Patient-centered Translation of Evidence Into Practice

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  – American Diabetes Association (ADA)
  – Mayo Clinic Foundation for Medical Education and Research
  – Mayo Clinic CTSA
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ATP III Guidelines At-A-Glance
Quick Desk Reference

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

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

LDL Cholesterol – Primary Target of Therapy
- <100: Optimal
- 100-129: Near optimal/above optimal
Key problem:
Do not follow advice

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

Poor health despite cost and side effects

Complicated patient-clinician relationship

Cutler and Everett NEJM 2010  10.1056/NEJMp1002305
Patient makes decision about medication.

Clinician and patient discuss medication options.

Clinician begins consultation with clinician.

Patient leaves consultation with prescription.
Evidence synthesis

Field testing

Observations clinical encounter

Initial prototype

- Designers
- Study team
- Patients advisory groups
- Clinicians

Modified prototype

Final Decision aid

Evaluation
Diabetes Cards

• Nature of diabetes medication discussions
• Summarizing the research evidence

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

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

Iterative process – *Choice Architecture*
# Baseball Cards

## Enoxatide
- **Form:** Injection injection
- **Use:** Weight loss with metformin or sulfonylureas
- **Efficacy:** Requires 2-3 months to see results
- **Side Effects:**
  - **Metformin:**
    - **Weight Loss:**
      - Initial: 2-5times/week
      - 2-3 times/week after 1 month
    - **Monitoring Needs:**
      - Occasional

## Insulin
- **Form:** Injection injection
- **Use:** Weight loss with metformin or sulfonylureas
- **Efficacy:** Requires 1-2 years to see results
- **Side Effects:**
  - **Metformin:**
    - **Weight Loss:**
      - Initial: 2-5times/week
      - 2-3 times/week after 1 month
    - **Monitoring Needs:**
      - Occasional

## Glitazones
- **Form:** Oral capsules
- **Use:** Weight loss with metformin or sulfonylureas
- **Efficacy:** Requires 6-8 months to see results
- **Side Effects:**
  - **Metformin:**
    - **Weight Loss:**
      - Initial: 2-5times/week
      - 2-3 times/week after 1 month
    - **Monitoring Needs:**
      - Occasional

## Sulfonylureas
- **Form:** Oral capsules
- **Use:** Weight loss with metformin or sulfonylureas
- **Efficacy:** Requires 6-8 months to see results
- **Side Effects:**
  - **Metformin:**
    - **Weight Loss:**
      - Initial: 2-5times/week
      - 2-3 times/week after 1 month
    - **Monitoring Needs:**
      - Occasional

## Metformin
- **Form:** Oral capsules
- **Use:** Weight loss with metformin or sulfonylureas
- **Efficacy:** Requires 6-8 months to see results
- **Side Effects:**
  - **Metformin:**
    - **Weight Loss:**
      - Initial: 2-5times/week
      - 2-3 times/week after 1 month
    - **Monitoring Needs:**
      - Occasional
  
---

### Diabetes Advisory Group
- **Live Clinical Setting:**
- **Research Evidence + Practice Review:**
- **Decision Aid:**
**Exenatide**

**Form**: Injectable medication

**Typically Used With**: Metformin or Sulfonylureas

**Efficacy/Adverse Effects**
- Efficacy: When used with Metformin, there is no risk of severe hypoglycemia and the chances of minor hypoglycemia is about 5 in 100. When used with Sulfonylureas, the risk of severe hypoglycemia is less than 1 in 100 and for minor hypoglycemia 30 in 100 (within 30 days).
- Adverse Effects: Other side effects of Exenatide include nausea and diarrhea. Of 100 people treated, 40 will experience initial nausea with 60 of those experiencing persistent nausea. A total of 13-26 of 100 people will have some form of diarrhea.

**Dosing**
- Twice daily: at the morning and evening before eating.
- Monitoring: If taking Sulfonylureas, monitor daily after meals. On stable, you may monitor less often.

