MAYO CLINIC

KER UNIT
KNOWLEDGE AND EVALUATION RESEARCH

Advancing Patient Centered Care Through Shared Decision Making

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Mayo Clinic

Disclosures

We do not draw funding from for-profit corporations.

What does best look like?

HbA1c < 7%

4 Statin Benefit Groups

- Clinical ASCVD*
- LDL-C ≥190 mg/dL, Age ≥21 years
- Primary prevention – Diabetes: Age 40-75 years, LDL-C 70-189 mg/dL
- Primary prevention - No Diabetes†: ≥7.5%‡ 10-year ASCVD risk, Age 40-75 years, LDL-C 70-189 mg/dL

*Atherosclerotic cardiovascular disease

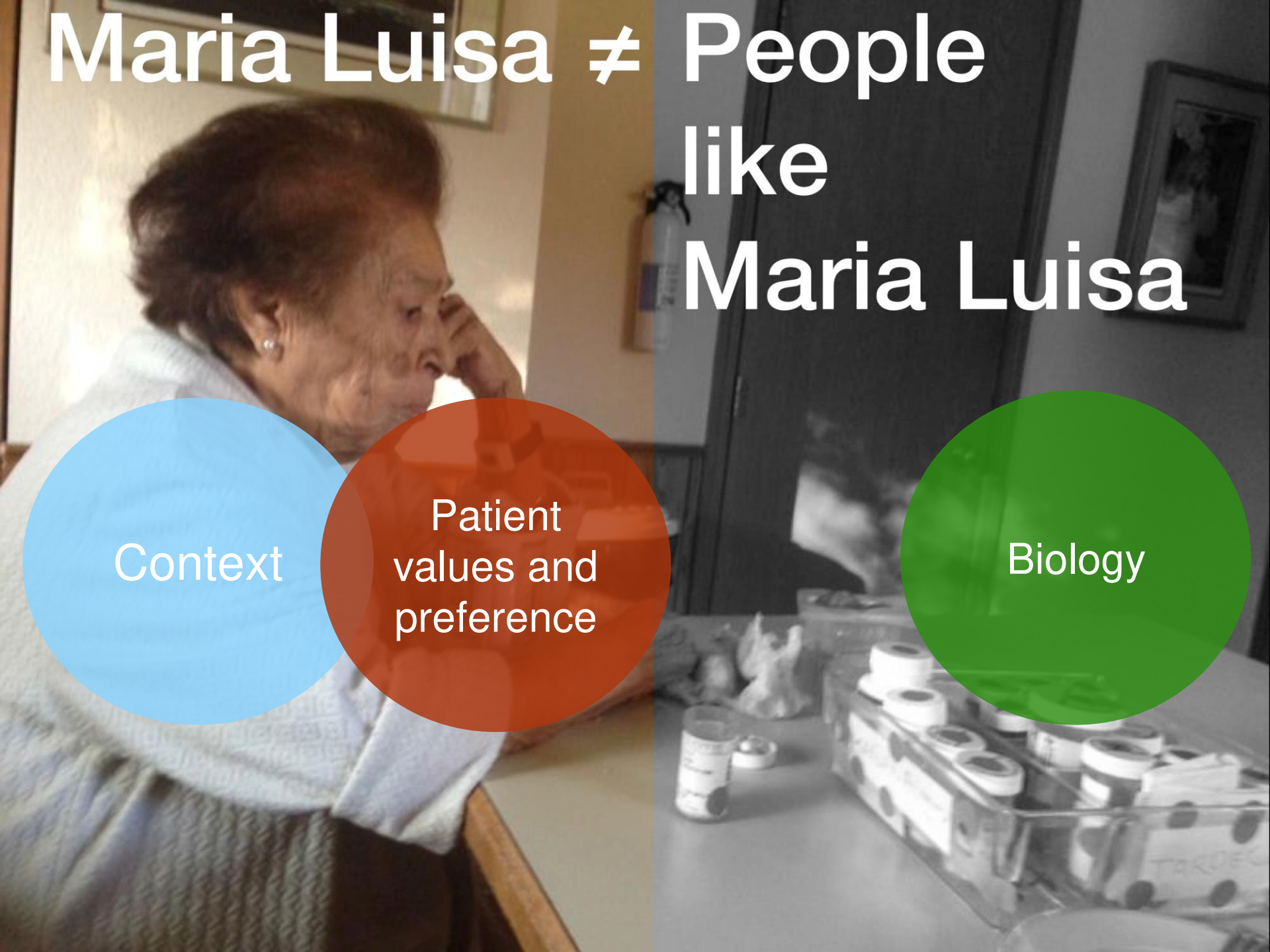
†Requires risk discussion between clinician and patient before statin initiation

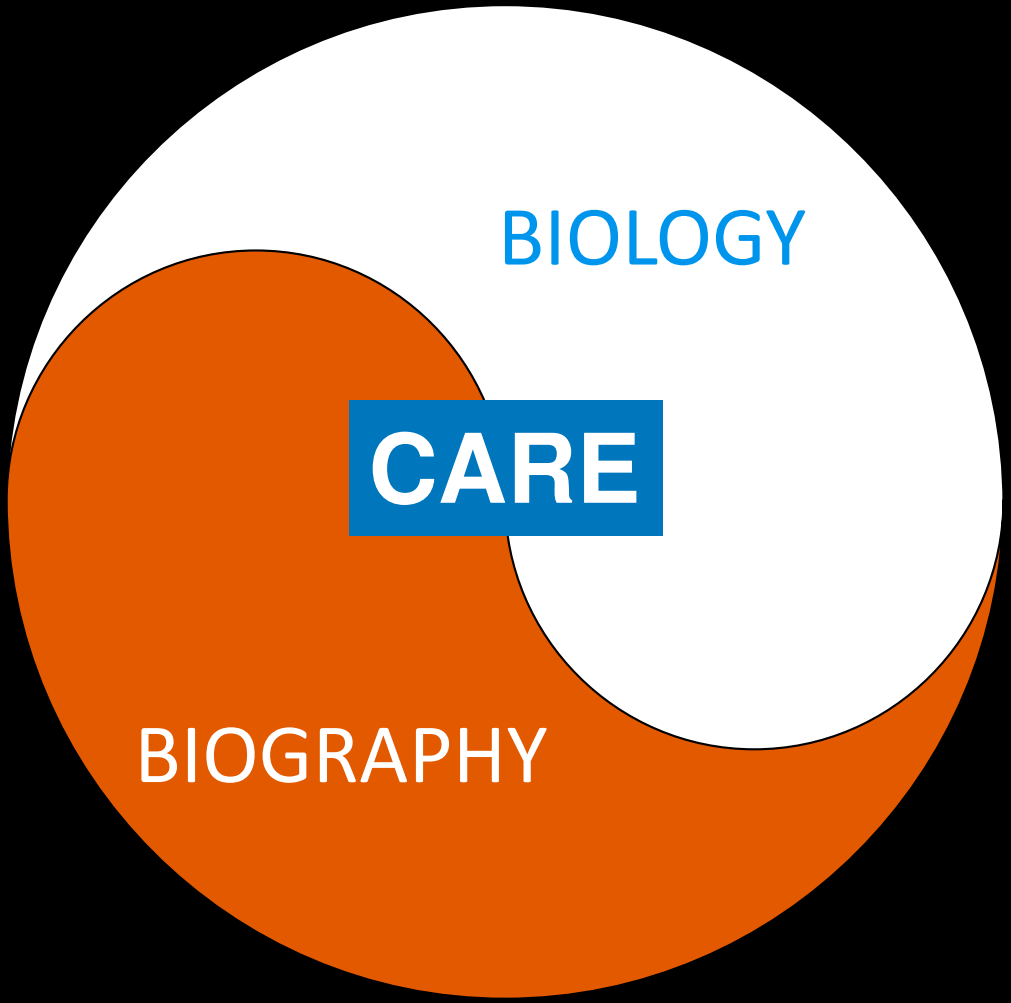
‡Statin therapy may be considered if risk decision is uncertain after use of ASCVD risk calculator

