

Patient-Centered Outcomes Research and the Use of Decision Aids to Facilitate Shared Decision Making

March 18, 2015

3:30 p.m. – 5 p.m. ET

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Effective Health Care Program

Presenters and Moderator Disclosures

The following presenters and moderator have no financial interest to disclose:

- ▶ **Nilay Shah, Ph.D., M.S.**, Mayo Clinic
- ▶ **Johann Chanin, RN, M.S.N.**, Patient-Centered Medical Home and Neighborhood
- ▶ **Victor Montori, M.D.**, Mayo Clinic
- ▶ **Alaina Fournier, Ph.D.**, AHRQ

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Learning Objectives



At the conclusion of this activity, the participant will be able to:

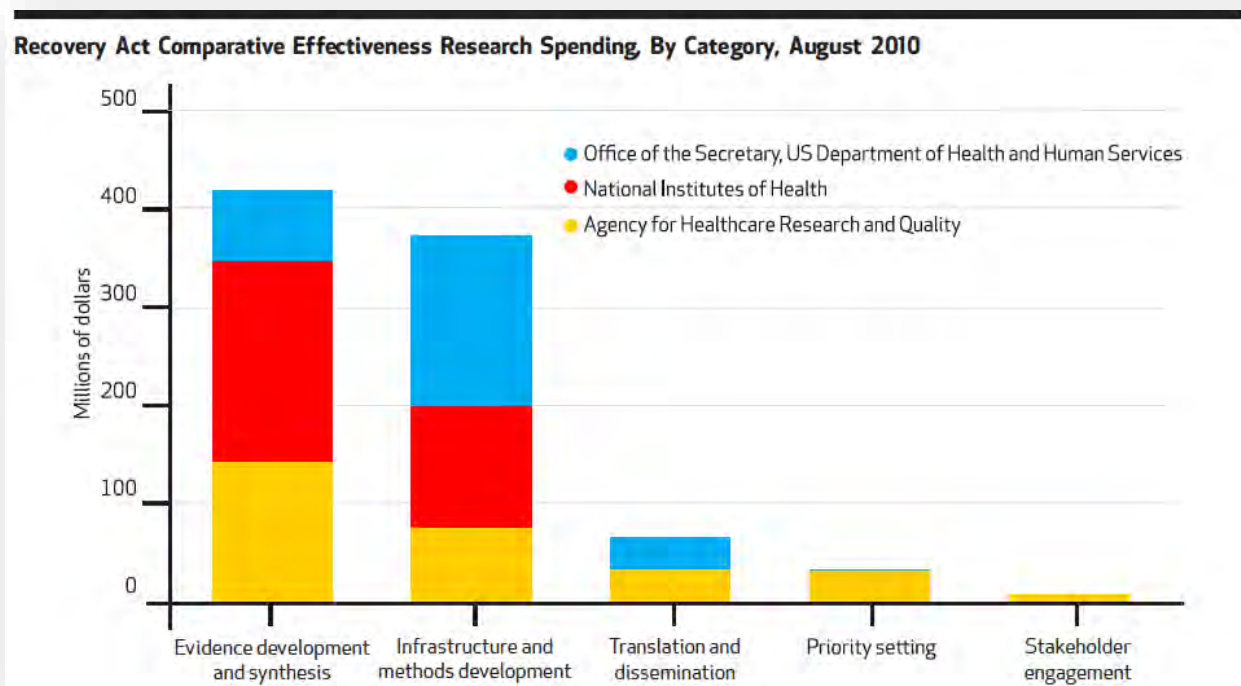
1. Define patient-centered care and shared decision making, and current NCQA requirements for patient-centered medical homes (PCMH) and Accountable Care Organizations (ACOs).
2. Describe the attributes/advantages of patient-centered outcomes research (PCOR) and decision aids in augmenting patient-centered care in the context of shared decision making.
3. Identify AHRQ as a key source of PCOR resources and shared decision-making materials.

Overview

- ▶ ***Crossing the Quality Chasm*** called for
 - “system that provides care that is respectful to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions”
- ▶ **Affordable Care Act**
 - Call for new Shared Decision-Making Resource Centers (Section 3506) to help integrate shared decision making into practice
 - Section 3021 (Center for Medicare and Medicaid Innovation [CMMI]) to examine how support tools can be used to improve patients understanding of their treatment options
 - Formation of Patient Centered Outcomes Research Institute (PCORI)

Comparative Effectiveness Research

- ▶ “provide comparative effectiveness information to assist patients, clinicians, purchasers, and policy makers in making informed health decisions”



Source:
Benner 2010

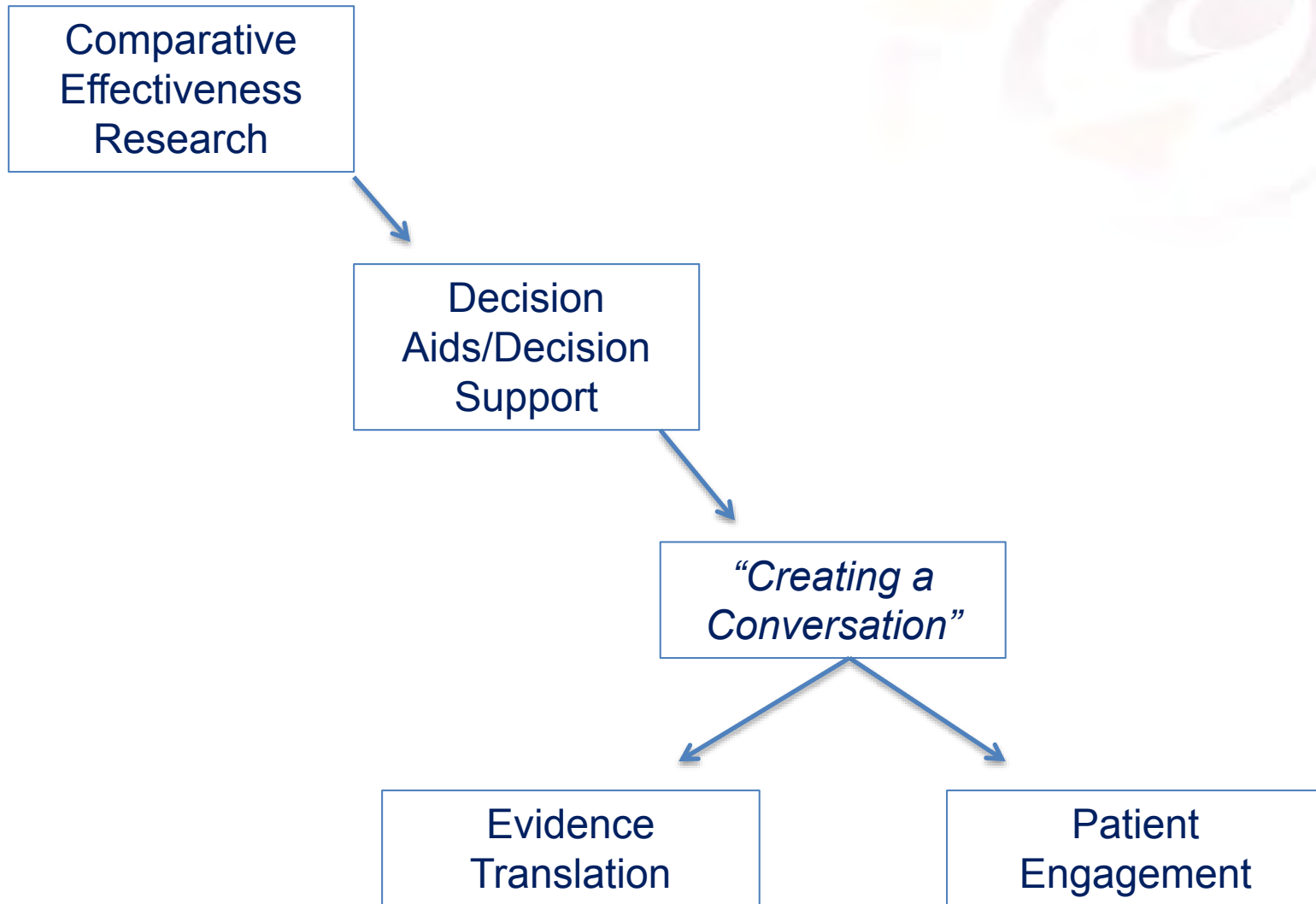
CER Translation Gap

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

Why?