**Insulin**

**Form**: Injectable medication

**Typically Used With**: Alone or with Metformin and/or Sulfonylureas

**Efficacy/Adverse Effects**
- Efficacy: There is no limit to the amount of AS that you can receive with insulin.
- Adverse Effects: Infusion is often associated with weight gain. On average, most patients who use insulin will see a weight gain of around 4-5 pounds.

**Dosing**
- Once (1) or twice (2) daily. On stable, you can monitor less often.

**Glitazones**

**Form**: Pill

**Typically Used With**: Alone or with Metformin and/or Sulfonylureas

**Efficacy/Adverse Effects**
- Efficacy: With Metformin, Glitazones typically lower A1C by 1%. With Metformin and Sulfonylureas, Glitazones may be able to lower A1C by 2-4%.
- Adverse Effects: A common effect of Glitazones is weight gain. When combined with Metformin, which does not typically have a weight gain effect, the average weight gain is 2-4 pounds. When combined with Sulfonylureas, which do have a weight gain effect, the combined average weight gain is between 2-33 pounds.

**Dosing**
- Once daily.

**Sulfonylureas**

**Form**: Pill

**Typically Used With**: Alone or with Metformin

**Efficacy/Adverse Effects**
- Efficacy: Sulfonylureas typically lower A1C by 1-2%.
- Adverse Effects: A common effect of Sulfonylureas is weight gain. The average gain is between 6-14 pounds. Although it should be noted that some people do not gain any weight at all and others may gain more than the average.

**Dosing**
- Once (1) or twice (2) daily. On stable, you can monitor less often.

**Metformin**

**Form**: Pill

**Typically Used With**: Alone or with Sulfonylureas

**Efficacy/Adverse Effects**
- Efficacy: Metformin has shown to lower your A1C by 1-2%.
- Adverse Effects: Metformin causes no risk of severe hypoglycemia. The risk of minor hypoglycemia is 2-3 people out of 100 by yourself experiencing some symptoms within one year of use.
- Side Effects: When first starting Metformin, you may experience some nausea, diarrhea or flatulence. In the first few (2) weeks. After that, most people become accustomed to the drug.
More helpful
Improved knowledge
Increased patient involvement
No difference in adherence (perfect adherence in control gr)
No significant impact on HbA1c levels

Mullan RJ et al. Archives of Internal Medicine 2009
Final Iteration: Issue Cards
ATP III Guidelines At-A-Glance Quick Desk Reference

Step 1

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

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

<table>
<thead>
<tr>
<th>LDL Cholesterol – Primary Target of Therapy</th>
<th>Optimal</th>
</tr>
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<tbody>
<tr>
<td>&lt;100</td>
<td></td>
</tr>
<tr>
<td>100-129</td>
<td>Near optimal/above optimal</td>
</tr>
<tr>
<td>130-159</td>
<td>Borderline high</td>
</tr>
<tr>
<td>160-189</td>
<td>High</td>
</tr>
</tbody>
</table>
Risk-Treatment Paradox

Probability of a statin prescription

- Low: 37.7
- Intermediate: 26.7
- High: 23.4

Ko, Mamdani and Alter JAMA 2004
1. USER-CENTERED OBSERVATION

Observations were conducted in real office visits.

Observers learned how patients and clinicians made decisions.

Artifacts were collected, notes taken, and sketches made about the observations.

2. MULTI-DISCIPLINARY SYNTHESIS

A board displayed the collective findings of the group's observations.

The collective observations of the group were discussed. There were no observations of patient participation in the decision to start statins.

It was decided to create a decision aid. The Statin Choice development focused on three facets of the decision aid: content, risk, and the interface.

3. ITERATIVE DEVELOPMENT

The final version incorporated the collective research and feedback from topic experts and end users.

Insights regarding the conveying of risk, and the design of the interface were gathered from the development of prototypes used during real office visits.