People
like
Maria Luisa

People like Maria Luisa

Biology


Maria Luisa ≠ People like Maria Luisa
Context
Patient values and preference
Biology

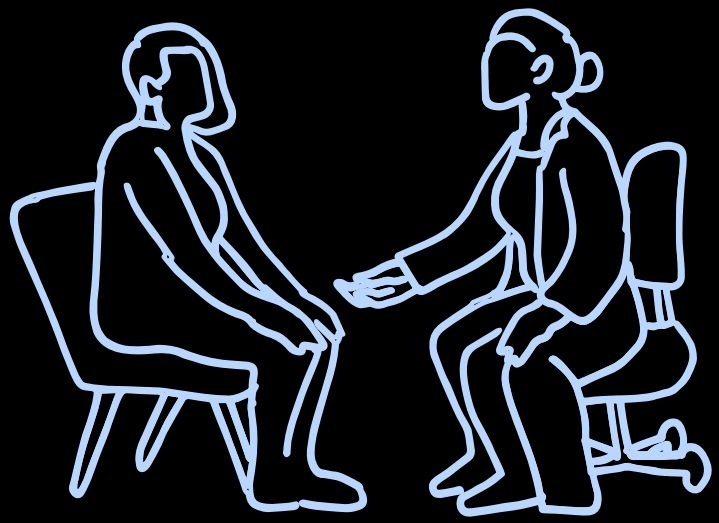


Method to individualize care is shared decision making.

Shared Decision Making

A conversation in which patients and clinicians work out what to do

To form care that makes intellectual, practical, and emotional sense



2014 ACC/AHA Guidelines

CLASS I

1. In patients with AF, antithrombotic therapy should be individualized based on shared decision making after discussion of the absolute risks and RRs of stroke and bleeding and the patient's values and preferences. *(Level of Evidence: C)*

But how?

Different SDMs

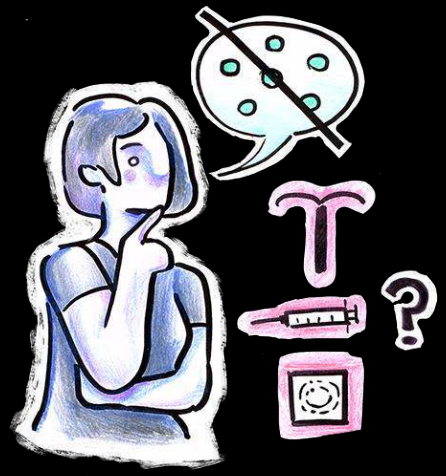
Situations

Problems

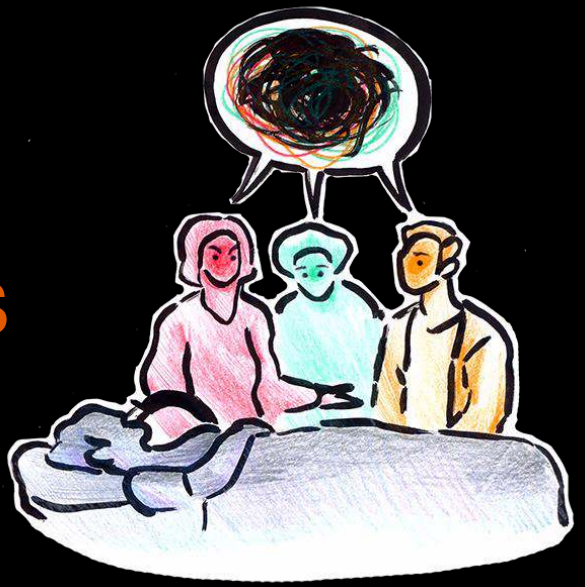
Discussions

Interactions

Purposes



Which is best for me?

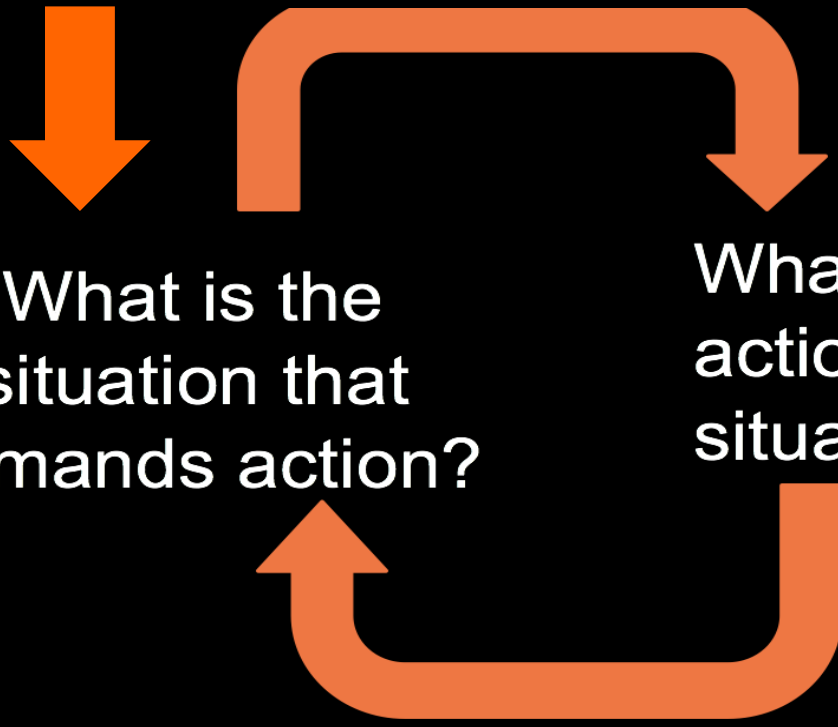


What matters?

What do we want?

How do we manage?

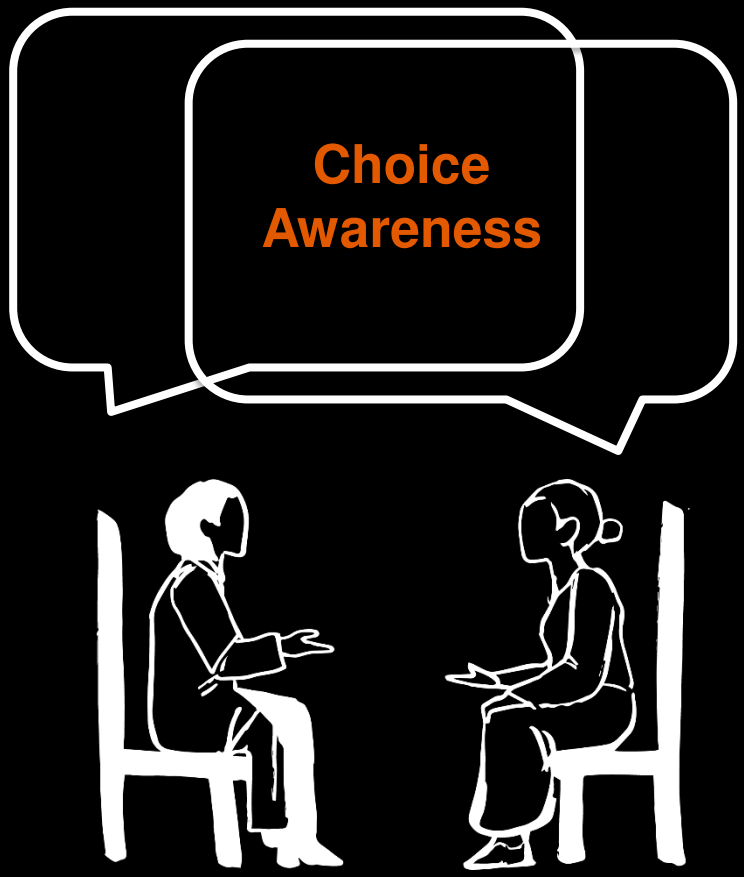
What to do?
Your input matters



Intellectual
Emotional
Practical

Sense

Why are options discussed?
Why patient involvement matters?