- ▶ Misalignment of financial incentives
- ▶ Complexity of research
- ▶ Biases in interpretation of results
- ▶ Applicability of the evidence
- ▶ Limited use of decision support



Enabling Patient Choice in the Patient-Centered Medical Home

Johann Chanin, RN, M.S.N.,
Patient-Centered Medical Home and Neighborhood



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Effective Health Care Program

Agenda



- ▶ National Committee for Quality Assurance (NCQA)
- ▶ Definition of patient-centered care
- ▶ Definition of shared decision making
- ▶ NCQA's requirements
 - Patient-Centered Medical Home 2014 (PCMH)
 - Patient-Centered Specialty Practice (PCSP)
 - Accountable Care Organizations (ACO)

National Committee for Quality Assurance (NCQA)



- ▶ Improves health care quality through
 - Transparency
 - Measurement
 - Accountability
- ▶ Provider-based quality programs
 - Accountable Care Organization Accreditation
 - Diabetes Recognition Program & Heart/Stroke Recognition Program
 - Patient-Centered Medical Home & Patient-Centered Specialty Practice Recognition

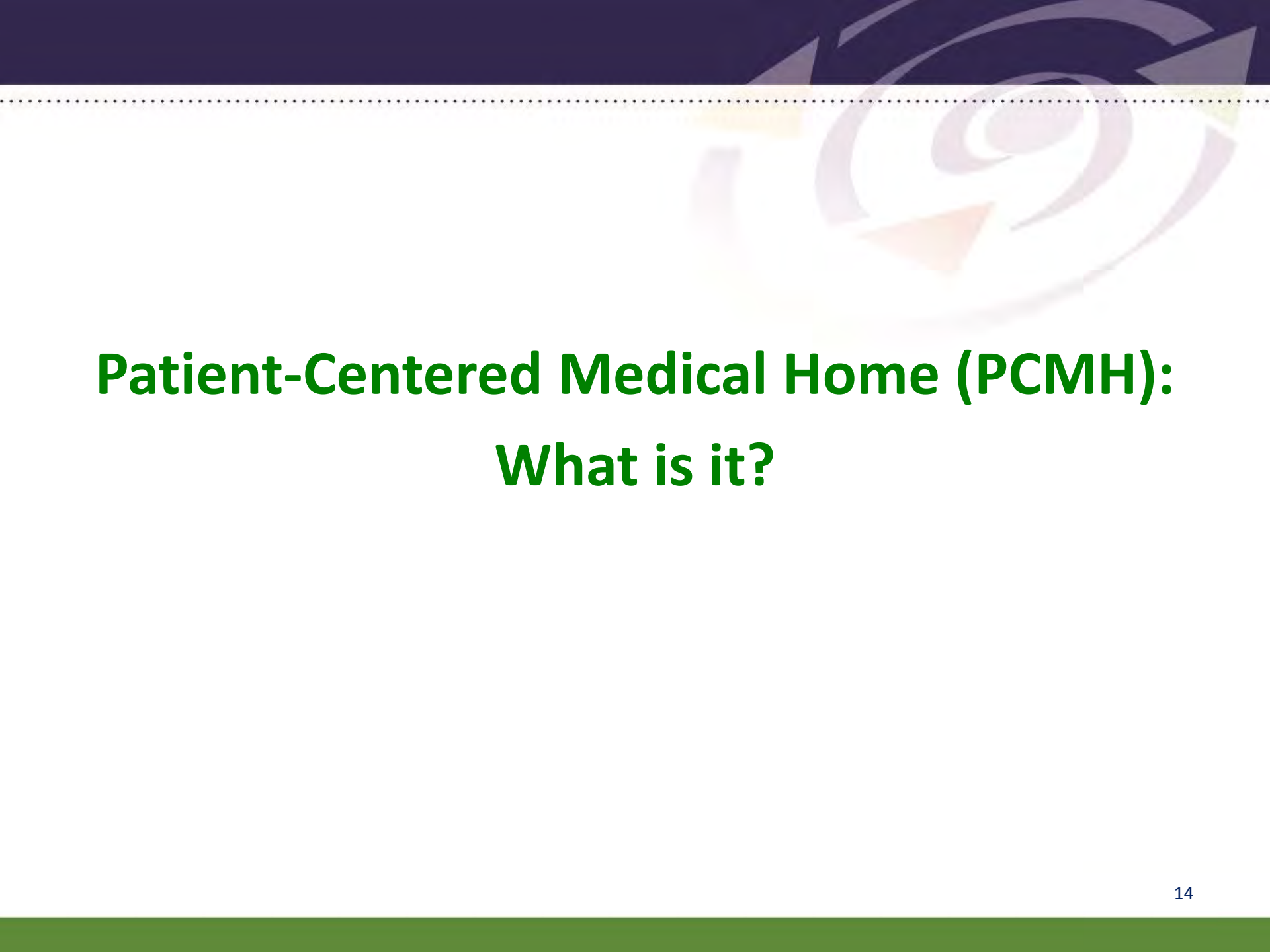


Shared Decision Making (SDM)

Shared Decision Making (SDM)



- ▶ The purpose is to help patients make informed, values-based decisions with their care team.
- ▶ It's used when there is no “BEST” choice.
- ▶ Decision process takes into account:
 - Evidence-based information about health care options
 - Benefits and harms of each option
 - Provider's knowledge and experience
 - Patient's values and preferences
- ▶ Not all decisions need to be shared (e.g., surgery for acute appendicitis, repairing compound fracture).



Patient-Centered Medical Home (PCMH): What is it?

What is a Patient-Centered Medical Home?

Patient-Centered Medical Home

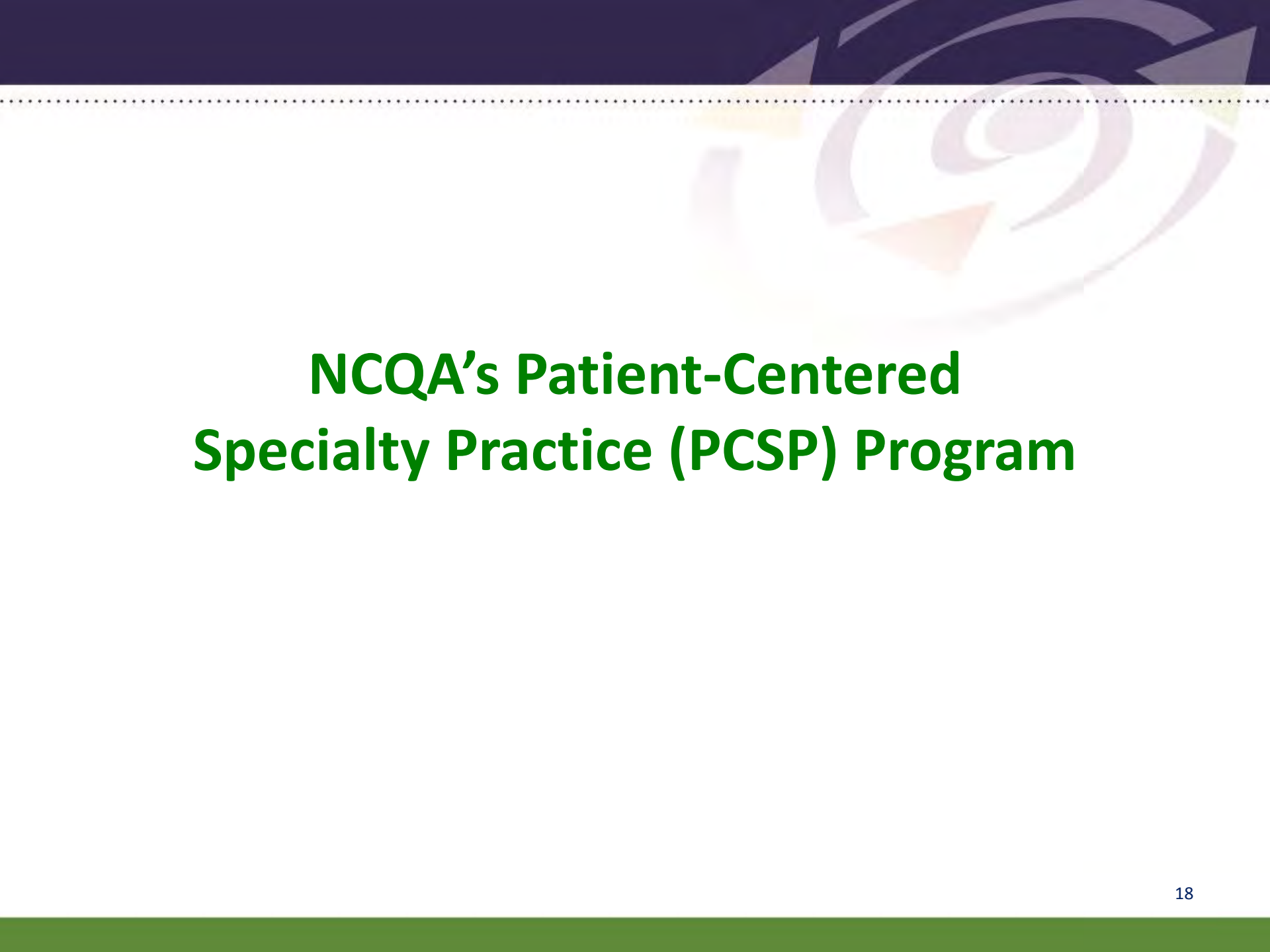
- ▶ “Whole-person” coordinated care to provide primary care “as patient wants it to be”
- ▶ Clinician-patient relationship to keep patient healthy between visits
- ▶ “Team-based care” so providers can work at highest level of training
- ▶ Use information technology to support the Triple Aim and improve population health

