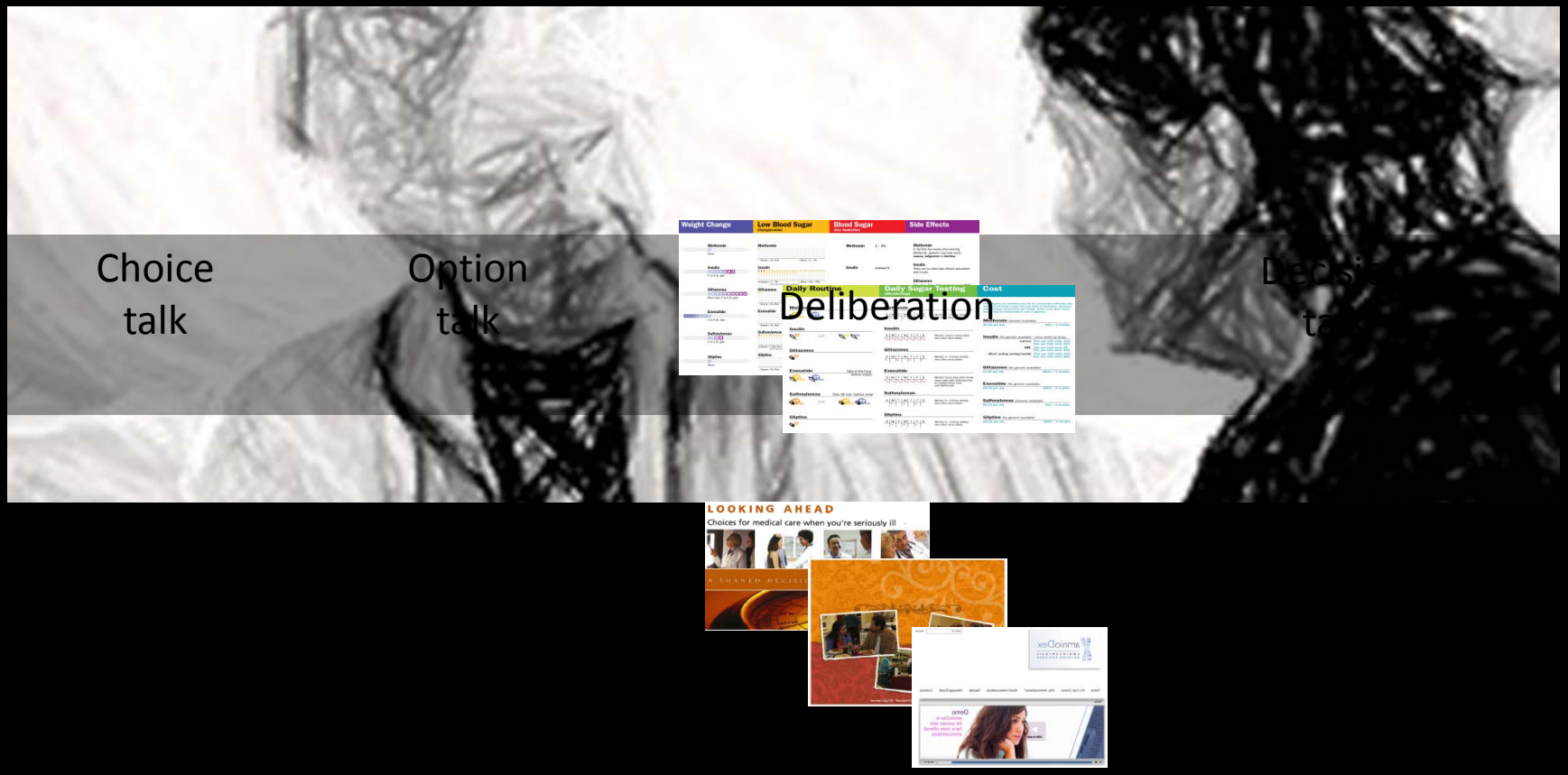
(1) What are my options?

What happens if I do nothing else?

(2) What are the risks and benefits of each option?

(3) How likely are these risks and benefits to happen?

Point of care implementation



The case of Depression Care

Depression Medication Choice

Depression

Can be improved by

Lifestyle changes, self-care practices
psychotherapy, pharmacotherapy

But of different

efficacy, safety, cost, burden to the patient

Comparative efficacy and acceptability of 12 new-generation antidepressants: a multiple-treatments meta

Effective Health Care Program

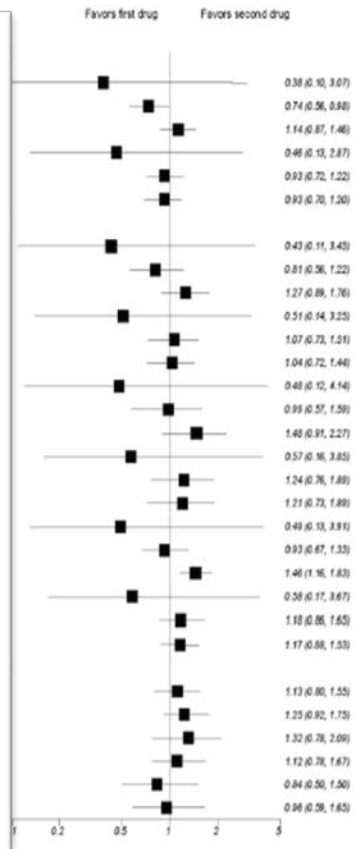
Comparative Effectiveness Review Number 46

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

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



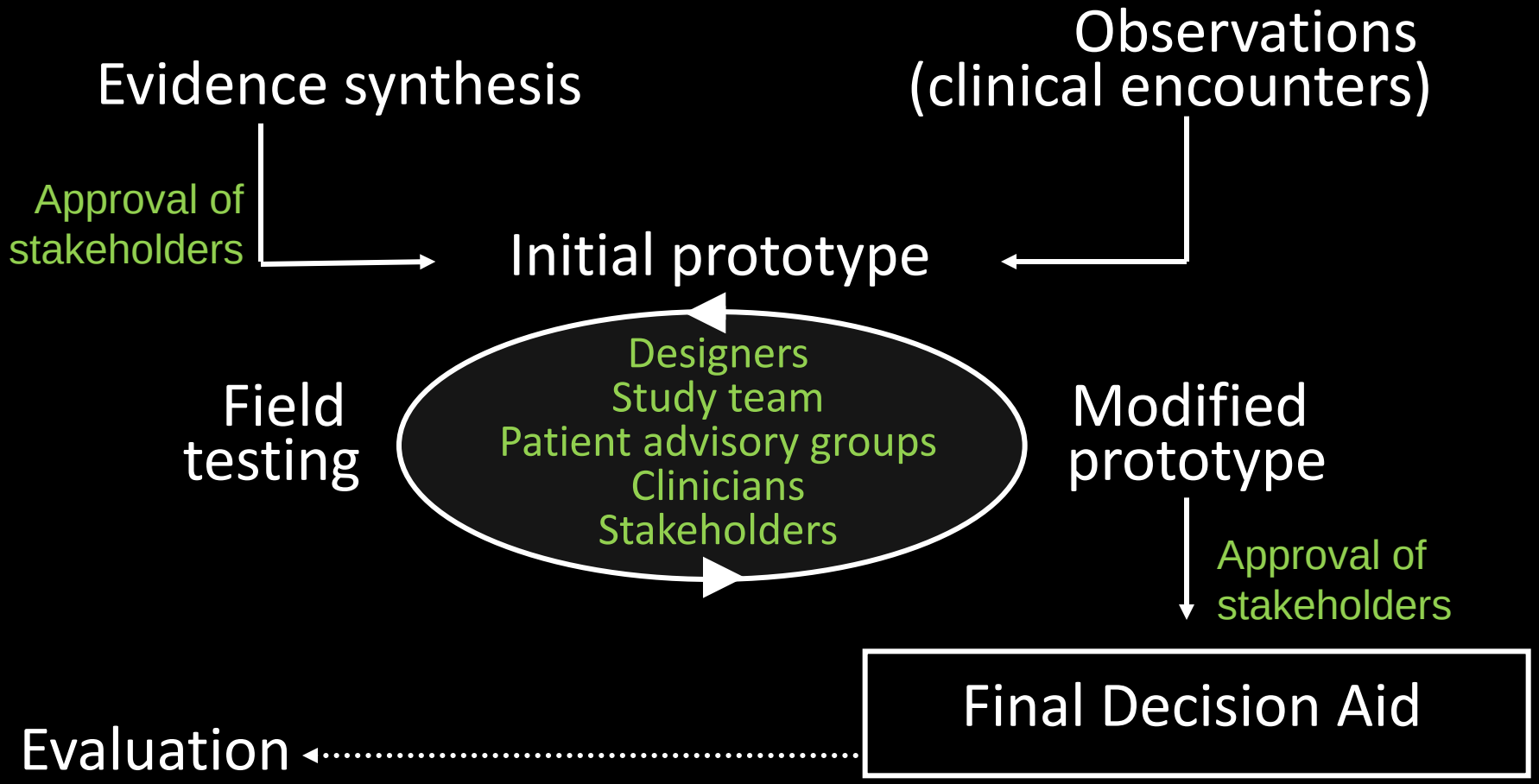
ve efficacy for	Low	substantial differences in efficacy exist among second-generation antidepressants for treatment of accompanying insomnia. Results are limited by study design; differences in outcomes are of unknown clinical significance.
ve effectiveness for	Insufficient	No evidence
ve efficacy for	Insufficient	Results from one placebo-controlled trial of bupropion XL are insufficient to draw conclusions about treating depression in patients with coexisting low energy. Results from head-to-head trials are not available.
ve effectiveness for	Insufficient	No evidence