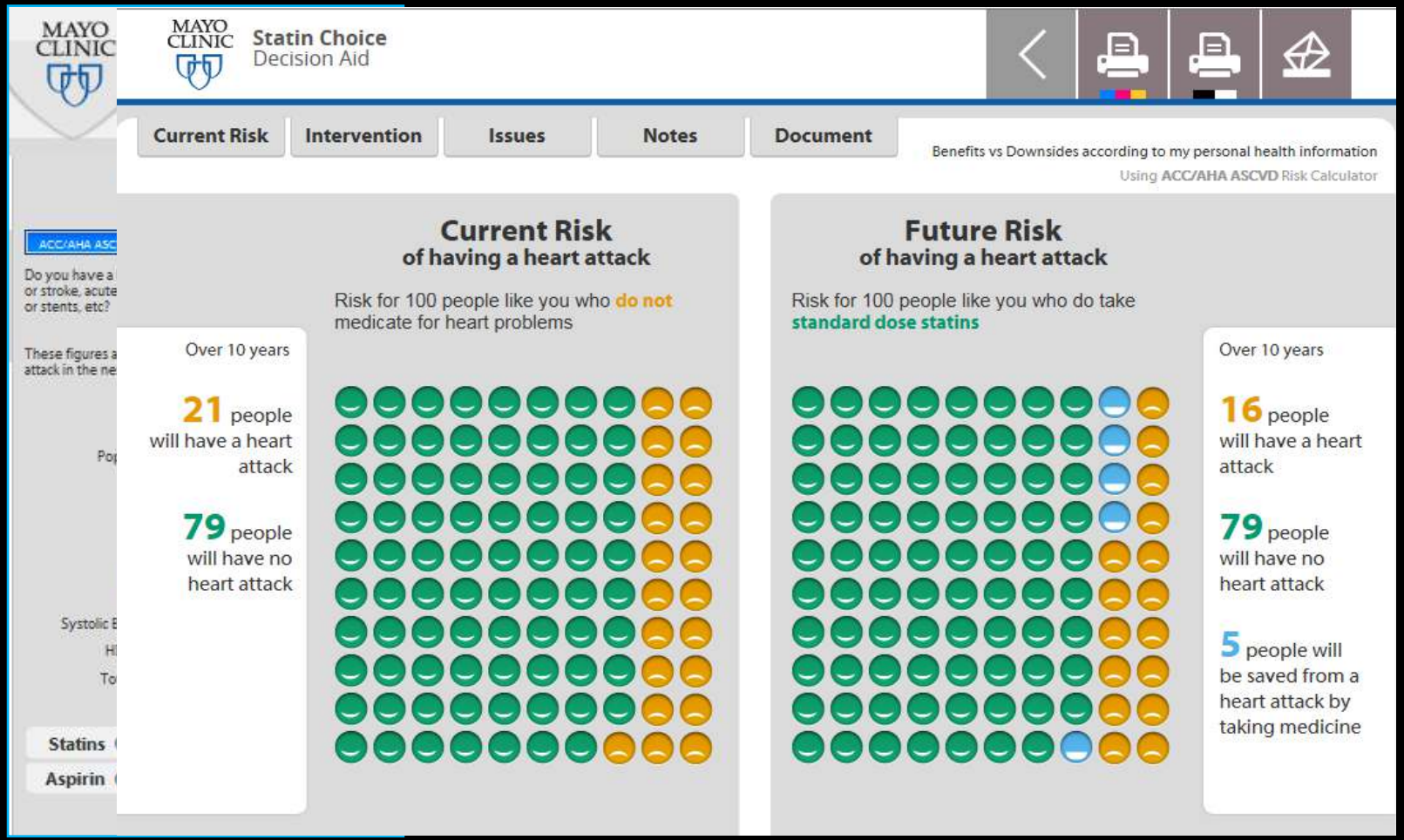
No technically correct answer

Best answer depends on matters about which patients have unique expertise

Avoid premature closure (recommendation without or before patient involvement)

Statin Choice

statindecisionaid.mayoclinic.org



Compared to usual care,
patients using the decision aid were
22 times more likely
to have an accurate sense of their baseline risk and risk reduction with statins.

70% fewer statin Rx in low risk (<10%) group

3-fold increase in self-reported adherence

Weymiller et al. Arch Intern Med 2007

Summary of Mayo experience

Age: 40-95 (avg 65)

Primary care, ED, hospital, specialty care

Adds ~3 minutes to consultation

58% fidelity without training

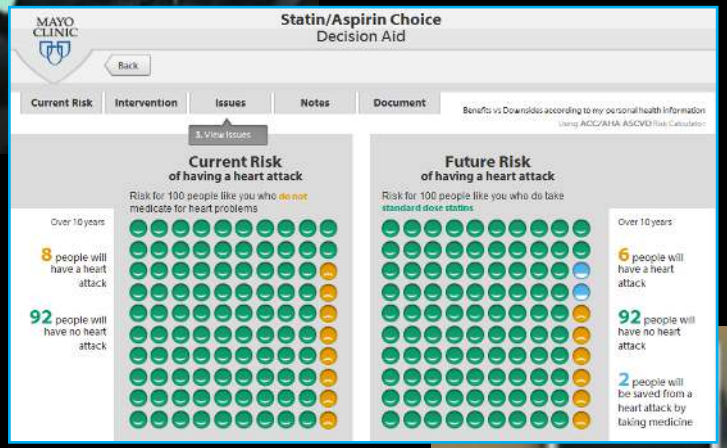
Outcomes

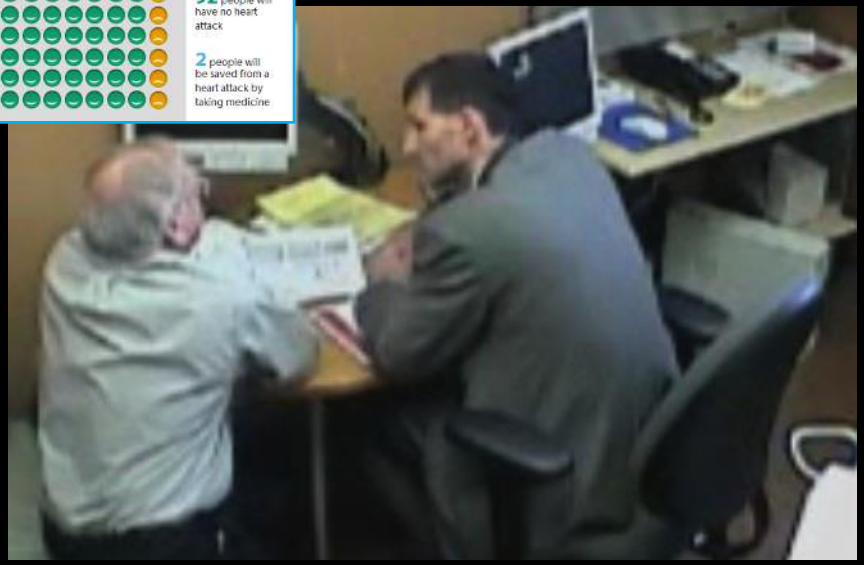
74-90% clinicians want to use tools again

Effects on SDM are similar in vulnerable populations

Variable effect on clinical outcomes, cost

Wyatt et al. Implement Sci 2014; 9: 26
Coylewright et al CCQO 2014, 7: 360-7


MAYO CLINIC
Statin/Aspirin Choice
Decision Aid
Back
Current Risk
Intervention
Issues
Notes
Document
3. View Issues
Benefits vs Downsides according to my personal health information
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
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