Summary: NCQA's Patient-Centered Medical Home 2014 Standards

1. Enhance Access/Continuity: Appointment access, 24/7 access to clinical advice, electronic access
2. Team Care: Continuity, culturally/linguistically appropriate, team care
3. Identify/Manage Patient Population: Use patient information, assessment, evidence-based guidelines to manage populations
4. Plan/Manage Care: Individual patient-care planning, medication management, self-care support with shared decision making
5. Track/Coordinate Care: Test/referral tracking and followup, coordinate care transitions
6. Performance Measurement/Quality Improvement: Measure clinical performance, resource use, patient experience; report performance and show continuous quality improvement

Shared Decision Making in Patient-Centered Medical Home Program

- ▶ Manage patient populations
 - Use evidence-based guidelines to manage populations
- ▶ Plan/manage individual patient care
 - Care planning, medication management, support self-care/**shared decision making**
- ▶ Measure patient experience
 - PCMH CAHPS includes shared decision making items



NCQA's Patient-Centered Specialty Practice (PCSP) Program

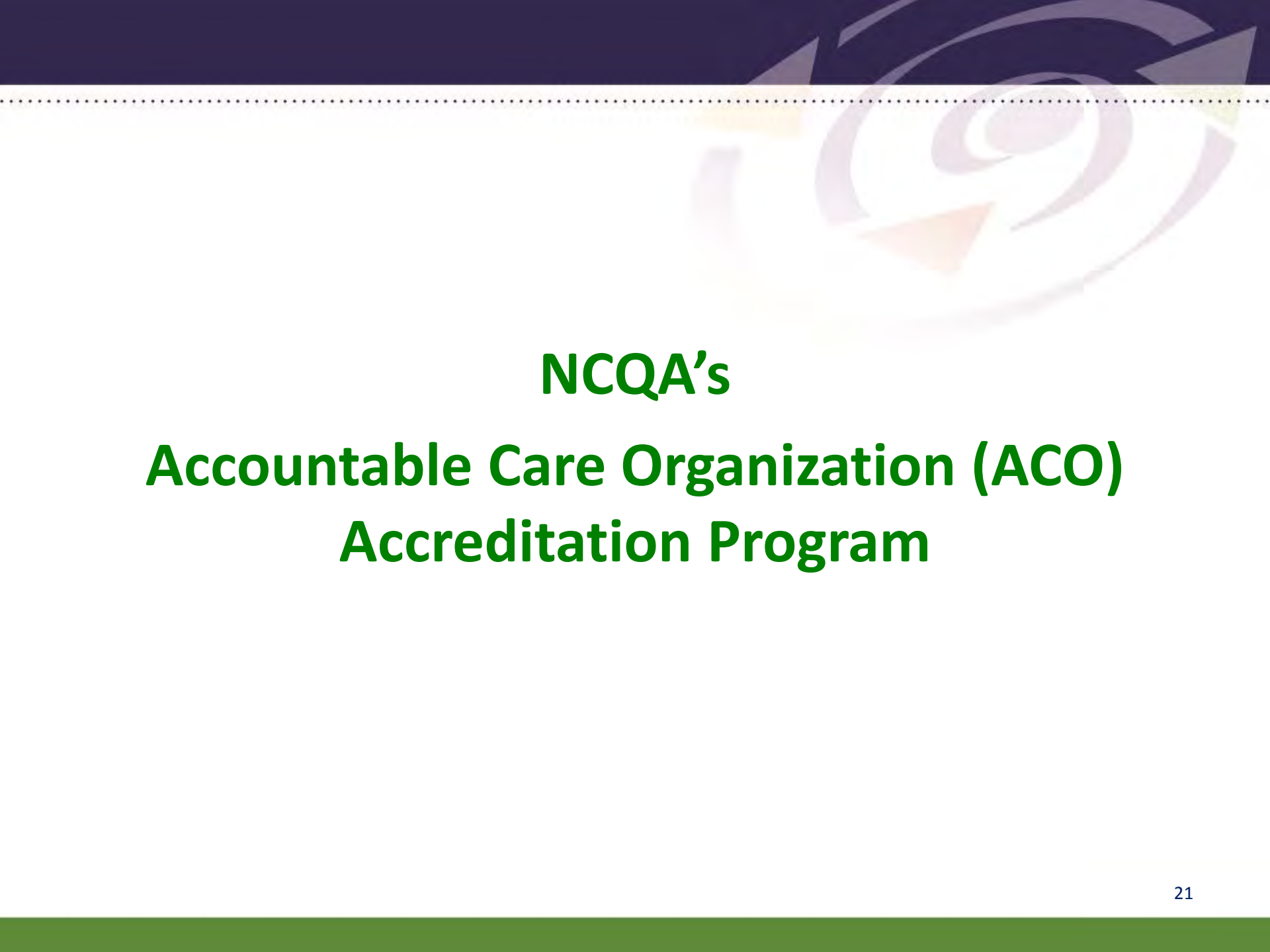
NCQA's Patient-Centered Specialty Practice (PCSP) Program: Key Aims

1. Patient access (timely appointments/advice)
2. Agreements with PCP to coordinate care
3. Timely information exchange with PCP, including referral summary to referring clinician
4. Care plan coordination with PCP
5. Communication with patient and PCP
6. Reduce hospitalizations/ED visits, duplication of tests
7. Measure performance
8. Align with Meaningful Use Requirements

Shared Decision Making in PCSP Program



- ▶ Coordinate with primary care; process/information shared with PCP.
- ▶ Collaborate with PCP on care management and self-care.
- ▶ Measure patient experience.



NCQA's Accountable Care Organization (ACO) Accreditation Program

NCQA's ACO Standards

ACO: Provider-based organization accountable for quality and cost of care for defined population

1. Program Operations: Infrastructure/leadership, provider payments/contracting arrangements
2. Access/Availability: Full range of health care services (primary care, specialists, community/home)
3. Primary Care: Access to PCPs
4. Care Management: Support care management/self-care
5. Care Coordination/Transitions: Information exchange
6. Patient Rights/Responsibilities: Communicate with patients about ACO performance/payments
7. Performance Reporting/Quality Improvement

Shared Decision Making in ACOs



- ▶ Adopt evidence-based guidelines and disseminate decision-support tools.
- ▶ Make decision-support aids available to ACO providers to promote patient engagement.
- ▶ Report patient experience.

Shared Decision Making is Vital...



- ▶ Enables patient-centered care
- ▶ Supports patient involvement in planning/managing care and self-care
- ▶ Enhances patient experience
- ▶ Supports containment of cost (hospitalizations, ED visits, duplication of services, improved coordination/ transitions of care)
- ▶ Improves quality of patient care

"Implementing shared decision making will help organizations...to achieve the Triple Aim of better care, better health, and lower costs"

Health Policy Brief: Patient Engagement. *Health Affairs*, February 14, 2013.



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Patient-Centered Medical Home and Neighborhood