748 www.thelancet.com Vol 373 February 28, 2009


Fresher! Cleaner!
NEW IMPROVED LIFE!
Better Than Ever!
#1
Prozac
MOOD BRIGHTENER
Wash Your Blues Away!


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

Developing decision aids



LeBlanc et al. 2013

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?

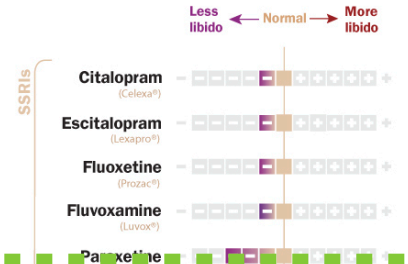
- Most people need to take an antidepressant regularly for at least 6 weeks to begin to get the full effect.

Understanding side effects

- Most people taking ant… one side effect.
- Many side effects go … but some only go away

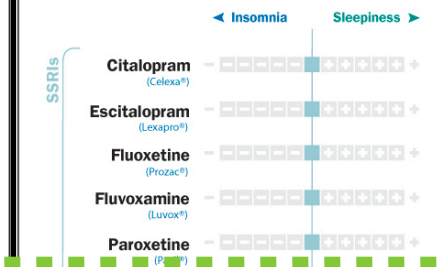
Sexual Issues

Some people may experience loss of sexual desire (libido) or loss of ability to reach orgasm because of their antidepressant.



Sleep

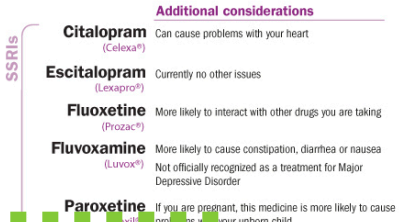
Some people may experience sleepiness or insomnia because of their antidepressant.



Keep in Mind

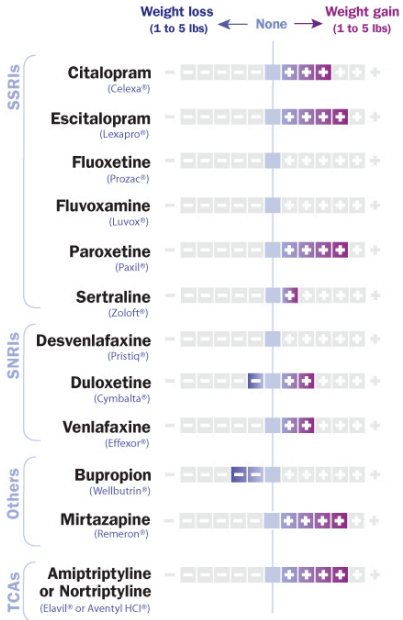
Depression medicines may cause some:

- constipation, diarrhea and nausea
- increased risk of suicidal thoughts and behaviors (18- to 24-year-olds)
- harm to an unborn child
- risk of developing serotonin syndrome, a potentially life-threatening condition
- possible drug-drug interactions



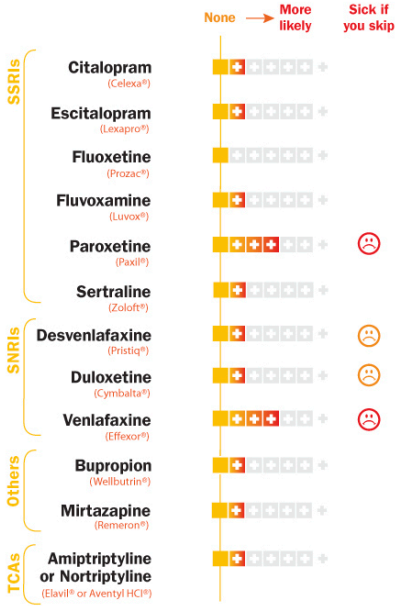
Weight Change

Some people may experience weight change. It is most likely to occur over six to twelve months and depends on your actual weight. The chart below is based on a 150 lb person.



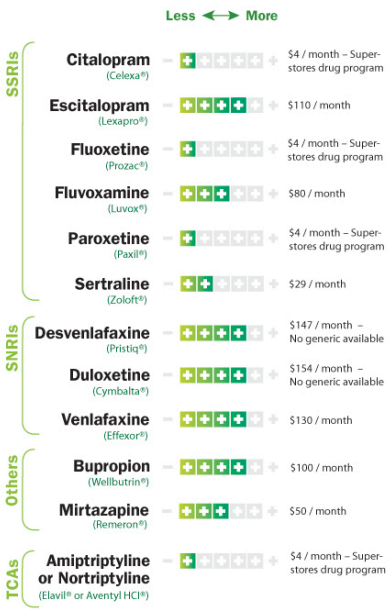
Stopping Approach

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).



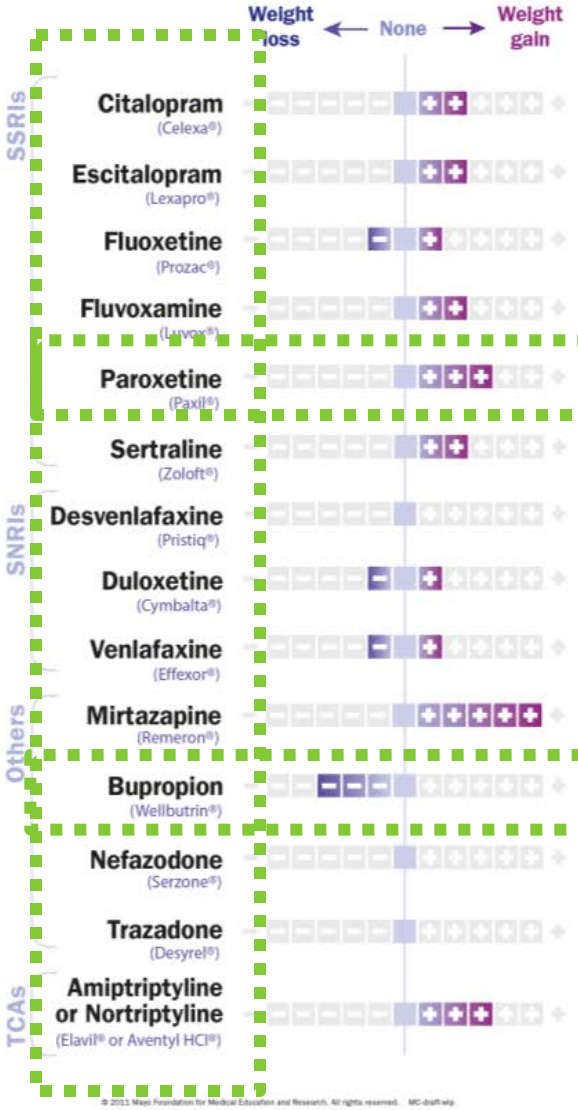
Cost

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.