NOVEMBER 2014

check to see if

Call & confirm Dr Schesl[illegible] appointment tomorrow the Tuesday 11th

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
			5 [illegible] Clinic upt	8 PM NA @ Sal. Army		1 612-321-3429
2 Get copy of rent amount from Olive. DAYLIGHT SAVING TIME ENDS	3 Out, the Hospital HigherGround	4 TBI ccc Got shot Schles BP	5 Salvation Army started	6 call Marcel @ Emerge	7 Go to Housing Auth	8 9AM Dr. Curry @ Salvation start adds depacote
9 call 6 [illegible] at G.A. about Rent.	10 started day com. ser Marcia 8:30a Bring Nurse Meds	11 HCMC Rheumatology 9AM saw Marcel Emerge ELECTION DAY (US) VETERANS DAY (US) REMEMBRANCE DAY (CAN)	12 Dr. Schles er 2:40pm Rheumatology parkside	13 8:30AM Disinfect 1PM Emerge Marcel Marshell 10AM Josh R	14 HCMC TBI-New 1PM Dr. Berchens Purple Building Pick-up 10 Tramadol Park CVS	15 Susannah Laquan 20-25.90 cost
16 Robin in Sal Army 1PM	17 HCMC OT-1PM SLP-KRC-1PM speech Lang 2pm Dr. [illegible]	18 HCMC ccc 2Pm Mobic 7.5 increasing today	19 Sunnah in at 7:30AM call Christian Sussanah AM	20 Housing Authority REVOLUTION ANNIVERSARY (MEX)	21 House Charity work 10AM 12 NOON Susanna 10AM	22 off
23 10-24 ccc 8pm off / 30 work	24 OT 8AM Blue Speech Pathology 2PM Chang 5th purple 8AM ccc 10AM ccc	25 Go to 6A for Voucher Do not Go! work	26 OT 1PM 3/7 Blue Building work Pathology 2PM Speech	27 worked THANKSGIVING DAY (US)	28 worked	29

Dem-A[illegible] com com. ser Don't call [illegible] relay just say I am done

OCTOBER 2014						
S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

NOVEMBER 2014						
S	M	T	W	T	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30						

DECEMBER 2014						
S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

JANUARY 2015						
S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

FEBRUARY 2015						
S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

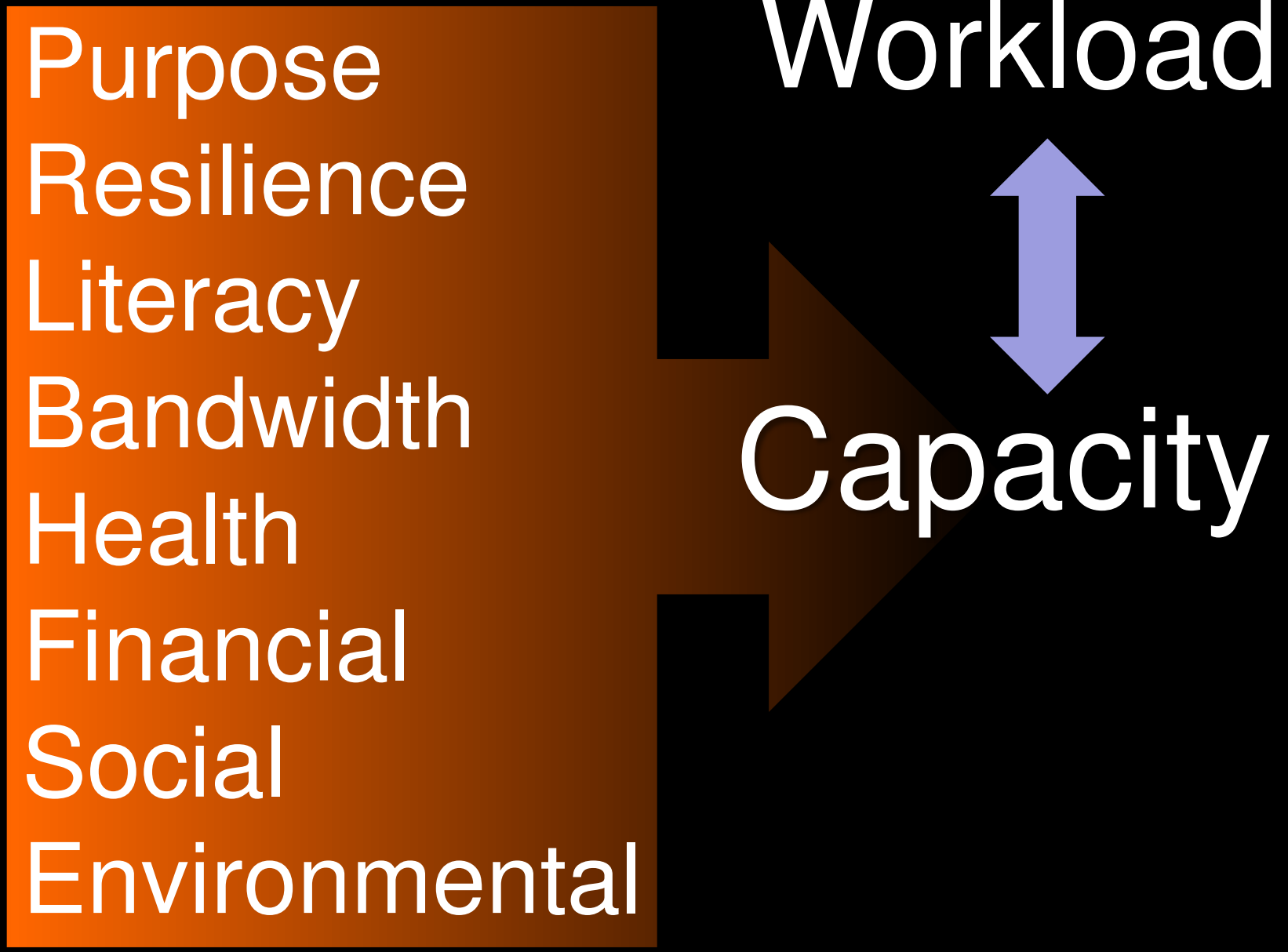
75%

reported high and unsustainable

treatment burden

Spencer G. In prep
Tran et al. In prep


NONCOMPLIANCE


Purpose
Resilience
Literacy
Bandwidth
Health
Financial
Social
Environmental
Workload
Capacity


Imbalance
workload
+
capacity

Workload-capacity imbalance?

Treatment burden

Prioritize (SDM)
De-prescribe

Capacity

Capacity Coaching
Self management training

Palliative care
Mental health
Physical and occupational therapy

Financial and resource security services
Community and governmental resources

HbA1c

My clinical approach

Burden of illness: pain, fatigue, symptomatic hyper/hypo

Burden of treatment: workload + capacity

Promote health: diet, activity, stress

Estimate and reduce CVD risk

- Smoking
- Hypertension
- Statin (even high doses), aspirin
- GLP-1 agonists? Glucoretics?

Glycemic control: A1c target (nl-8%) + regimen

Failure: intensification vs. minimally disruptive care

Why not do everything to the patient?

For a patient at 30% at 10 years

Statin low dose reduce by 25% to 22.5% (-7.5)

20%

Statin high dose reduce by 15% to 19.1% (-3.9)

Aspirin reduces risk by 15%* to 16% (-3)

Antihypertensive treatment by 20% to 13% (-3)

Glycemic control by 15% to 11% (-2)

10%

Liraglutide by 13% to 9.6% (-1.4)

Empagliflozin by 14% to 8.3% (-1.3)

Burden of treatment, cost to patient, and value to patient CV risk to take low dose statins >20%

*ASCEND Trial, NEJM 379;16

Shared decision making is…

A human expression of kind and careful care.