Making Better Decisions Together Translating PCOR into PCare

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Disclosures

Relevant Financial Relationships

None

Off-Label Usage

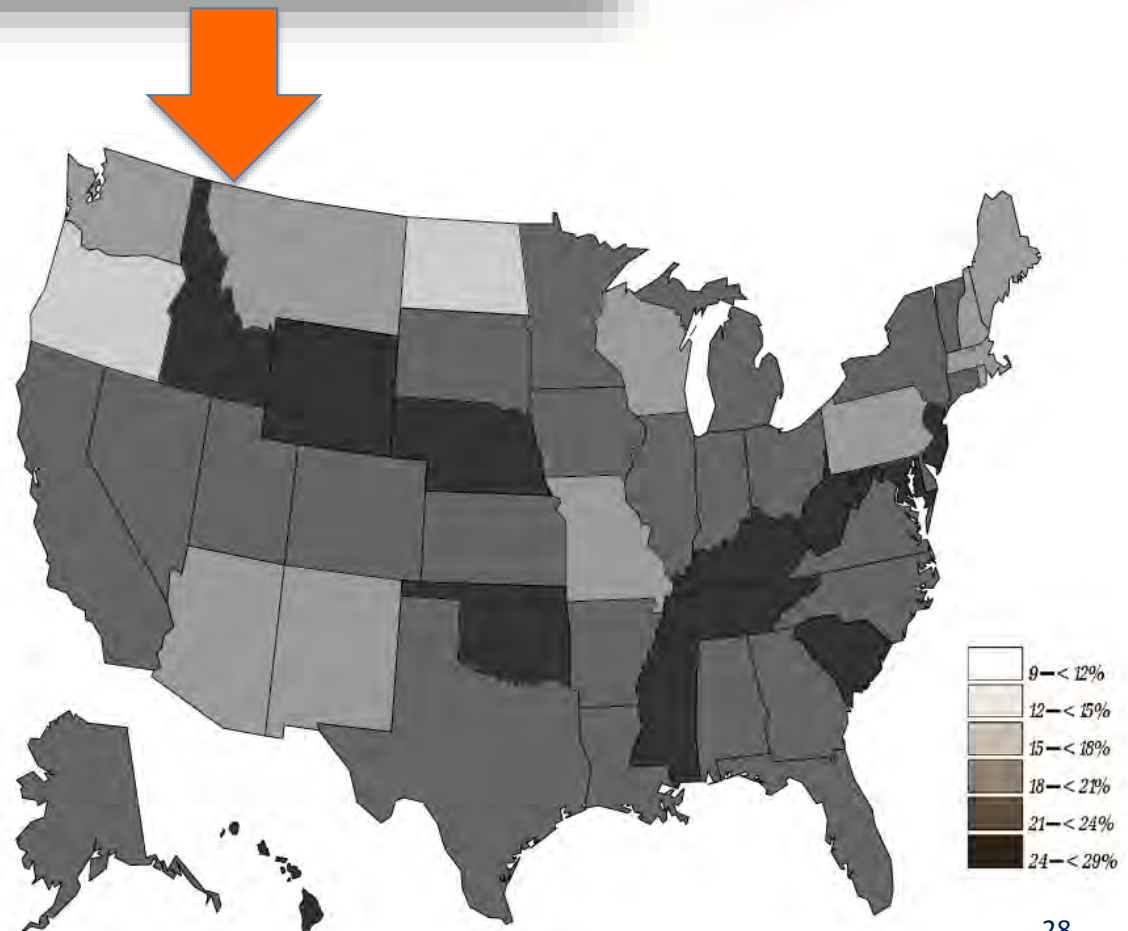
None

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



Wrong treatment?

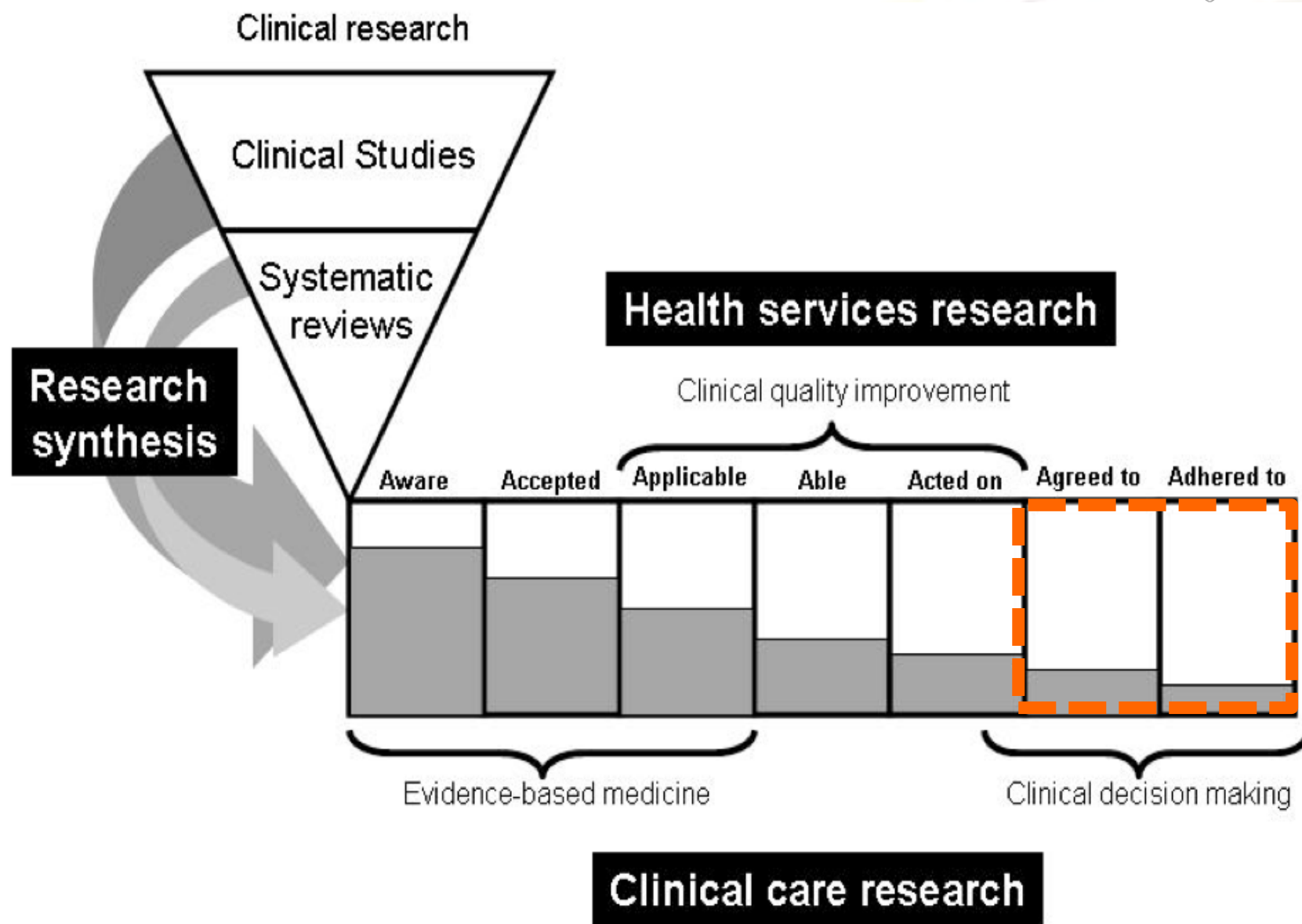
Wrong person

Wrong diagnosis

Wrong procedure

Wrong preferences





Engaging patients and families in their care:

Stage 3 Priorities



Health IT Policy Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT

Stage 1 + 2 Functional Objectives

- View, download, transmit
- Clinical summary
- Patient-specific educational resources
- Patient reminders
- Secure messaging
- Advance directives

Stage 3 Functionality Goals

- Provide patient and caregivers online access to health information
- Provide ability to contribute information in the record, including PRO
- Patient preferences recorded and used

MU Outcome Goals


- Patients understand their disease and treatments
- Patients participate in shared decision making
- Patient preferences honored across care teams

Shared Decision Making



Right thing to do.

Decision-Making Models

	Parental	Clinician-as-perfect agent	Shared decision making	Informed
Options	Informed consent	Clinician  Patient		
Deliberation	Clinician	Clinician after discussion	Joint	Patient (after discussion)
Decision	Clinician orders	Clinician recommends	Consensus	Patient requests



Empathic Decision Making
Partnership Dance
across models
support deliberation

The Body of Evidence

Systematic review of 115 RCTs

Compared to usual care, decision aids:

Increase patient involvement by 34% (++++-)

Increase patient knowledge of options by 13% (++++)

Increase consultation time by ~2.6 minutes

Reduce decisional conflict by ~7%

Reduce % undecided by 40%

No consistent effect on choice, adherence,
health outcomes, or costs

Statin Choice

Prepared exclusively for _____

1 What goes into figuring out my risk of having a heart attack in the next 10 years?

- Age
- Sex
- Years of diabetes
- Smoking
- Hemoglobin A1C
- Blood pressure
- Cholesterol
- Protein in your urine

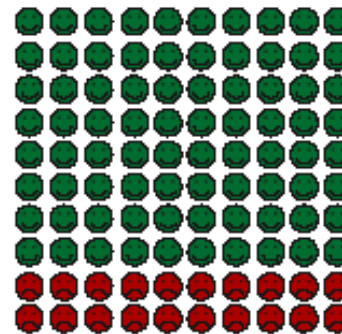
2 What is my risk of having a heart attack in the next 10 years?

NO STATIN

80 people DO NOT have a heart attack (green)

20 people DO have a heart attack (red)

The risk for 100 people like you who DO NOT take statins.



YES STATIN

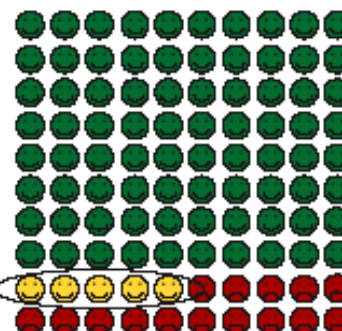
80 people still DO NOT have a heart attack (green)

5 people AVOIDED a heart attack (yellow)

15 people still DO have a heart attack (red)

85 people experienced NO BENEFIT from taking statins

The risk for 100 people like you who DO take statins.




- had a heart attack
- avoided a heart attack
- didn't have a heart attack

3 What are the downsides of taking statins (cholesterol pill)?

- Statins need to be *taken every day* for a long time (maybe forever).
- Statins cost money. (to you or your drug plan)
- **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)

4 What do you want to do now?

- ☐ Take (or continue to take) statins
- ☐ Not take (or stop taking) statins
- ☐ Prefer to decide at some other time

A stylized graphic of a human eye, composed of concentric, overlapping circles in shades of purple, pink, and yellow, located in the top right corner of the slide.

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 prescriptions in the low-risk
($<10\%$) group.