Weight Change

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



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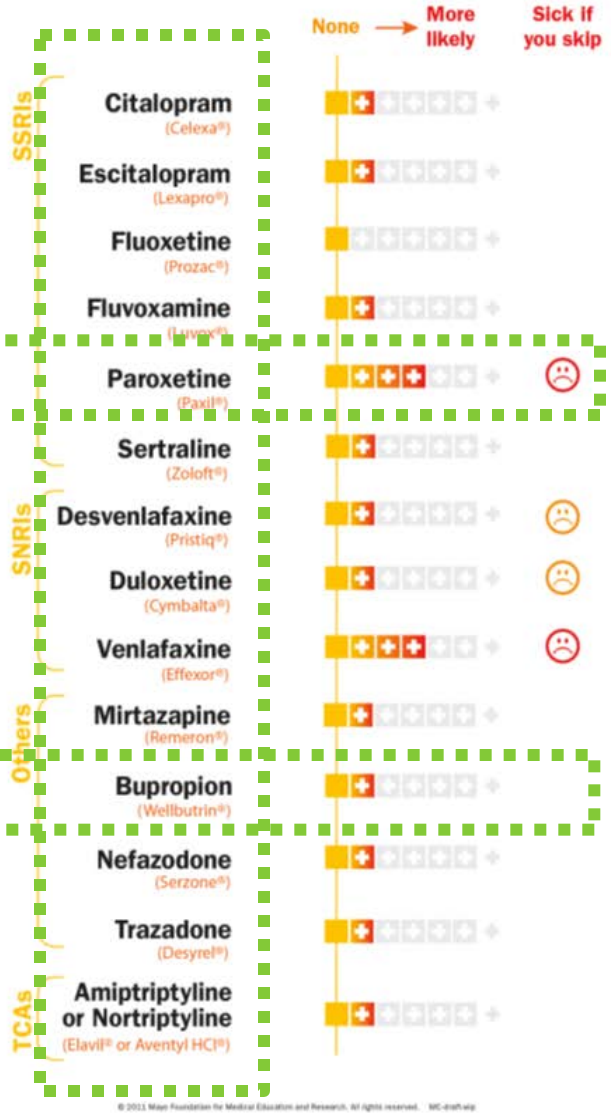
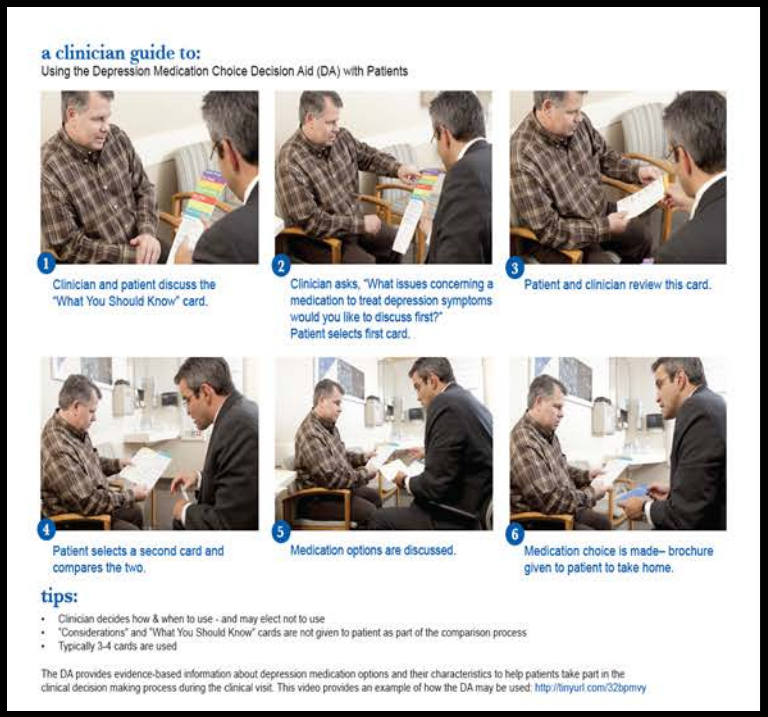


Associated Resources



a clinician guide to:

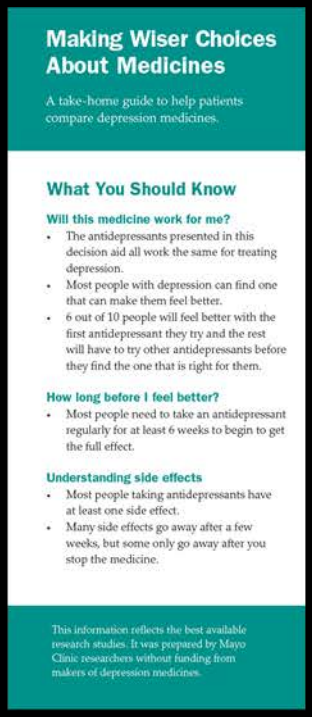
Using the Depression Medication Choice Decision Aid (DA) with Patients

1. Clinician and patient discuss the "What You Should Know" card.
2. Clinician asks, "What issues concerning a medication to treat depression symptoms would you like to discuss first?" Patient selects first card.
3. Patient and clinician review this card.
4. Patient selects a second card and compares the two.
5. Medication options are discussed.
6. Medication choice is made– brochure given to patient to take home.

tips:

- Clinician decides how & when to use - and may elect not to use
- "Considerations" and "What You Should Know" cards are not given to patient as part of the comparison process
- Typically 3-4 cards are used

The DA provides evidence-based information about depression medication options and their characteristics to help patients take part in the clinical decision making process during the clinical visit. This video provides an example of how the DA may be used: http://tinyurl.com/32bpmvy



Making Wiser Choices About Medicines

A take-home guide to help patients compare depression medicines.

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.

This information reflects the best available research studies. It was prepared by Mayo Clinic researchers without funding from makers of depression medicines.

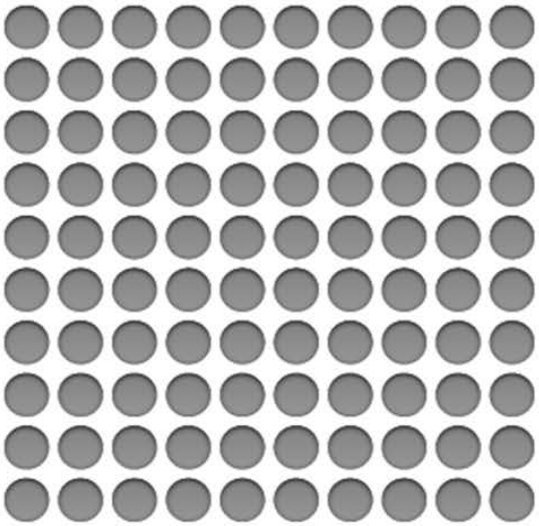
http://shareddecisions.mayoclinic.org

(Free to access/download)

Additional decision aid examples

MAYO CLINIC

Statin/Aspirin Choice
Decision Aid



Welcome to the Statin/Aspirin Choice Decision Aid.