Careful and kind care

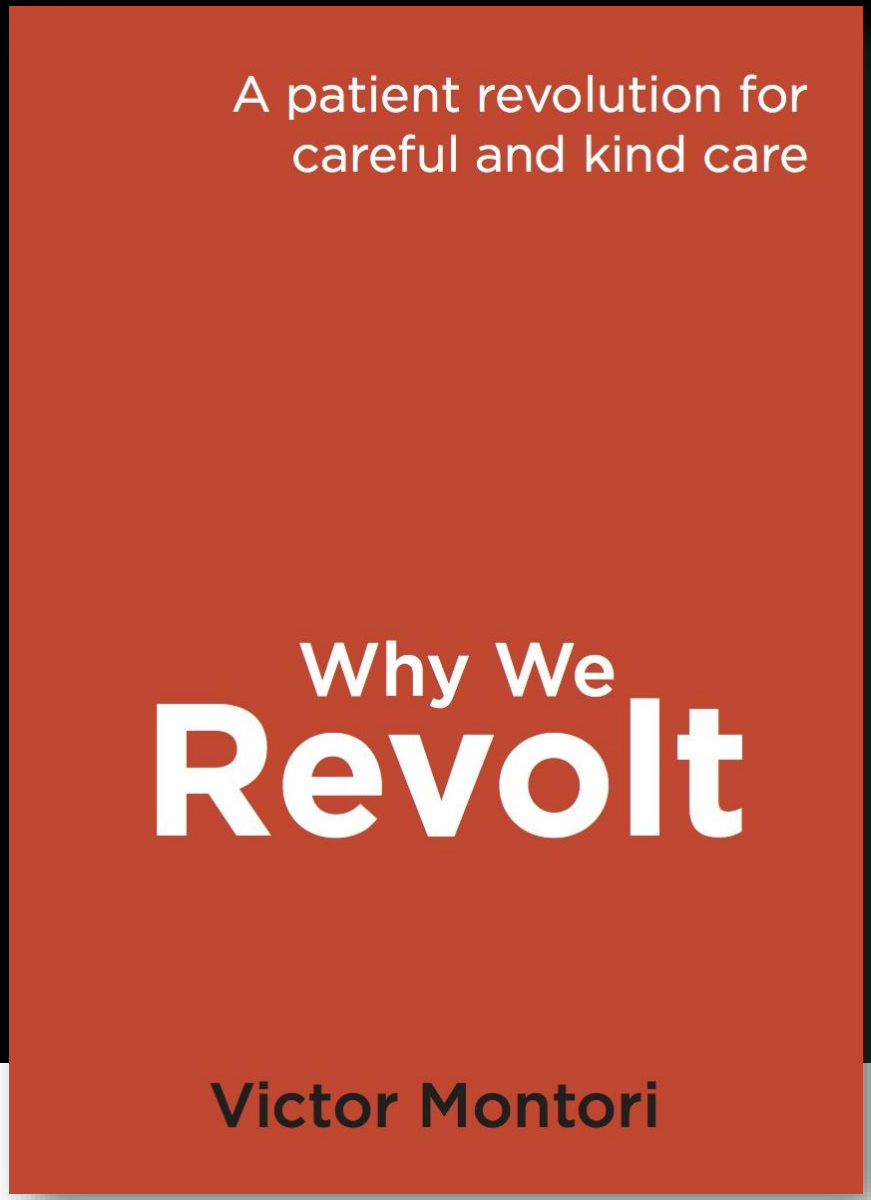
HD
Situation

Unhurried Conversation

CARE

Sensible resolution

patientrevolution.org



THE PATIENT REVOLUTION

KER Unit Workshop

October 7-8, 2019

Mayo Clinic

Rochester, Minnesota

CE.mayo.edu/carethatfits2019


montori.victor@mayo.edu


@vmontori

MAYO CLINIC

Anticoagulation Choice
Decision Aid

1 YEAR RISK
5 YEAR RISK

MEDICAL SITUATION | RISK OF STROKE | ISSUES | DOCUMENT

CHA2DS2-VASC **2**

To begin, let's review your medical situation

Sex M F

Age 62

History of Hypertension Yes No

Congestive Heart Failure Yes No

Stroke / TIA / Thromboembolism Yes No

History of Vascular Disease Yes No

Diabetes Mellitus Yes No

Continue

MAYO CLINIC

Anticoagulation Choice
Decision Aid

1 YEAR RISK
5 YEAR RISK

MEDICAL SITUATION | RISK OF STROKE | ISSUES | DOCUMENT

CHA2DS2-VASC **2**

Over the next 5 years

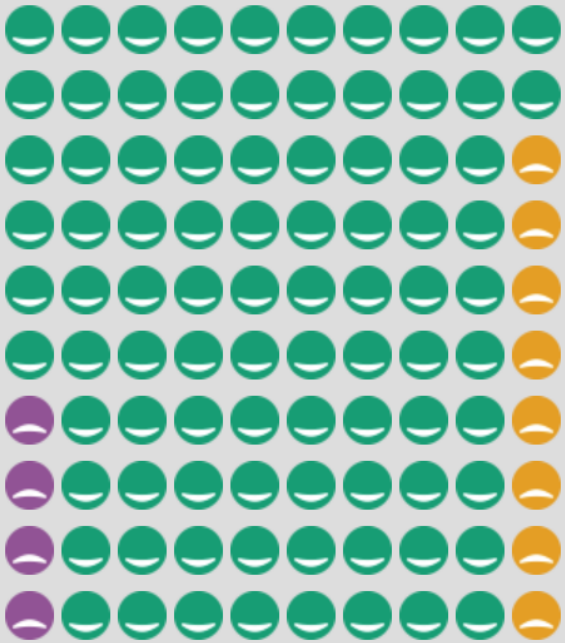
88
people will have no stroke

4
people will have a fatal or disabling stroke

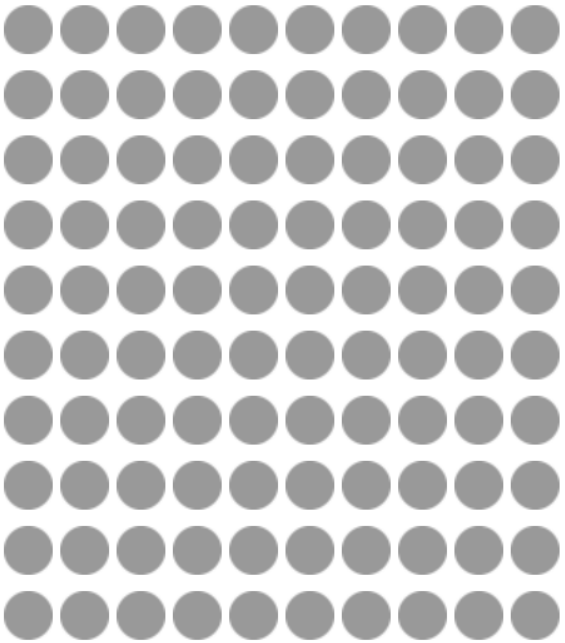
8
people will have a non-disabling stroke

Current
Risk of Stroke
Without Anticoagulation

In 100 people like you who **are not** taking an anticoagulant, **at 5 years...**



With Anticoagulation



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Anticoagulation Choice
Decision Aid

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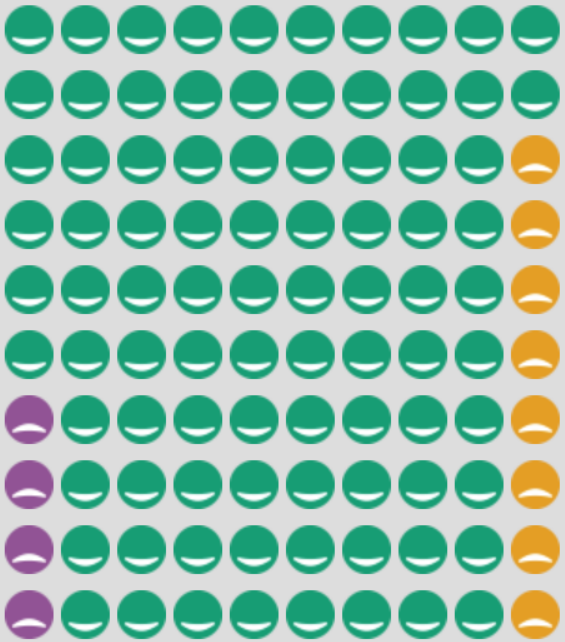

Future
Risk of Stroke
With Anticoagulation

In 100 people like you who **are** taking an anticoagulant, **at 5 years...**

Over the next 5 years

93
people will have no stroke

2
people will have a fatal or disabling stroke

5
people will have a non-disabling stroke

5
people will avoid a stroke by taking anticoagulation

MAYO CLINIC

Anticoagulation Choice
Decision Aid

1 YEAR RISK
5 YEAR RISK

MEDICAL SITUATION | RISK OF STROKE | ISSUES | DOCUMENT | CHA2DS2-VASC 2

Anticoagulation C

There are ch

To choose bet
about how t

Bleeding

When taking an anticoagulant you may...