Threefold increase in self-reported adherence



Prepared exclusively for patient

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

Using information about your health, we've estimated that you have a **36.9%** chance of having a heart attack sometime in the next 10 years. This table shows you how we estimated this risk.

It shows you are lowering your cardiovascular risk by regularly using **metoprolol** and **perindopril** (Lipitor).

Risk Factor	100%	50-99%	0-49%
Age	65	55	45
Cholesterol	240	160	100
Blood Pressure	160/90	120/80	90/60
Diabetes	Yes	No	No
Smoking	Yes	No	No
Family History	Yes	No	No
Current Medication	Metoprolol, Perindopril, Lipitor	Metoprolol, Perindopril	Metoprolol

WHAT DOES THIS ESTIMATE MEAN?
It means that out of 100 people like you, about 37 will have a heart attack in the next 10 years. And about 63 will not.

None is perfect that we do not know what will happen to you. If you want to have a heart attack, we cannot tell when this will happen.

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

NO STATIN
Our guess of what will happen to 100 people like you if they want to decide to take statins out of 100 people like you, about 15 will have a heart attack in the next 10 years, and about 85 will not. About 5 people will avoid a heart attack by taking statins; about 95 did not change their outcome by taking statins.

YES STATIN
Our guess of what will happen to 100 people like you if they want to decide to take statins out of 100 people like you, about 15 will have a heart attack in the next 10 years, and about 85 will not. About 5 people will avoid a heart attack by taking statins; about 95 did not change their outcome by taking statins.

ATTENTION
If you want to decide to take statins, we will not know if you should be taking them or not. We cannot tell you if taking a heart attack or not having one depends on taking statins or not taking them. We cannot tell you if taking statins or not taking them will change your outcome.

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

- Statins need to be taken daily for years.
- Some statins may not suit you depending on your other drugs.
- Common side effects:** muscle pain, diarrhea, constipation, liver problems, low potassium.
- Muscle aching/tiredness:** 1 in 100 patients (about 1% need to stop statins because of this).
- Liver enzymes go up:** 1 in 100 patients (about 1% need to stop statins because of this).
- Muscle and kidney damage:** 1 in 20,000 patients (requires patients to stop statins).

4 What do you want to do now?

- ☐ Take (or continue to take) statins
- ☐ Not take (or stop taking) statins
- ☐ Discuss with your clinician today
- ☐ Discuss with your clinician in the future (when?)
- ☐ Discuss with others: What?



Weight Change

Metformin

None

Insulin

4 to 6 lb. gain

Pioglitazone

More than 2 to 6 lb.

Liraglutide/Exenatide

3 to 6 lb. loss

Sulfonylureas

Glipizide, Glimepiride, Glyburide

2 to 3 lb. gain

Gliptins

None

SGLT2 Inhibitors

3 to 4 lb. loss

<http://shareddecisions.mayoclinic.org>
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[Video](#) / [Web](#)

Low Blood Sugar (Hypoglycemia)

Metformin

Daily Routine

Metformin



OR



Insulin



OR



Pioglitazone



Liraglutide / Exenatide



Take in the hour before meals.

Sulfonylureas

Glipizide, Glimepiride, Glyburide



OR



Gliptins



SGLT2 Inhibitors



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MC5733-10rev0214

Blood Sugar (A1c Reduction)

Metformin

1 - 2%

Daily Sugar Testing (Monitoring)

Metformin

S	M	T	W	T	F	S

No monitoring necessary.

Insulin

S	M	T	W	T	F	S
•	•	•	•	•	•	•

Monitor once or twice daily, less often once stable.

Pioglitazone

S	M	T	W	T	F	S

No monitoring necessary.

Liraglutide/Exenatide

S	M	T	W	T	F	S
•	•	•	•	•	•	•

Monitor twice daily after meals when used with Sulfonylureas. Otherwise not needed.

Sulfonylureas

Glipizide, Glimepiride, Glyburide

S	M	T	W	T	F	S
•			•		•	

Monitor 2 - 5 times weekly, less often once stable.

Gliptins

S	M	T	W	T	F	S

No monitoring necessary.

SGLT2 Inhibitors

S	M	T	W	T	F	S

No monitoring necessary.

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MC5733-11rev0214

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. Under some plans name brands may be comparable in cost to generics.

Metformin (Generic available)

\$0.10 per day

\$10 / 3 months

Insulin (No generic available - price varies by dose)

Lantus: Vial, per 100 units: \$10

Pen, per 100 units: \$43

NPH: Vial, per 100 units: \$6

Pen, per 100 units: \$30

Short acting analog insulin: Vial, per 100 units: \$10

Pen, per 100 units: \$43

Pioglitazone (Generic available)

\$10.00 per day

\$900 / 3 months

Liraglutide/Exenatide (No generic available)

\$11.00 per day

\$1,000 / 3 months

Sulfonylureas

Glipizide, Glimepiride, Glyburide

\$0.10 per day

\$10 / 3 months

Gliptins (No generic available)

\$7.00 per day

\$630 / 3 months

SGLT2 Inhibitors (No generic available)

\$8.00 per day

\$750 / 3 months

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MC5733-13rev0214

Mullan et al Arch Intern Med 2009

Weight Change

Low Blood Sugar

Blood Sugar

Daily Routine

Daily Sugar Tests
(Monitoring)

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. Under some plans name brands may be comparable in cost to generics.

Metformin (Generic available)

\$0.10 per day \$10 / 3 months

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Pioglitazone (Generic available)

\$10.00 per day \$900 / 3 months

Liraglutide/Exenatide (No generic available)

\$11.00 per day \$1,000 / 3 months

Sulfonylureas

Glipizide, Glimepiride, Glyburide

\$0.10 per day \$10 / 3 months

Gliptins (No generic available)

\$7.00 per day \$630 / 3 months

What aspect of your next diabetes medicine would you like to discuss first?

Weight Change

Stopping Approach

Cost

Sexual Issues

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.

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).

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 (libido) or loss of ability to reach orgasm because of their antidepressant.

Weight loss
(1 to 5 lbs) ← None → Weight gain
(1 to 5 lbs)

Sleep

Keep in Mind

SELF REPORT

Patients and clinicians confident about choice (.001)

Knowledge 12% better (p=.02)

Satisfaction with process 35% better (p=0.002)

VIDEO

Patient involvement 40% better (p=.001)

70% vs. 92% patient voices preference

92% vs. 95% clinician voices preference

0% vs. 63% patient identifies top issue

Fidelity = 48%

OTHER OUTCOMES

No difference in PHQ-9 or medication adherence

Risk of Stroke

Your Risk of Stroke without Anticoagulation

In 100 people like you in the next year there will be



2 fatal or disabling strokes
5 non-disabling strokes
93 no strokes

Your Risk of Stroke with Anticoagulation

In 100 people like you in the next year there will be



5 strokes avoided by taking anticoagulation
fewer than 2 fatal or disabling strokes
fewer than 1 non-disabling stroke
98 no strokes

CHA₂DS₂-VASc 5

Risk of Serious Bleeding

Cost

Diet and Medication Interactions

Work, Home & Fun Activities

Anticoagulation Routine

Warfarin requires committing to regular blood tests.

There is no testing required with a New Anticoagulant.

Warfarin

Cumedin
Jantoven
Marevan
Uniwafin



Once daily



Regular blood tests



Am I available to do the regular blood tests that Warfarin requires?

Work / travel / family demands?
Transportation?

New Anticoagulants

Dabigatran

Pradaxa 110mg, 150mg



AM



PM

Apixaban

Eliquis



AM



PM

Rivaroxaban

Xarelto



Once daily

Edoxaban

Lixiana



Once daily

Summary of Mayo Experience

Age: 40-92 (avg 65)

Primary care, ED, hospital, specialty care

74-90% clinicians want to use tools again.

Adds ~3 minutes to consultation.

58% fidelity without training.

20% improvement in patient knowledge.

17% improvement in patient involvement.

Effects are similar in vulnerable populations.

Variable effect on clinical outcomes, cost

Training

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.



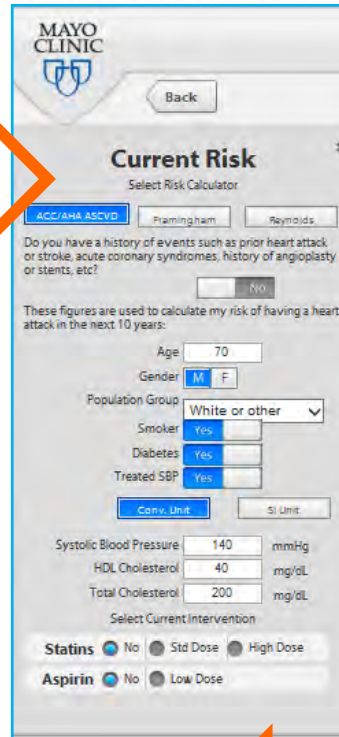
6

Medication choice is made— brochure given to patient to take home.