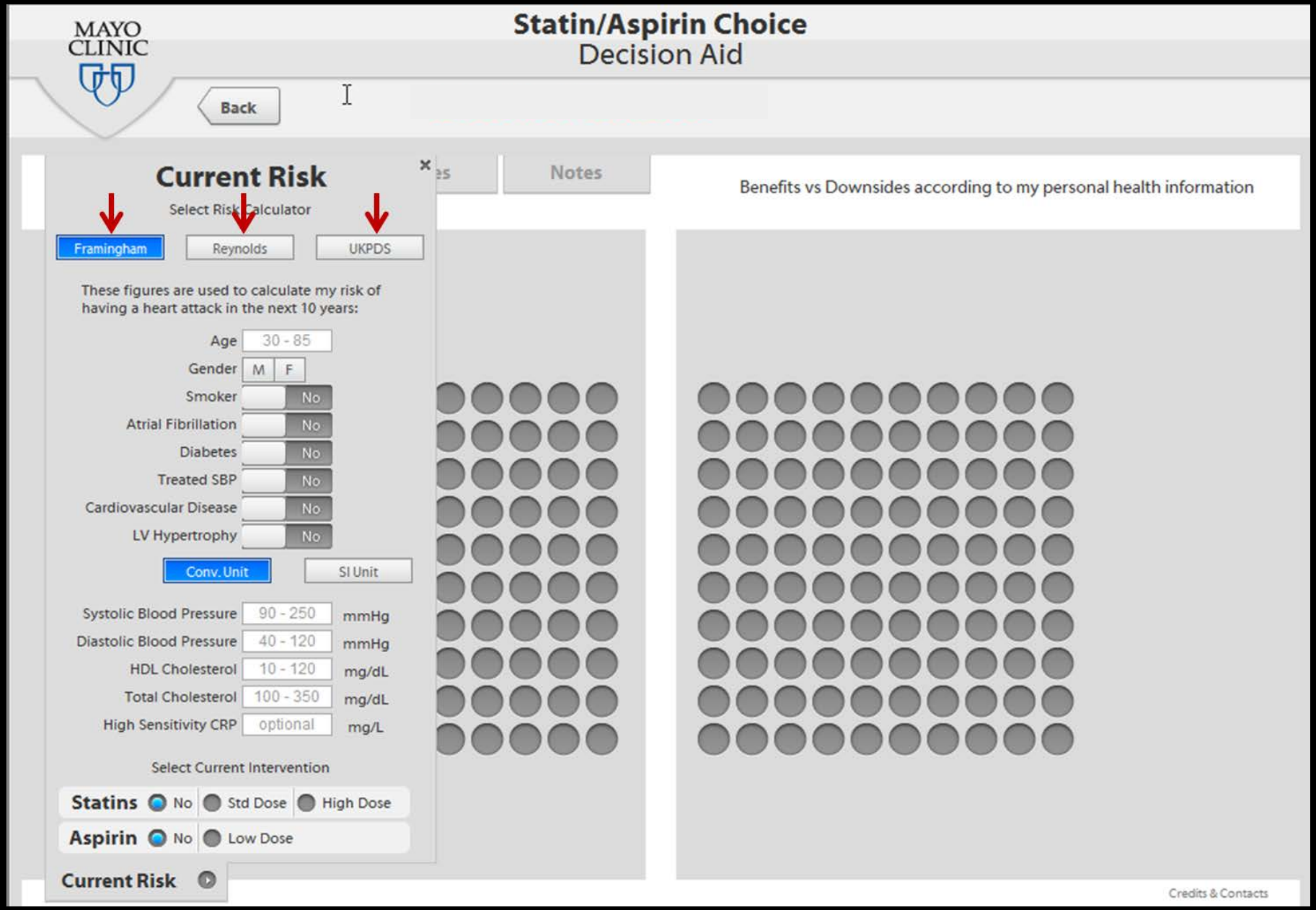
This tool will help you and your doctor discuss how you might want to reduce your risk for heart attacks.

Let's get started

Caution: This application is for use exclusively during the clinical encounter with your clinician

Credits & Contacts

http://statindecisionaid.mayoclinic.org/



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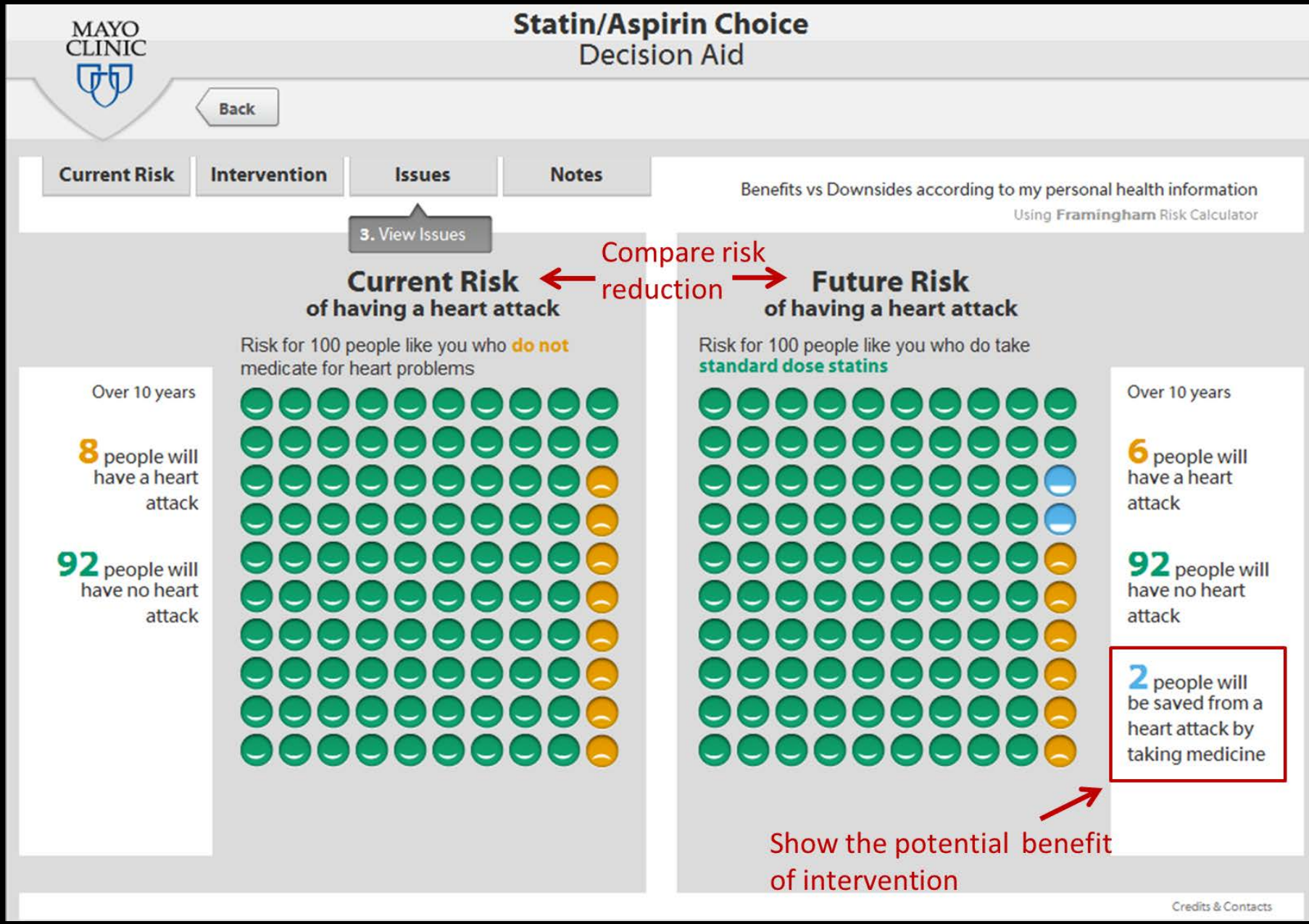