- bruise more easily
- bleed more easily
- require emergency treatment

Risk of needing emergency treatment

Cost

Warfarin *Coumadin* +

$545 per year
including cost of blood tests

Direct Anticoagulants + + + + +

$2,930 per year

Apixaban	*Eliquis*
Dabigatran	*Pradaxa*
Edoxaban	*Savaysa*
Rivaroxaban	*Xarelto*

Cost will depend on your insurance plan. Average cost without insurance shown.

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Anticoagulation Choice
Decision Aid

1 YEAR RISK
5 YEAR RISK

MEDICAL SITUATION | RISK OF STROKE | ISSUES | DOCUMENT

CHA2DS2-VASC 2

Fitting anticoagulation in your life:

Which issue would you like to discuss first?

- Bleeding
- Anticoagulation Routine
- Reversing Anticoagulation
- Cost
- Diet & Medication Interaction

Bleeding

In your day-to-day life...

Are there activities at work, home, or during recreation where you might fall or hurt yourself?

Exit

Discuss your medical risk factors

MAYO CLINIC

Anticoagulation Choice
Decision Aid

1 YEAR RISK
5 YEAR RISK

MEDICAL SITUATION | RISK OF STROKE | ISSUES | DOCUMENT | CHA2DS2-VASC 2

Fitting anticoagulation in your life:

Which issue would you like to discuss first?

- Bleeding
- Anticoagulation Routine
- Reversing Anticoagulation
- Cost
- Diet & Medication Interaction

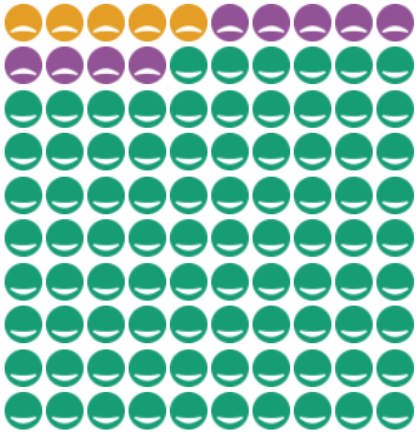
Bleeding

In your medical situation...

Age	67
Uncontrolled Hypertension	Yes / No
Renal Disease	Yes / No
Liver Disease	Yes / No
History of Stroke	Yes / No
Prior, or Predisposition to Bleeding	Yes / No
Unstable or High INR	Yes / No
Medication Predisposing Bleeding	Yes / No
More than 8 Drinks per Week	Yes / No

Exit

Average Risk



Over 5 years

9 more people will need emergency treatment because they take an anticoagulant

serious bleed **without** anticoagulation

additional serious bleed **with** anticoagulation

MAYO CLINIC

Anticoagulation Choice
Decision Aid

1 YEAR RISK
5 YEAR RISK

MEDICAL SITUATION | RISK OF STROKE | ISSUES | DOCUMENT

CHA2DS2-VASC **2**
HAS-BLED **2**

We have discussed that this patient has a 5-year risk of stroke associated with atrial fibrillation of **12%** and that this risk can be reduced with anticoagulation by **5%** to **7%**.

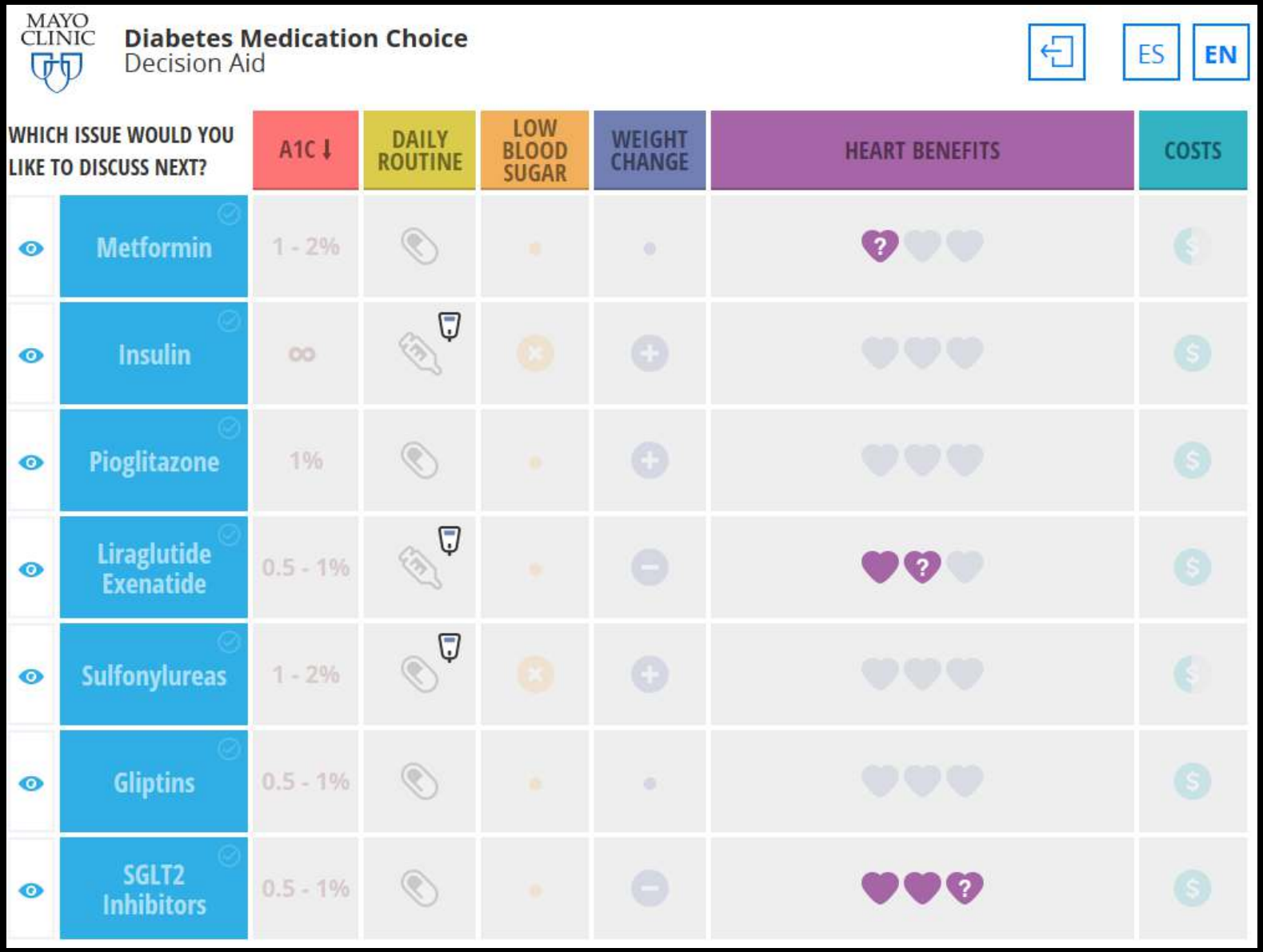
We have discussed the pros and cons of the available options, including their impact on the risk of bleeding, cost, and practical considerations in using them regularly. After thorough discussion, we have decided to use **a Direct anticoagulant**