Integration Into Electronic Workflow

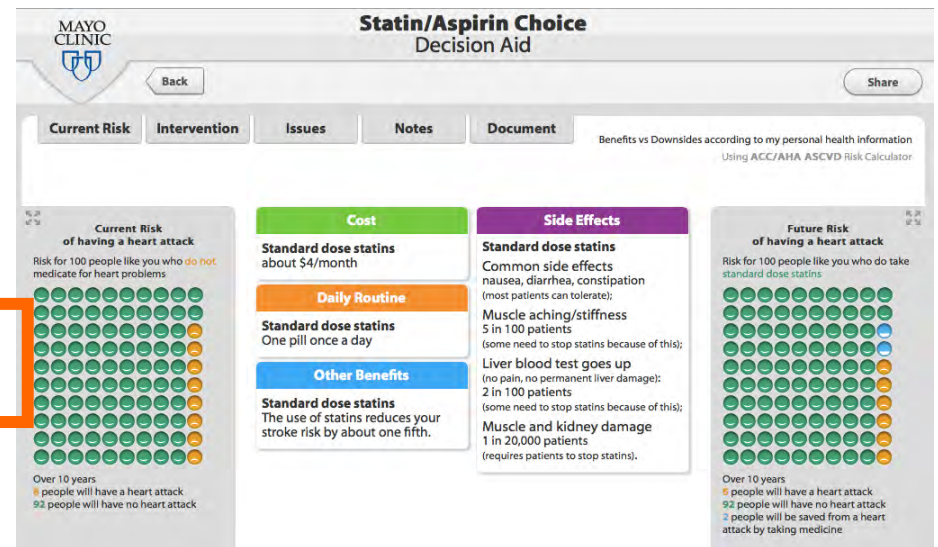
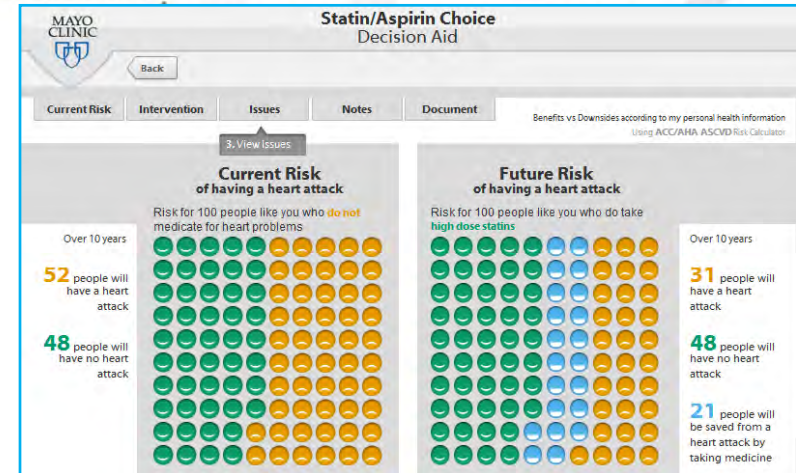
EMR Link

Web



Mayo Clinic logo and navigation buttons (Back, Print, Email, etc.) are at the top. The title is 'Current Risk' with a subtitle 'Select Risk Calculator'. Below are tabs for 'ACC/AHA ASCVD', 'Pamphlet', and 'Reynolds'. A question asks about history of heart events with a 'No' button. A note states: 'These figures are used to calculate my risk of having a heart attack in the next 10 years:'. Input fields include Age (70), Gender (M/F), Population Group (White or other), Smoker (Yes/No), Diabetes (Yes/No), and Treated SBP (Yes/No). Unit converters for 'Conv. Unit' and 'SI Unit' are present. Blood pressure is 140 mmHg, HDL Cholesterol is 40 mg/dL, and Total Cholesterol is 200 mg/dL. At the bottom, 'Select Current Intervention' shows 'Statins' with 'No', 'Std Dose', and 'High Dose' options, and 'Aspirin' with 'No', 'Low Dose', and 'High Dose' options.

EMR
Documentation

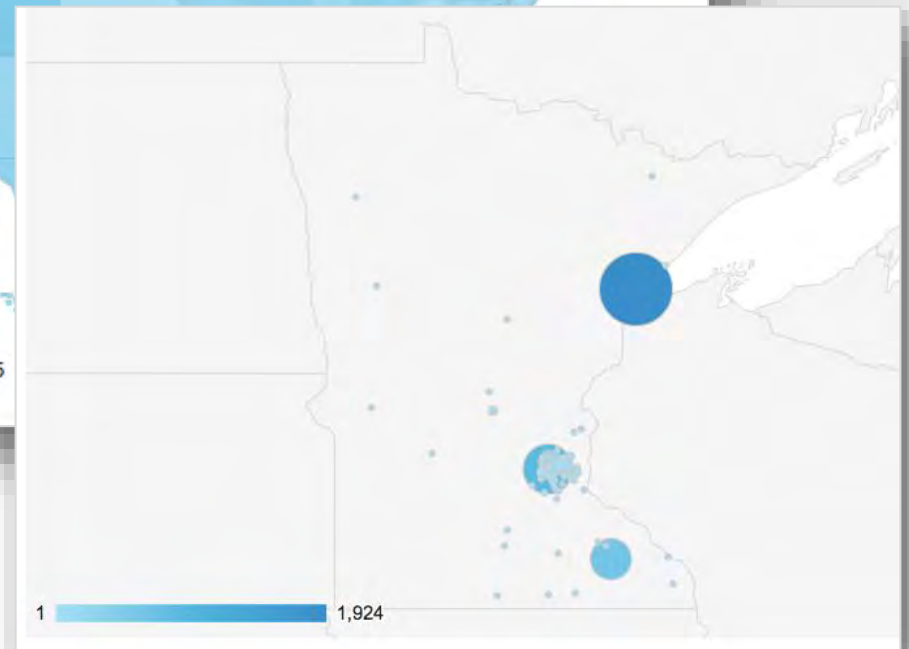
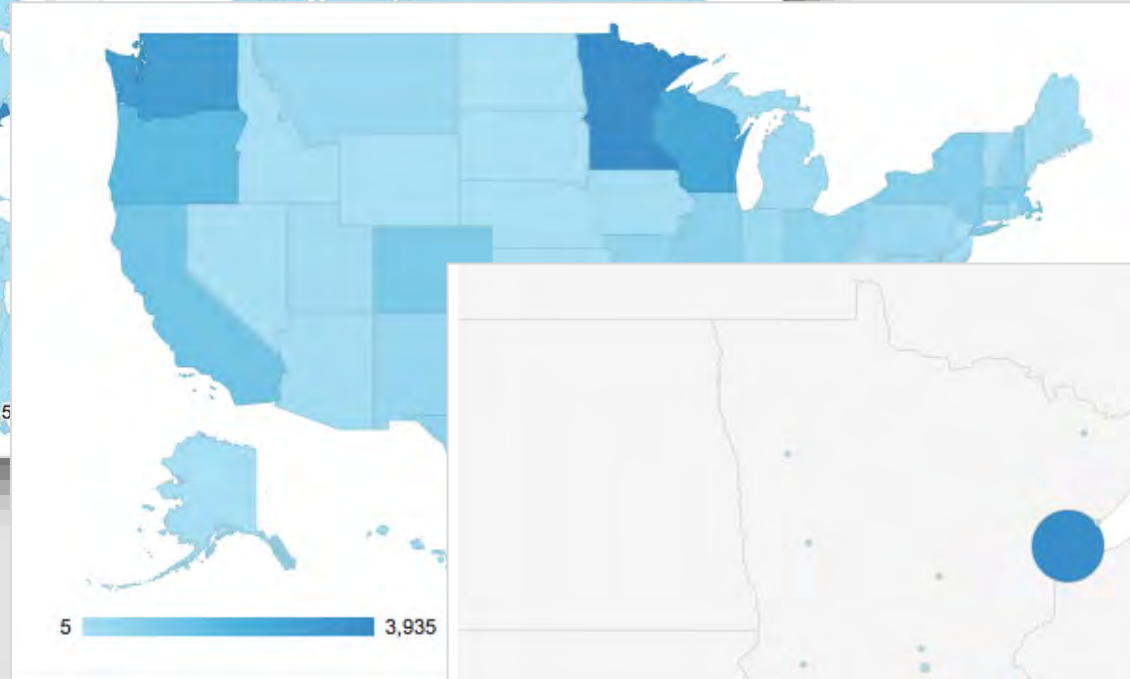
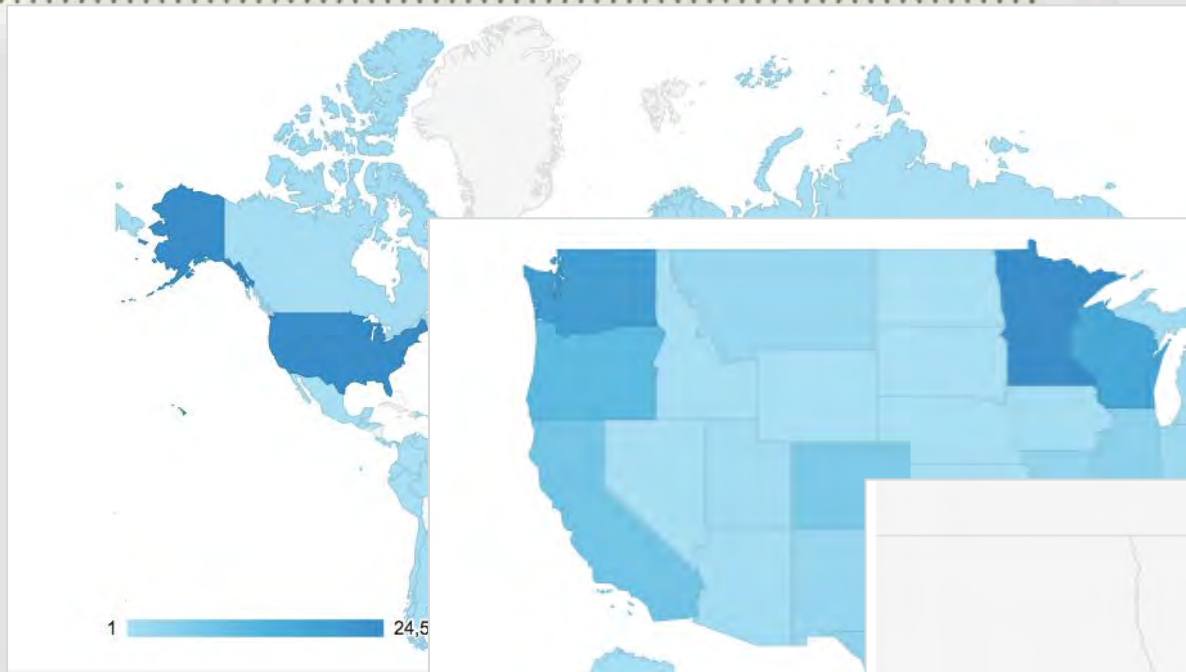