http://statindecisionaid.mayoclinic.org/

MAYO CLINIC

Statin/Aspirin Choice
Decision Aid

Back

Share

Current Risk | Intervention | Issues | Notes

Benefits vs Downsides according to my personal health information

Using **Framingham** Risk Calculator

Discuss issues with intervention

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

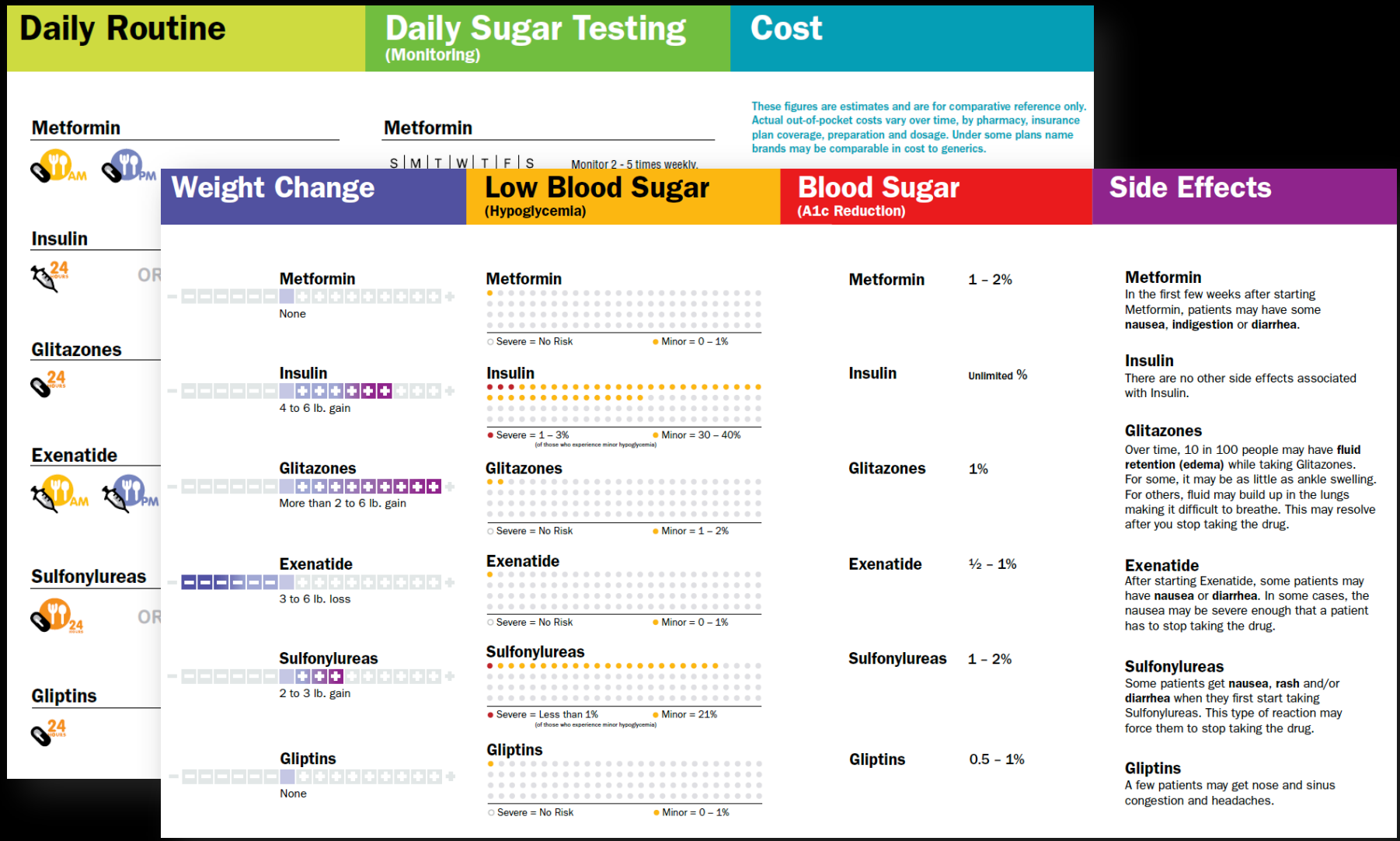
Risk for 100 people like you who do take standard dose statins

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

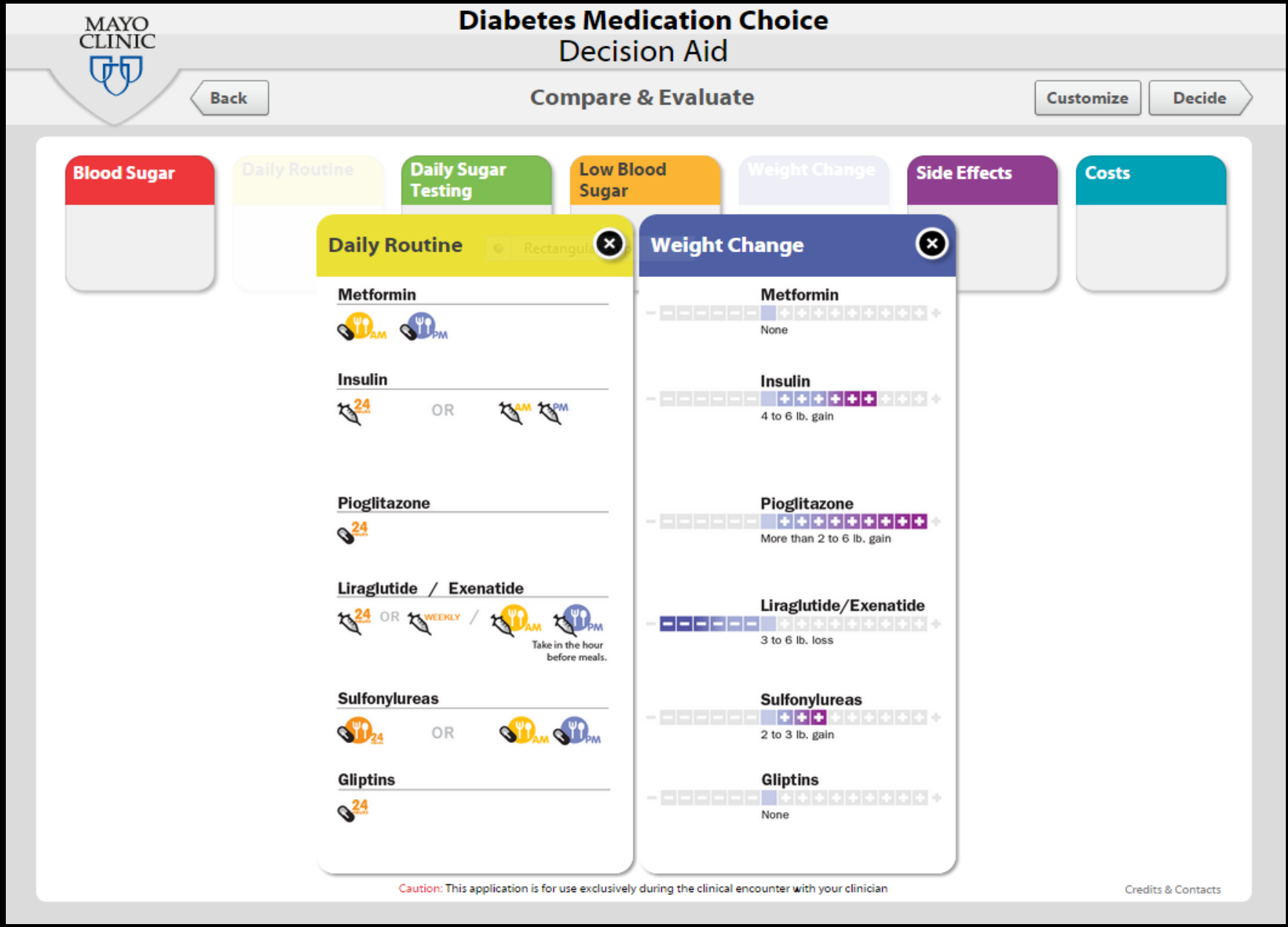
Credits & Contacts

http://statindecisionaid.mayoclinic.org/

Diabetes Medication Choice



Mullan et al. 2009



http://diabetesdecisionaid.mayoclinic.org/

Work	Setting	Evaluation
Statin Choice	**Primary + specialty care**	**Feasible, effective, implemented in EHR, multicenter trial**
DM2 Med Choice	**Primary care**	**Feasible, effective, multicenter trial**
Aspirin Choice	Primary care (group)	Not evaluated
Depression Choice	**Primary care**	**Design phase**
Genomic Choice	Experimental	Design phase
Osteoporosis Choice	**Primary care**	**Feasible, effective**
ICD Choice	Specialty care	Design phase
Smoking choice	**Primary care**	**Design phase**
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	Design phase
Mammography < 40	Primary care	Design phase
Menopause symptoms	Primary care	Design phase

Bold type: Randomized trials

“Does it work?”