Intervention selected: ○ No Anticoagulation ○ Warfarin ◉ Direct anticoagulant

Document Options: ☑ Generate report ☑ Copy to Clipboard

Document

New tools



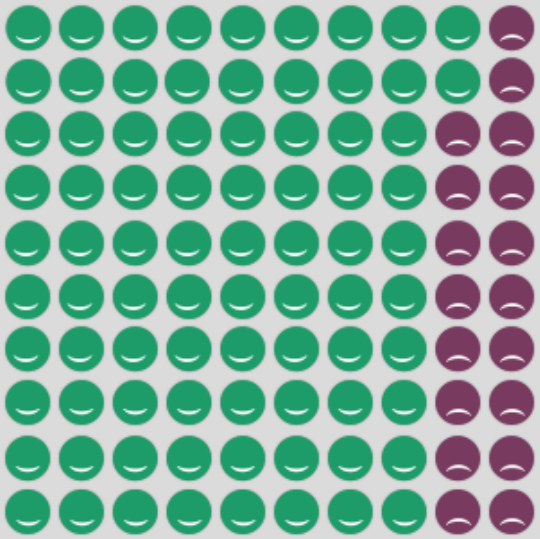
LINK

MAYO CLINIC **Heart Health**
Decision Aid

Risk of Heart Attack :: Approaches :: Review Risk :: Decision

Current Risk
of having a heart attack

In 100 people like you…



Over the next 10 years

82 people will have no heart attack

18 people will have a heart attack

There are two ways to reduce your risk

by changing:

- ☐ Way of Life
- ☐ Medicines

Select one to continue

LINK

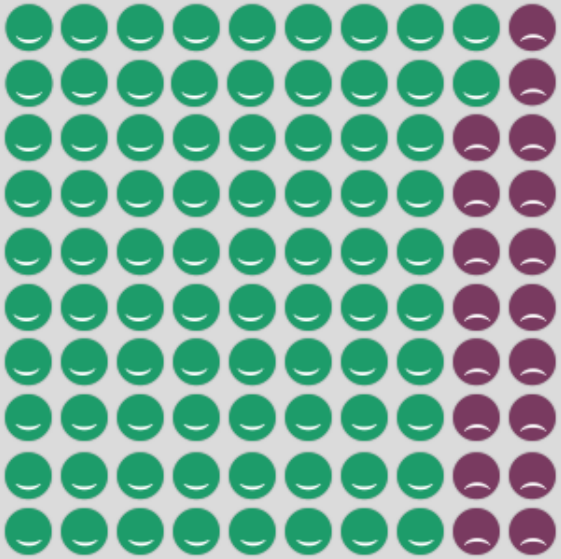
MAYO CLINIC

Heart Health Decision Aid

Risk of Heart Attack :: Approaches :: Review Risk :: Decision

Current Risk
of having a heart attack

In 100 people like you...



Over the next 10 years

82 people will have no heart attack

18 people will have a heart attack

Future Risk
of heart attack

In 100 people like you...

Consider Approaches?

☐ Way of Life

☑ Medicines

Over the next 10 years

88 people will have no heart attack

12 people will have a heart attack

Up to **6** people will avoid a heart attack by taking medication

LINK

MAYO CLINIC **Heart Health**
Decision Aid

Risk of Heart Attack :: **Approaches** :: Review Risk :: Decision

Approaches

Are they right for you, can they work in your life?

	Lowering Risk	Daily Routine	Burdens	Other Benefits	Cost
Physical Activity	⊕⊕⊕	⊖	⊖	⊕	Equipment, gym fees ?
Mediterranean Diet	⊕⊕⊕	⊖	•	⊕	Additional food costs ?
Stopping Smoking	⊕⊕⊕	?	⊖	⊕	Stopping smoking medications, programs
Omega 3 Supplements	•	•	⊖	⊕	Supplement costs
Blood Pressure Mediciations	⊕⊕⊕	⊖	⊖	?	Medication costs
Diabetes Medications	⊕⊕	⊖	⊖	?	Medication costs
Statins	⊕⊕	?	⊖	•	Medication costs
Aspirin	⊕	?	⊖	•	Medication costs

Review Risk


MAYO CLINIC
Anticoagulation Choice
Decision Aid
Medical Situation
Risk of Stroke
Anticoagulation
Issues
CHA2DS2-VASC 4
HAS-BLED 1
Current Risk
of Stroke without Anticoagulation
Future Risk
of Stroke with Anticoagulation
Over the next year
4 people will have a fatal or disabling stroke
5 people will have a non-disabling stroke
91 people will have no stroke
1 Year Risk
5 Year Risk
CHA2DS2-VASC 5
Work, Home & Fun Activities
Anticoagulation Routine
Risk of Serious Bleeding
Cost
Diet & Medication Interactions
Cost
The cost to you of each medication will depend on your insurance plan.
The figures below provide a comparison of average costs without insurance.
Warfarin
$545 per year
Costs include the medication and blood tests.
Direct Anticoagulants
$2,930 per year
Apixaban Eliquis
Dabigatran Pradaxa 110mg, 150mg
Edoxaban Lixiana
Rivaroxaban Xarelto
Anticoagulation Routine
Warfarin requires committing to regular blood tests.
There is no testing required with a Direct Anticoagulant.
Warfarin
Once daily
Regular blood tests
Am I available to do the regular blood tests that Warfarin requires?
Work / travel / family demands? Transportation?
Direct Anticoagulants
Apixaban Eliquis AM PM
Dabigatran Pradaxa 110mg, 150mg AM PM
Edoxaban Lixiana Once daily
Rivaroxaban Xarelto Once daily

Agents that reduce CV risk

Pioglitazone (IRIS)*

Canagliflozin (CANVAS)*

Empagliflozin (EMPA-REG)

Dapagliflozin (DECLARE-TIMI 58)

Liraglutide (LEADER)*

Semaglutide (SUSTAIN-6)

* Inconsistent results within the class

EMPA-REG

- RCT at low risk of bias (blinding)
- 7028 >5y DM2 (A1c 7-10%)+ CV
- Empagliflozin (10 or 25 mg) vs. Placebo
- At 2.5y: 14% RRR in CV death, nonfatal MI, nonfatal stroke, from 12 % to 10.5%
- **Certainty:** Consistent with prior trials and CANVAS (cana), but not with DECLARE (dapa), a 17160-patient 4y trial: no effect on MACE/CV death

Empagliflozin (HbA1c 0.5%)

Participants with additional:	Placebo	Empagli-flozin
Glucose-lowering medications added in concordance with an escalated 'standard of care'	31.5%	19.5%
Insulin	11.5%	5.8%
Dipeptidyl peptidase 4-inhibitor	8.3%	5.6%
Sulfonylurea	7.0%	3.8%
Thiazolidinedione	2.9%	1.2%

Concerns: change in protocol, posthoc outcomes, 40% deaths uncertain

N Engl J Med 2015;373:2117-28.