<http://statindecisionaid.mayoclinic.org>

Largest Test of Point-of-Care Shared Decision Making



Meanwhile...



More about shared decision making:
<http://shareddecisions.mayoclinic.org>

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AHRQ's SHARE Approach: Integrating PCOR into Shared Decision Making

Alaina Fournier, Ph.D.

Office of Communications and Knowledge Transfer
Agency for Healthcare Research and Quality (AHRQ)



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Effective Health Care Program

Disclosures

Relevant Financial Relationships

None

The Agency for Healthcare Research and Quality



- ▶ AHRQ is a Federal agency that is part of the U.S. Department of Health & Human Services.
- ▶ AHRQ works to produce and disseminate evidence to make health care safer, of higher quality, more accessible, equitable, and affordable.

Patient-Centered Outcomes Research (PCOR)

The Affordable Care Act directs AHRQ to disseminate and implement PCOR.

PCOR:

- ▶ Assesses preventive, diagnostic, therapeutic, palliative, or health delivery system interventions
- ▶ Compares the benefits and harms of interventions
- ▶ Aims to find out how well interventions work in everyday practice settings, not just in clinical trial settings
- ▶ Focuses on outcomes that matter to people

AHRQ's Effective Health Care Program

- ▶ **Synthesizes PCOR** through systematic reviews and comparative effectiveness reviews
- ▶ **Translates PCOR** findings into plain-language resources for patients and health care professionals to support decision making
- ▶ **Disseminates PCOR-based decision aids** to those who need them

Goal: Improve health care quality and patient health outcomes through informed decision making by patients, providers, and policymakers.

www.effectivehealthcare.ahrq.gov


Effective Health Care Products



Clinician Research Summaries

- ▶ More than 60 information products targeted to physicians, nurses, and other clinicians.
- ▶ Summaries provide:
 - The “clinical bottom line” on treatments
 - Graded descriptions of the strength of the evidence behind the research
- ▶ Most have online CME/CE activities available.

Clinician Research Summary

Effective Health Care Program

Mental Health
Depression

Treatment for Depression After Unsatisfactory Response to SSRIs in Adults and Adolescents

Research Focus for Clinicians

A systematic review of 44 clinical studies published between January 1980 and April 2011 examined the comparative effectiveness, benefits, and adverse effects of interventions for adults and adolescents with major depressive disorder (MDD) who have an unsatisfactory response to treatment with a selective serotonin-reuptake inhibitor (SSRI). The review also compared recommendations from 27 Clinical Practice Guidelines (CPGs) published from January 2004 to April 2011. The findings of this review do not apply to subjects who have a primary diagnosis of bipolar disorder, schizophrenia, or anxiety disorder. This summary is provided to inform discussions of options with patients and to assist in decisionmaking along with consideration of a patient's values and preferences and should not be construed to represent clinical recommendations or guidelines. The full report is available at www.effectivehealthcare.ahrq.gov/ssri-depression.cfm.

Background

Although patients with MDD have a 63-percent response rate during 6 to 12 weeks of treatment with second-generation antidepressants, 53 percent do not achieve remission.^{1,2}

Up to two-thirds of adult patients will not achieve remission with an SSRI.³ SSRIs are a frequently used class of second-generation antidepressants.

Clinicians are faced with a number of treatment options (see Table 1) after an inadequate response to an SSRI, including both monotherapy and combination therapy approaches.

Monotherapy approaches include:

- Optimizing the dosage or duration of the current SSRI
- Switching to another SSRI or another antidepressant
- Switching to a nonpharmacological treatment (e.g., psychological therapies or exercise)

Combination therapy approaches include:

- Adding medications (e.g., augmenting agents, a different SSRI, or other antidepressants)
- Switching to another agent (e.g., a different SSRI) and adding another medication
- Adding a nonpharmacological treatment
- Combinations of these treatments

In the studies included in the systematic review, the definition of an adequate response to SSRI medications is not consistent but generally refers to a 50-percent decrease in symptom severity. Remission from depression is defined as being free or nearly free of symptoms for the current episode. The systematic review evaluated treatment options for patients who only had a partial response or who had no response to an SSRI medication.


Conclusion

Evidence remains limited to support clinical decisionmaking about the available approaches for treating patients with MDD who have an inadequate response to SSRIs. For adults with MDD, evidence is insufficient to guide decisionmaking for comparisons among monotherapies, monotherapies versus combination therapies, and comparisons among combination therapies with a few exceptions. Adding an atypical antipsychotic—risperidone or olanzapine—to ongoing SSRI treatment may slightly improve response and remission rates when compared with continuing SSRI treatment alone. Low-level evidence suggests that comparable response and remission rates are obtained from switching to a new antidepressant versus combining the new antidepressant with pharmacological or nonpharmacological treatment. For adolescents with MDD, low-level evidence suggests that combining an antidepressant and cognitive behavioral therapy (CBT) may be superior to medication alone. For adults, most reported adverse effects were consistent with those typically associated with antidepressant use. Comparative evidence is insufficient to guide decisionmaking about adverse effects both in adults and in adolescents.

¹ Gartlehner G, et al. *Ann Intern Med*. 2011;155:772-85. PMID: 22147715.

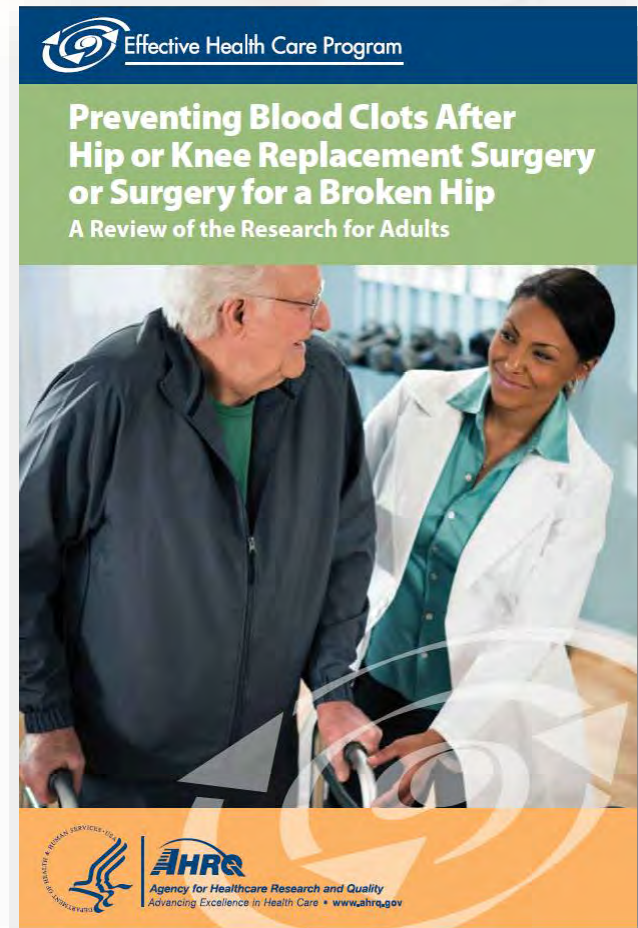
² First generation antidepressants may include tricyclic antidepressants and monoamine oxidase inhibitors. More recently developed second-generation antidepressants include SSRIs, selective serotonin and norepinephrine reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, and other second-generation antidepressants (bupropion, nefazodone, and trazodone).