Objectives

To determine the ability of a decision aid
(used by clinicians & patients during encounters)
to
translate the best available evidence
enable shared decision making
impact patient/clinician/practice outcomes

What we found (Depression)

Patients & clinicians were

more comfortable with the decision made (>20% ↑)

more satisfied with the decision process (30% ↑)

Patients were

more knowledgeable (14% ↑)

more involved in the decision making process (50% ↑)

**No difference in adherence to medication or in depression outcomes*

What we found (Depression)

158 clinicians

Used DMC in encounters = 81%

Found easy to very easy to use = 72%

Fidelity to intended use = 48%

Additional observations

Clinician stated more than one option

DMC=81% vs. UC=54%

Clinician noted interactions/health considerations

DMC=40% vs. UC=8%

Clinician invited pt to choose issue of greatest salience

DMC=63% vs. UC = 0%

Clinician voiced a preference for treatment

DMC=95% vs. UC=92%

Patient voices a preference for treatment

DMC=92% vs. UC=69%

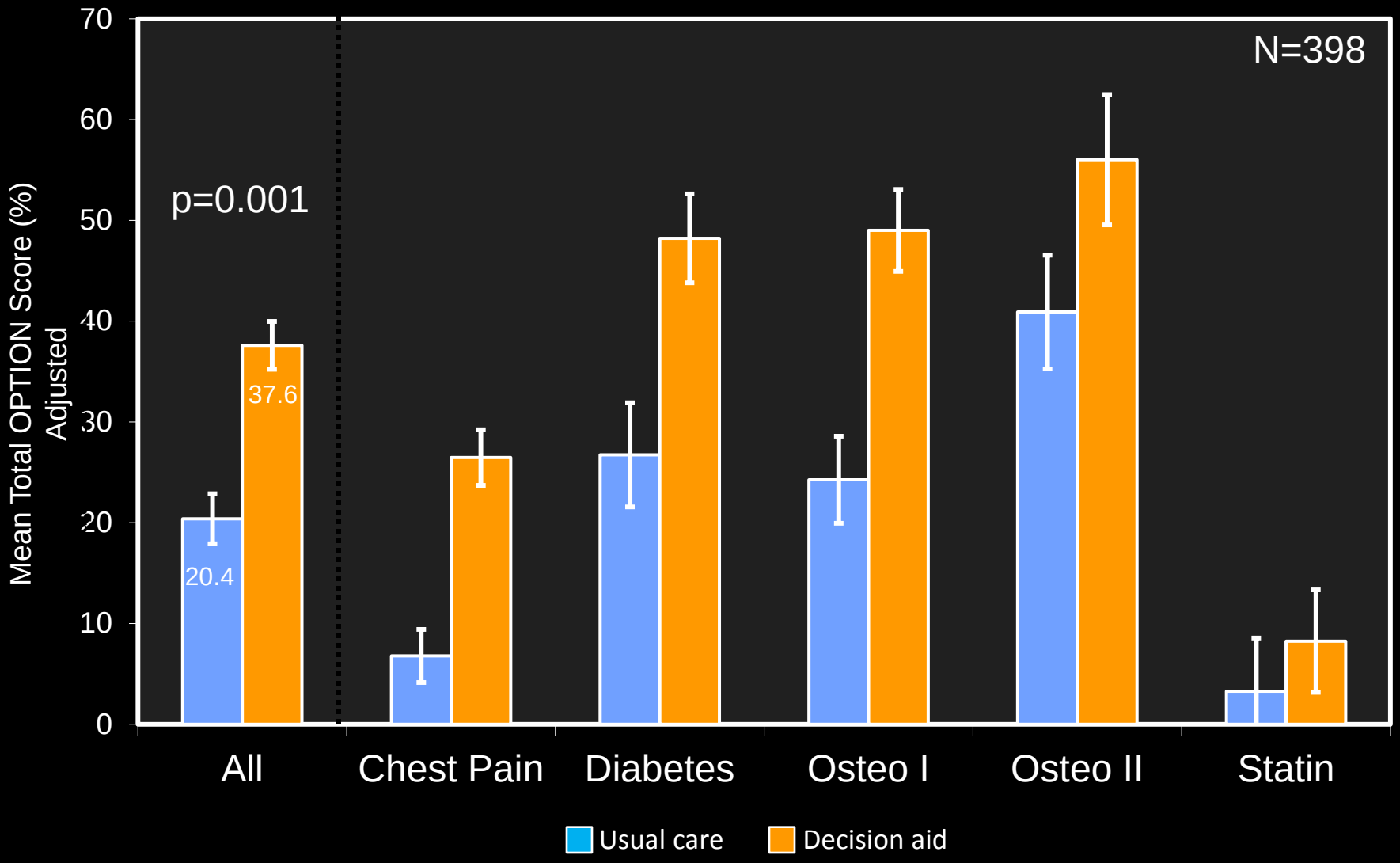
They have been helpful within our Decision Support Center; especially when time is of the essence because they are so easy to use. They have been great tools to use when someone might have a lot of anxiety surrounding looking for resources/information from the computer (Lawrence, Kansas)

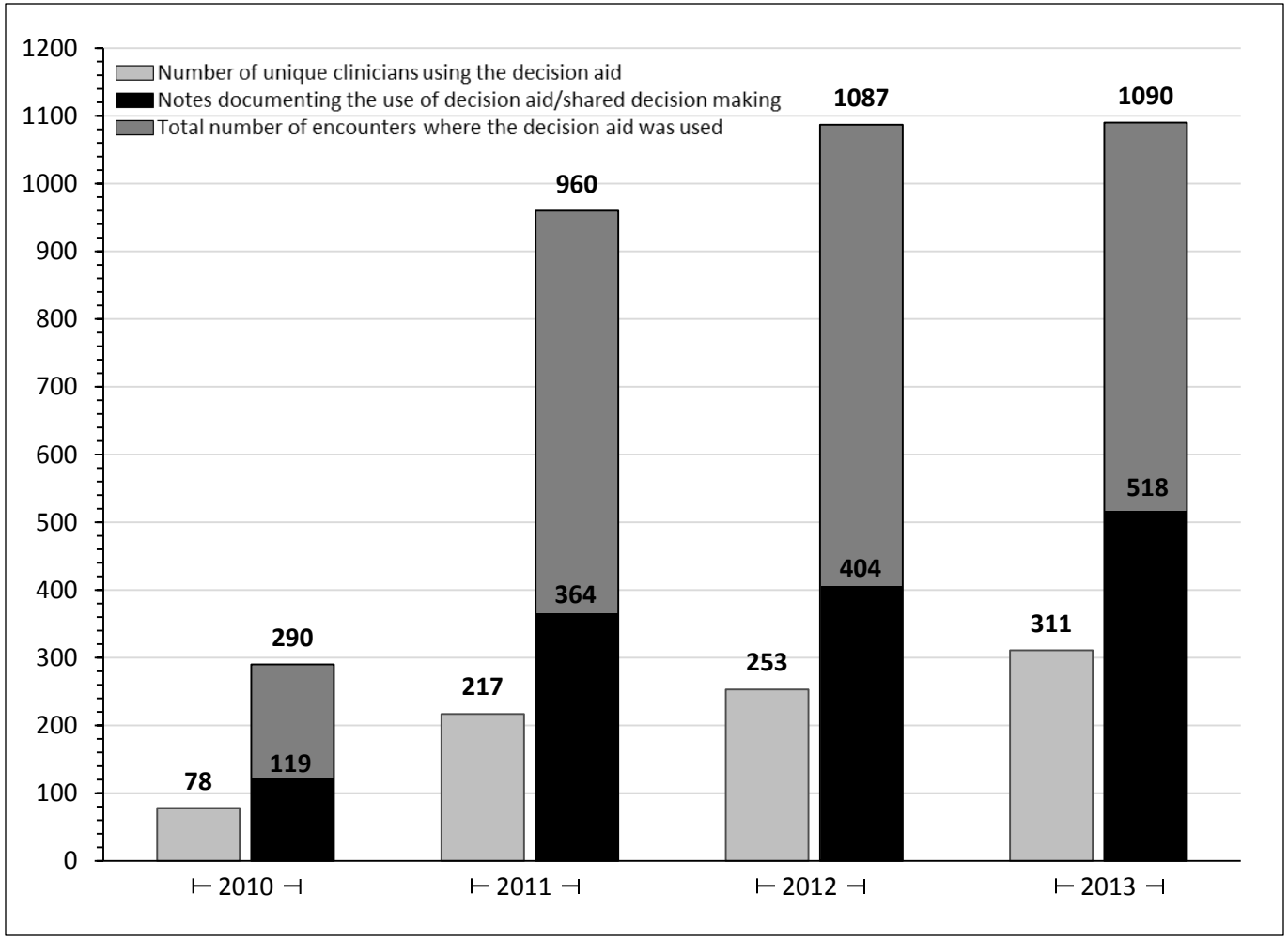
I experienced attending physicians who previously were reluctant to prescribe antidepressants, change their behaviors when they have the cards to help guide the conversation. The feedback has been unanimously positive and every provider who sees me demo the cards asks me for a set. (NYC)

we are actively using the depression shared decision making cards that you gave us. They are wonderful. Our job becomes much easier when the patients feel active participants in their treatment. Thank you so much! (Morrisania D&Tcenter, NY)