LEADER

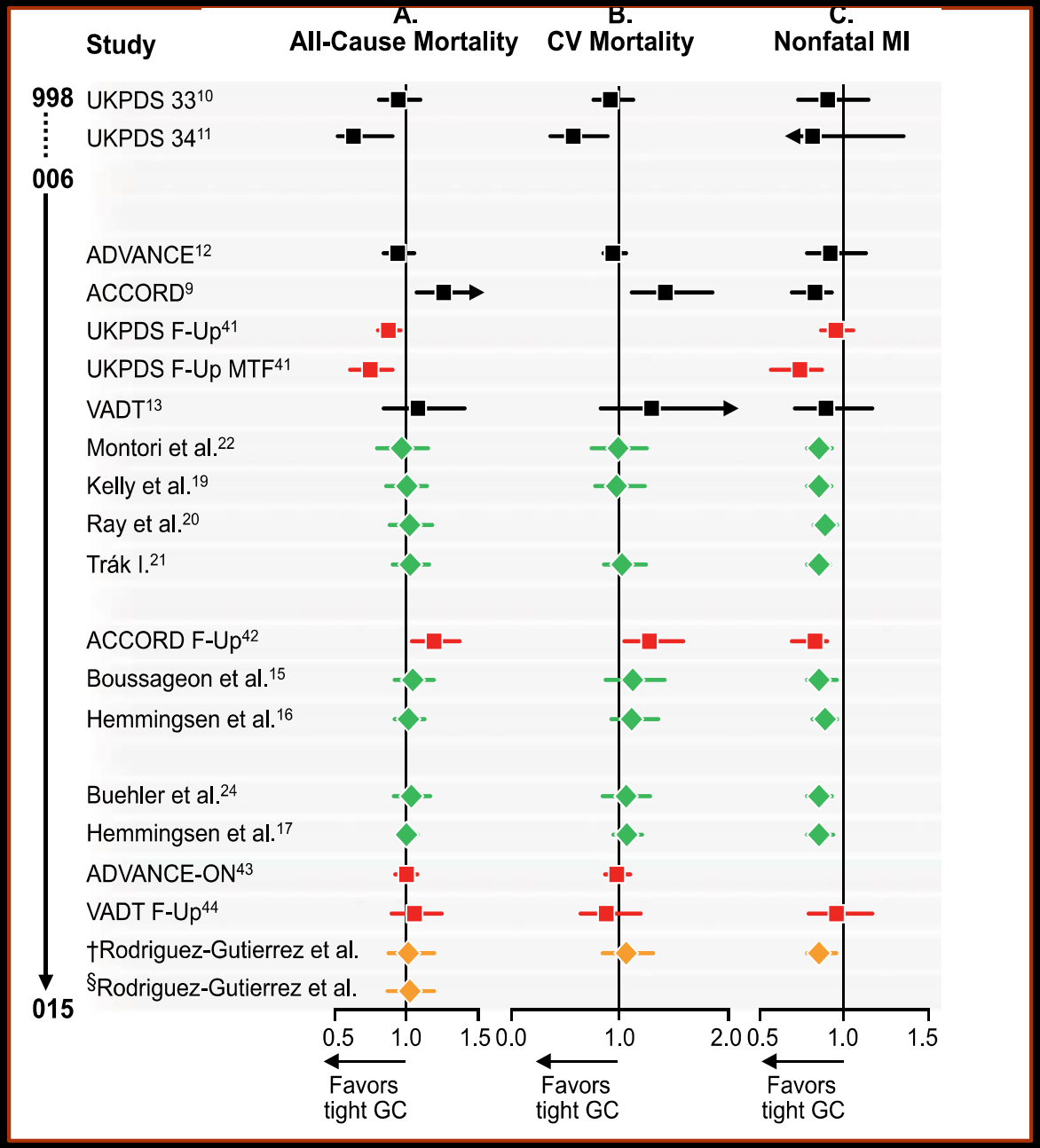
Liraglutide (HbA1c 0.5%)

RCT at low risk of bias (blinding)
9340 DM2 (A1c 7-10%)+ 80% CV
Liraglutide (1.8 mg daily) vs. placebo
At 3.5y: 13% RRR in CV death, nonfatal MI, nonfatal stroke from 15% to 13%

Concerns:
Differences between arms in diabetes treatments
Adverse effects in patients with advanced heart failure?
Class effect?

Exenatide weekly (EXSCEL, n=14752) Neg
Semaglutide weekly (SUSTAIN-6, n=3297)
Pos
Lixisenatide daily (ELIXA, n=6068 ACS)
Neg

N Engl J Med 2016;375:311-22.



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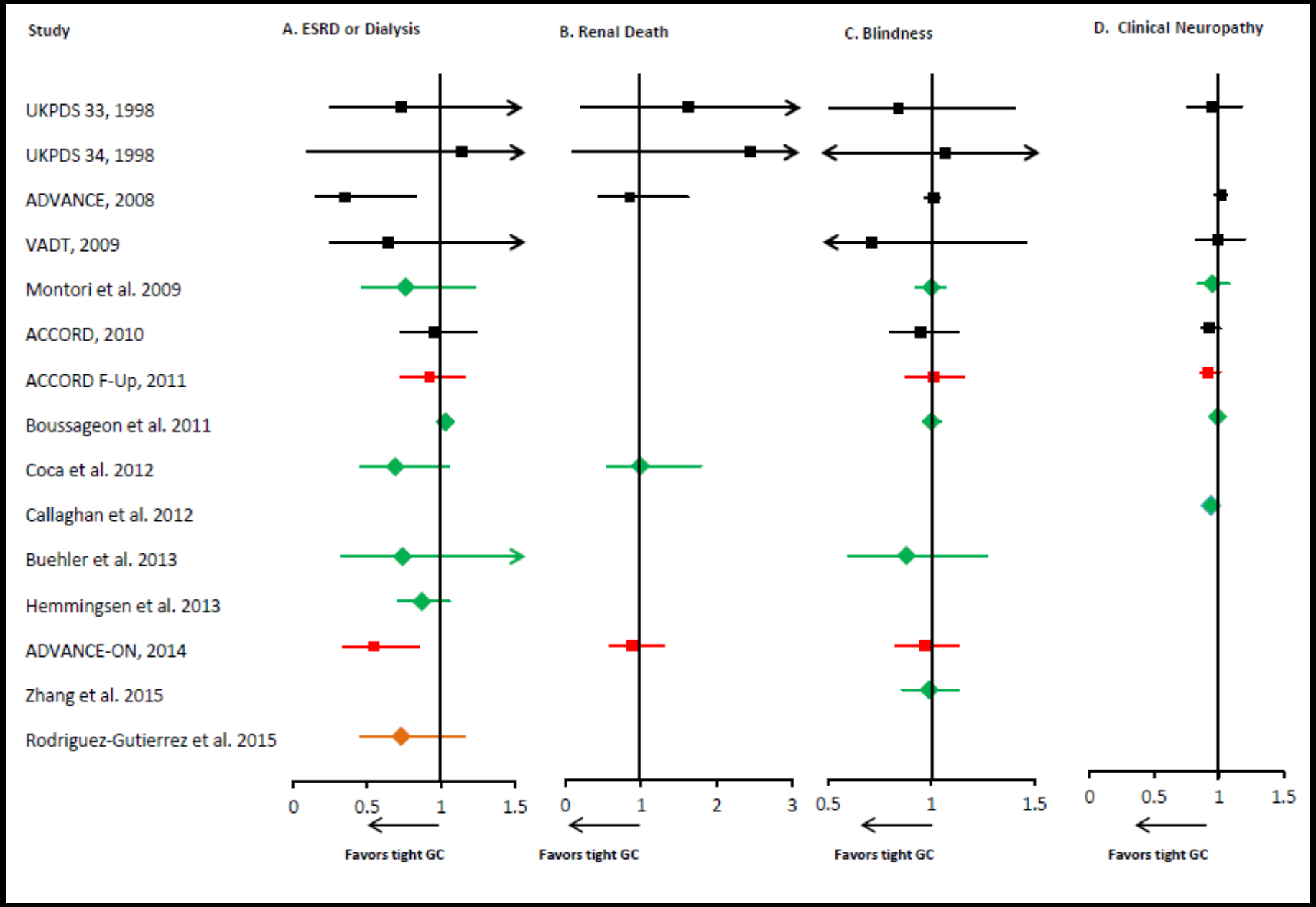
Rodriguez-Gutierrez and Montori; Circ Cardiovasc Qual Outcomes. 2016;9



Rodriguez-Gutierrez and Montori; Circ Cardiovasc Qual Outcomes. 2016;9