³ Peratza DG, et al. *J Psychiatr Res*. 2009;43(5):512-6. PMID: 18797603.

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Consumer Research Summaries

- ▶ Over 50 plain-language information products summarize PCOR findings on treatments for chronic conditions.
- ▶ Each summary includes:
 - Background on the condition
 - Benefits, risks, and side effects of treatment options
- ▶ Available in English and Spanish, and with companion audio versions.



Patient Decision Aids

- ▶ Online, interactive tools to help patients with certain clinical conditions think about what's important to them when talking to their doctor.
- ▶ AHRQ Decision Aids include:
 - Information on the condition
 - Information on treatment options



Shared Decision Making in the Health Care Landscape



- ▶ Health transformation initiatives call for improvements in patient engagement and shared decision making.
- ▶ PCOR provides evidence to discuss benefits, harms, and risks of treatment options.
- ▶ Health care providers need training in
 - using evidence-based decision aids
 - communications skills to discuss values and preferences with patients
 - implementing shared decision making in practice

Educating the Educators



- ▶ Create a **train-the-trainer workshop curriculum** and **collateral tools** to help clinicians learn how to use Effective Health Care and PCOR resources in shared decision making.
- ▶ Conduct **10 workshops** per year across the country.
- ▶ Provide support to trainees with **Webinars, technical assistance, and a learning network.**

Formative Research Approach



- ▶ Literature Review
- ▶ Health Educators Needs Assessment
 - Online Survey: Over 2,200 respondents
 - Focus Groups: Treating and non-treating clinicians
 - Key informant interviews
- ▶ Three types of questions
 - Who should we train?
 - What should be included in the training?
 - How should we train?

* OMB No. 0935-0179

Question 1: Who do we train?

- ▶ **Common Themes Identified (*Survey, Focus Groups, Interviews, Literature Review*)**
- ▶ Treating clinicians vs. non-treating clinicians are more likely to engage in discussions with patients about health care options.
 - A key goal for treating clinicians is providing patients (and caregivers) technical information about their condition and care options.
 - Key goals of non-treating clinicians appear to be assessing patients' needs and goals, and clarifying their concerns.
- ▶ Most available training programs target treating clinicians, but there is growing interest for programs that target interdisciplinary professionals and teams.

Question 2: What do we include in the training?

Common Themes Identified (*Survey, Focus Groups, Interviews, Literature Review*)

-
- The diagram uses blue curly braces on the left to group themes. The 'All Disciplines' brace groups five items, each marked with a green right-pointing triangle. The 'Treating Clinicians' brace groups two items, each marked with a green diamond.
- ▶ What CER/PCOR is and how it can be used in SDM
 - ▶ Where to find and how to easily access PCOR information for use in SDM
 - ▶ How to engage patients in the SDM process and elicit preferences
 - ▶ Approaches that can be used in a limited time context/finding time
 - ▶ Cultural competency
 - ❖ Communicating technical information about condition and options
 - ❖ Communicating harms/benefits, risk communication competencies

Question 3: How do we train?

Common Themes Identified (*Survey, Focus Groups, Interviews, Literature Review*)

- ▶ **Format**: Face to face (4-6 hours), with a possible Web-based tutorial component, and learning community for ongoing learning; should be interdisciplinary
- ▶ **Techniques**: Training should include role playing and case studies, video examples of SDM, and small breakout sessions

The **SHARE** Approach

Essential Steps of Shared Decision Making

Five steps for you and your patients to work together to make the best possible health care decisions.

Step 1:

Seek your patient's participation

Communicate that a choice exists and invite your patient to be involved in decisions.

Step 2:

Help your patient explore and compare treatment options

Discuss the benefits and harms of each option.

Step 3:

Assess your patient's values and preferences

Take into account what matters most to your patient.

Step 4:

Reach a decision with your patient

Decide together on the best option and arrange for a followup appointment.

Step 5:

Evaluate your patient's decision

Plan to revisit decision and monitor its implementation.



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Effective Health Care Program

www.ahrq.gov/shareddecisionmaking

April 2014 AHRQ Pub. No. 14-0026-2-EF

PCOR is introduced in Step 2: Help your patient explore and compare treatment options

- ▶ **Discuss the benefits and harms of each treatment option.**
 - Know the benefits and risks of each option.
 - Understand how they relate to your patient's situation and condition.
- ▶ **Use evidence-based decision-making resources to compare the treatment options.**

The SHARE Approach

Train-the-Trainer Workshop

- Consists of four modules and a training module (~6.5 hours of training)

Module 1: Shared Decision Making

Module 2: AHRQ PCOR Resources

Module 3: Communication

Module 4: Putting Shared Decision Making Into Practice

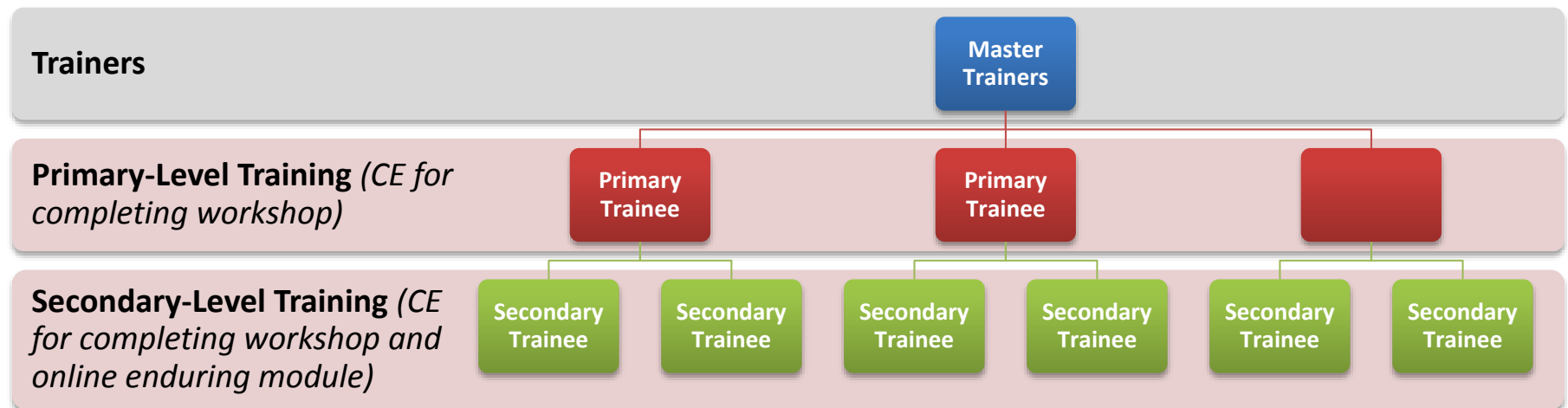
Training Module



About the SHARE Approach Implementation Strategy

► Implementation Model

- 10 accredited training sessions a year across the country
 - 25-50 participants per session (~250-500 primary trainees a year)
 - Primary trainees train local-setting colleagues and health provider stakeholders (to facilitate dissemination of curriculum concepts)



Shared Decision Making Support Materials and Activities from AHRQ

- ▶ **Shared decision-making toolkit on the AHRQ Web site**
 - Workshop curriculum modules
 - 9 informational tools
 - Video, screensaver, poster
 - Links to other AHRQ resources that support or are related to shared decision making
- ▶ **AHRQ provides ongoing support activities for participants of the workshop.**
 - SHARE Approach Web conferences
 - SHARE Approach Learning Network (coming soon!)

Ongoing Evaluation

- ▶ **AHRQ is conducting an ongoing evaluation of the initiative to learn about:**
 - Who is participating in training
 - The confidence of primary trainees in training others about the SHARE Approach and AHRQ's PCOR resources
 - The extent to which workshop participants have been able to conduct additional trainings, start new PCOR education programs, or integrate the workshop curriculum into their local settings
 - Participation in ongoing Web conferences and the Learning Network that are planned as part of this effort
 - How workshop participants are using what they have learned about PCOR and shared decision making in their own practice

The SHARE Approach



- ▶ All Effective Health Care materials described here may be found on AHRQ's Effective Health Care Web site:

<http://effectivehealthcare.ahrq.gov/>

- ▶ Shared decision making tools and resources are available on AHRQ's Shared Decision Making Toolkit Web site"

<http://www.ahrq.gov/shareddecisionmaking/>

The SHARE Approach Web site also contains information about upcoming SHARE Approach workshops around the country.



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Obtaining CME/CE Credits



If you would like to receive continuing education credit for this activity, please visit:

<http://afya.cds.pesgce.com>

How To Submit a Question

- ▶ At any time during the presentation, type your question into the “Q&A” section of your WebEx Q&A panel.
- ▶ Please address your questions to “All Panelists” in the dropdown menu.
- ▶ Select “Send” to submit your question to the moderator.
- ▶ Questions will be read aloud by the moderator.