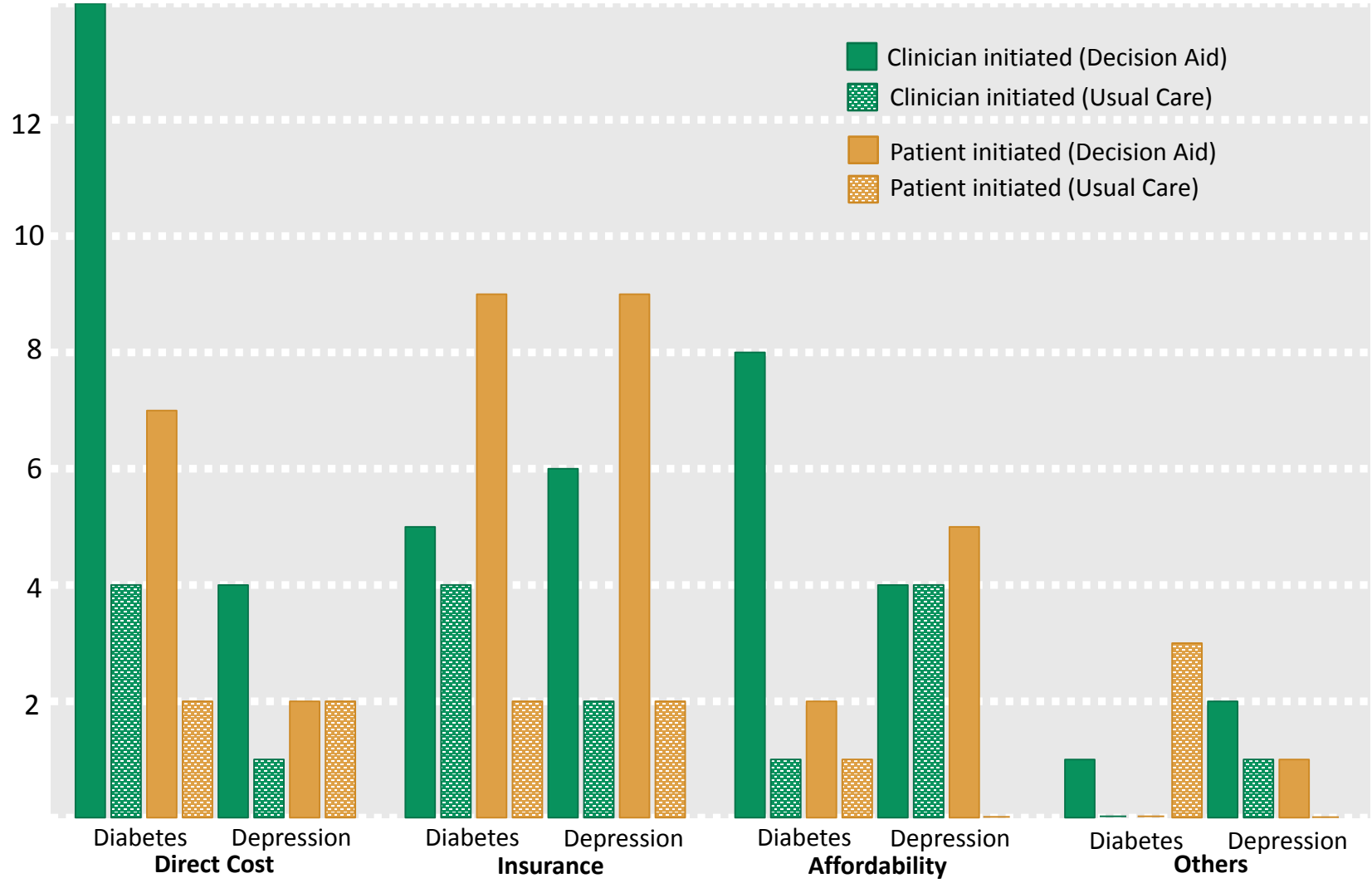
As the Montefiore Deputy Medical Director for DSRIP in the Hudson Valley, I will be responsible for engaging over 200 partners to do the systems redesign work needed to improve primary care for hundreds of thousands of medicaid and uninsured lives in the Hudson Valley. I wanted to let you know that I intend for us to disseminate the Antidepressant Decision Cards broadly across the NYS health system.

Patients involvement




Number of unique clinicians using the decision aid
Notes documenting the use of decision aid/shared decision making
Total number of encounters where the decision aid was used
1200
1100
1000
900
800
700
600
500
400
300
200
100
0
78
119
290
217
364
960
253
404
1087
311
518
1090
2010
2011
2012
2013

Frequency and type of cost discussions during clinical encounters



Summary of experience

Age: 20-92

74-90% clinicians want to tools again

Adds <3 minutes to consultation

60% fidelity without training

20% improvement in patient knowledge

17% improvement in patient involvement

Variable effect on clinical outcomes and cost

Summary of experience

Creating a conversation between patients and clinicians provides a way to deal with conflict which is an inevitable part of the healthcare delivery system

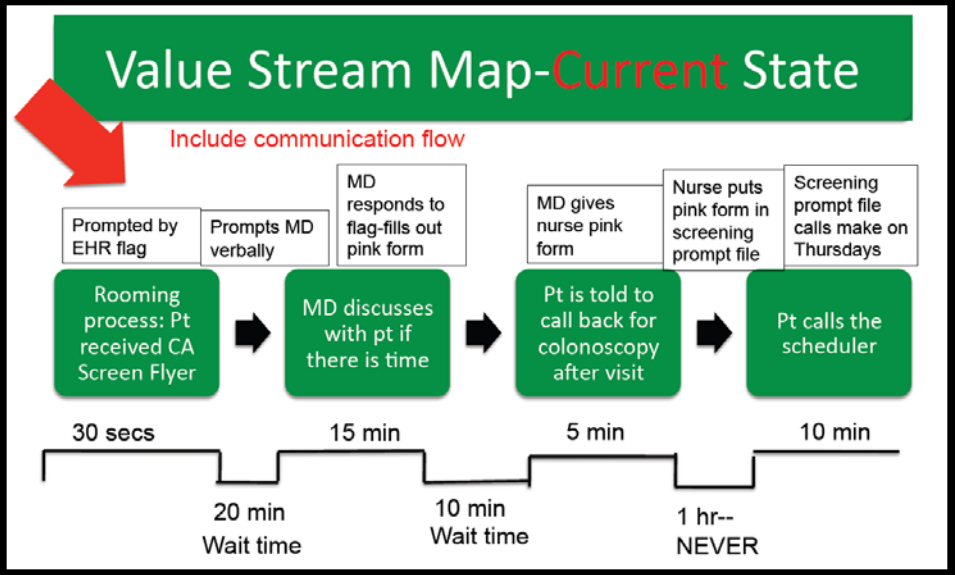
Gives permission to patients and clinicians to acknowledge factors in decision making

Lack of ability to provide a specific answer isn't viewed negatively

Tools structure the conversation and skill of both the patient and the clinician

Process Mapping

- Map patients' journey from door-in to door-out



- Once mapped, determine:
  - Where and when DAs will be introduced
    - Where will the DAs "live"
    - Who will make sure the DAs are available
  - Who will introduce DAs (example: diabetes educators, nurses, physicians)

SDM Presentations

- 15, 30, 60 minute presentations
- Content
  - Overview of shared decision making (SDM) and the evidence for SDM
  - Overview of the DAs and their evidence
  - Script provided
- Audience
  - General

Training videos for DAs

- 3 different versions
  - Role playing http://www.youtube.com/watch?v=xlmUvAcb-sM&feature=youtu.be
  - Voice over http://www.youtube.com/watch?v=xlmUvAcb-sM&feature=youtu.be
  - Clinician talking through a DA http://www.youtube.com/watch?v=qwyx7yAP5zA

EMR Templates

- Provide electronic links to the online DAs
- Give providers standardized language about SDM so they can:
  - copy and paste into note
  - include as part of note templates

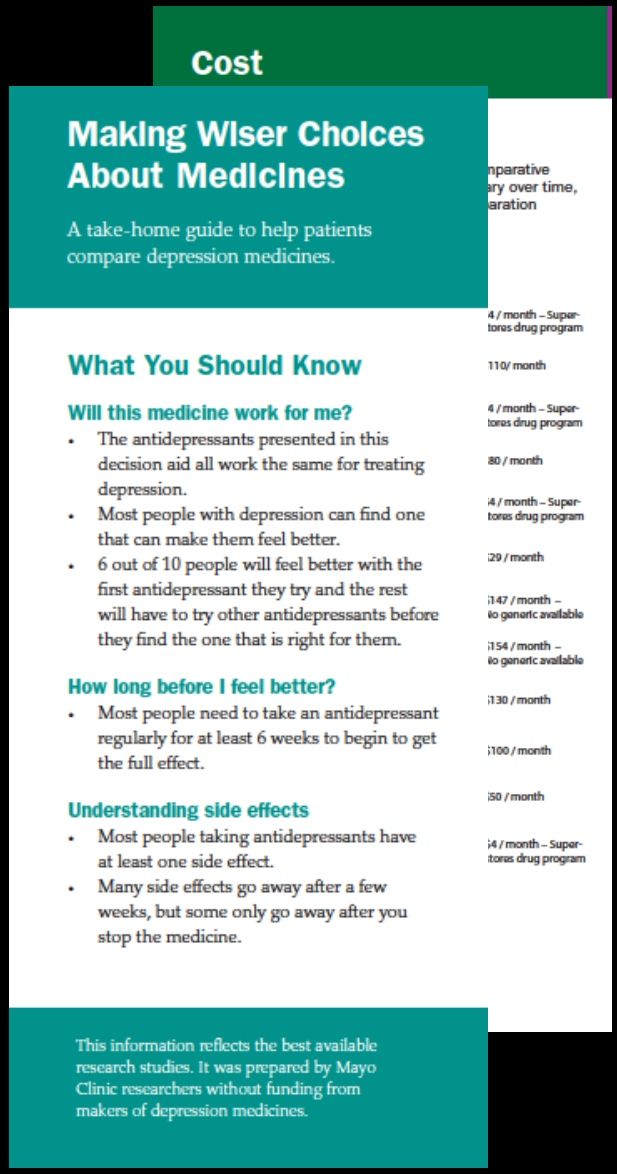
“I have used a decision aid to share decision making with the patient about interventions to reduce the risk of coronary events.

We estimated and discussed the patient's 10-year of coronary events *6%* and how this risk could be reduced with the use of statins and aspirin.

After considering the patient's unique circumstances and the pros and cons of the alternatives, we have decided to...”

Patient Education Materials

- Educate patients on SDM, so they are prepared when the providers use SDM during the encounter
- Format
  - Leaflets
  - Posters



Journal Club “Kit”

- Includes articles on SDM
- Study questions and case studies to go along with the article

CASE 1.

Mrs. Parker is a 58 year-old woman with type 2 diabetes. She has an LDL cholesterol level of 160 mg/dL, HDL cholesterol level of 60 mg/dL, and a total cholesterol level of 240 mg/dL, which has not changed with diet. Her average blood pressure readings are 135/80 mmHg, and she does not smoke. She comes to the consultation wondering if she should take a statin.

Cardiovascular Perspective

Reinitiation of Statins After Statin-Associated Musculoskeletal Symptoms

A Patient-Centered Approach

Juan P. Brito, MD; Victor M. Montori, MD, MSc

A 58-year-old man receives primary care for obesity, hypertension, smoking, and dyslipidemia. He used atorvastatin until a few months ago but stopped because of muscle discomfort with activity, night cramps, and tendon soreness. He comes today to discuss treatment for his dyslipidemia.

Coronary artery disease is a leading cause of premature morbidity and mortality worldwide.[1] Although highly prevalent, cardiovascular mortality has decreased over the last few decades in high-income countries.[2] This success has resulted from improvements in public health, control of cardiovascular risk factors, and increased use of evidence-based therapies to prevent and treat coronary disease.[3]

The use of 3-hydroxy-3-methylglutaryl-coenzyme A reductase inhibitors, or statins, stands tall among evidence-based therapies that are able to reduce cardiovascular risk. The ability of statins to reduce cholesterol blood levels and to reduce cardiovascular risk is well established. The use of adherent statin can reduce coronary risk by 25%, with greater reductions possible with higher doses.[4] Worldwide, practice guidelines reflect experts' confidence in this evidence of efficacy, recommending statins to at-risk patients, making statins one of the most prescribed medication classes in modern medicine.[5] This confidence contrasts with the limited or unknown efficacy in reducing coronary risk of other available and commonly used lipid-lowering agents (eg, fibrates, niacin, fish oil, ezetamibe).[6-9]

The efficacy of statins, however, is limited in part by statin discontinuation. In some cohorts, half of all patients, even those at highest risk of coronary events, discontinue statin therapy within 2 years of their prescription.[10,11] Much of this discontinuation may be attributed to the complex phenomenon of patient nonadherence. Another explanation is the development of side effects in general and of musculoskeletal complains in particular.

Estimates of the incidence of these musculoskeletal symptoms attributed to statins vary according to study design, statin studies, and definitions used. Randomized clinical trials with narrow exclusion criteria estimate the incidence of these complaints to be between 1% and 5%.[12] Large observational studies estimate their incidence at ≈10%.[13,14] A recent prospective study in clinical practice found these complaints to be as frequent as 15%.[15] Taken together, clinicians will have to address musculoskeletal complaints linked to statins in 1 of every 10 patients to whom they prescribe statins. The key challenge for the clinician is to find, when possible, a way to preserve the cardiovascular benefits of statins in patients experiencing musculoskeletal side effects attributed to statins.

Here, we present an approach to support clinicians and patients in making the decision to reinitiate statins. We offer a practical definition of the problem, identify risk factors for it, and formulate a model for engaging patients in making treatment decisions about statin reinitiation.

Need for a Practical Definition

Several expert societies have offered criteria for the diagnosis of musculoskeletal symptoms attributed to statins. The American College of Cardiology, American Heart Association, and the National Heart, Lung and Blood Institute of the National Institutes of Health define the presence of any muscle symptom without elevation of creatine kinase (CK) as myalgia and with CK elevation as myositis.[16] The attribution of musculoskeletal symptoms to statins is difficult, and most complaints are not associated with abnormalities of CK, an imperfect marker of muscle damage.[17] Therefore, these definitions relate symptoms to an unreliable marker of muscle damage and ignore a significant proportion of patients who present with tendinopathy[18] rather than with myalgias.

Statin-associated musculoskeletal syndrome (SAMS) comprises musculoskeletal symptoms or signs (muscle or tendon discomfort, pain, or impaired function) that develop while the patient is taking statins, decrease the health-related quality of life of the patient, and resolve after statin discontinuation. We have not been able to identify data to support the subclassification of SAMS according to whether CK levels are elevated at the time of diagnosis. In the absence of this evidence, we suggest managing all forms of SAMS, whether associated with CK elevations or not, similarly.

Rhabdomyolysis is a rare (1 in 20000 patients) and severe form of SAMS diagnosed on the basis of its clinical presentation supported by laboratory abnormalities suggestive of muscle breakdown and acute renal failure. We concur with existing guidelines that recommend discontinuation of statins in patients who have experienced rhabdomyolysis[16] and do not offer additional guidance here.

From the Division of Endocrinology, Diabetes, Metabolism, and Nutrition and Knowledge and Encounter Research Unit, Mayo Clinic, Rochester, MN. Reprint requests to Victor M. Montori, MD, MSc, Division of Endocrinology, Diabetes, Metabolism, and Nutrition, Mayo Clinic, 200 First St SW, Rochester, MN 55905. E-mail montori.victor@mayo.edu

(*Circ Cardiovasc Qual Outcomes.* 2013;6:243-247.)

Circ Cardiovasc Qual Outcomes is available at http://circoutcomes.ahajournals.org DOI: 10.1161/CIRCOUTCOMES.111.000039

Refresher Course

- Presentation and talking points
  - Facilitate discussions about how people are using the DAs and SDM
  - What is and is not working and how they can encourage and support each other

Take Home Message

Decision aids for use during clinical encounters

Design for use (and reuse) in planned visits

Efficacious, free, and accessible

Embed into the workflow of care

Considers team and setting

Add SDM to quality-of-care dashboard

Empower (and train) clinicians and patients

Evidence synthesis

Translation of evidence into action

Creating a conversation

Design of care around the needs of the patient

Patient important research

Shared decision making

Improve value of healthcare to the patient

Minimally disruptive medicine

FIT

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