Gathering patients' and clinicians' feedback allowed for further refinements in the development of the decision aid.
SHOULD I TAKE STATINS?
A decision making tool

High Risk (>30%)
**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?**

**Improved Knowledge**

- Risk estimation
- Comfort with the decision
- Total trust

**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 (start) statins
- Not take (start) statins
- Prefer to decide at some other time

**Action (70% fewer Rx in low risk patients)**

**Short-term adherence**

**Weymiller et al. Arch Intern Med 2007**
SHOULD I TAKE ASPIRIN?

A decision making tool

Average Risk (<15%)
BENEFITS AND HARMS OF ASPIRIN OVER 10 YEARS

The primary benefit of aspirin is that it may help prevent a heart attack. The primary harm of aspirin is a risk of bleeding from the stomach that will require you to receive emergency care, receive blood transfusion, undergo endoscopy, and stay in the hospital for about 3 days, expecting a full recovery.

NO ASPIRIN
If 1000 people like you, DO NOT take aspirin...
- 900 people DO NOT have a heart attack (green)
- 100 people DO have a heart attack (grey)
- 7 people DO experience bleeding that is NOT RELATED to aspirin (pink)

YES ASPIRIN
If 1000 people like you, DO take aspirin...
- 900 people DO NOT have a heart attack (green)
- 80 people DO have a heart attack (grey)
- 20 people AVOIDED a heart attack (yellow)
- 980 people experienced NO BENEFIT from taking aspirin
- 7 people DO experience bleeding that is NOT RELATED to aspirin (pink)
- 3 people DO experience bleeding RELATED to aspirin (red)
Statin Choice Decision Aid

Benefits vs Downsides according to my personal health information
Using UKPDS Risk Calculator

Your current risk
The risk for 100 people like you who do not take statins:
- Over 10 years: 20 people will have a heart attack;
  80 people will have no heart attack.

Cost
Std. dose statins: about $4/month

Daily Routine
Statin need to be taken every day for a long time.
(maybe forever)

Side Effects
Common side effects
- Nausea, diarrhea, constipation (most patients can tolerate)

Muscle aching/stiffness
- 5 in 100 patient
  (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)

Other Benefits
- Decreases risk of stroke by about 19%

Your risk by taking statins
The risk for 100 people like you who do take statins on standard dose:
- Over 10 years: 15 people will have a heart attack;
  85 people will have no heart attack;
  5 people will be saved from a heart attack;
Adherence after Initiating Bisphosphonates

Source: Rabenda et. al Osteoporosis 2008
Association Between Adherence and Risk of Fracture

![Graph showing the association between adherence and risk of fracture. The graph plots the probability of hip fracture against MPR (%). The black line represents the probability (prob), the red dashed line represents the lower confidence interval (LCI95%), and the red dashed line represents the higher confidence interval (HCl95%). As MPR increases, the probability of hip fracture decreases.]
Osteoporosis Choice

What is my risk of breaking a bone?

Benefits

- >75% MDs found helpful
- + 1 min to consultation time
- Improved knowledge & risk estimate
- No change in comfort or trust
- Increased patient involvement

Drawbacks

- Medical decision
  - Abdominal Problems
    - Some people may experience heartburn, nausea, or belly pain. This may be due to the medication. If the medication continues to cause discomfort, the problem will go away if you stop taking it.
  - Out of Pocket Cost
    - With insurance $80 | without insurance $70.90

Preparation

- Your fracture risk is estimated primarily by:
  - Your age
  - Your bone mineral density (T score)
- It is also affected by:
  - If you have had a fracture
  - If a parent had a fracture
  - If you currently smoke
  - If you drink more than 2 drinks a day
  - If you have taken prescription steroids
- Based on these risk factors, we estimate you have a 10-30% chance of breaking a bone within the next 10 years.

With Medication

- Roughly 2 in 100 have a fracture within the next 10 years. 76 will not have a fracture because of the medication.

What would you like to do?

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

Structural Intervention

Remove copay on recommended medications

- Statins
  - Full Coverage: 49.3%
  - Usual Coverage: 41.9%

- All Medications
  - Full Coverage: 24.3%
  - Usual Coverage: 19.3%

Choudhry N et. al. *NEJM* 2011
Imagine 1000 people like you recovering from a heart attack.

If over the next 6 months, those 1000 people DO NOT take any of the recommended medications,

- will die.
- will live.

If over the next 6 months, those 1000 people DO take the medications,

- will avoid death.
- won’t avoid death.

**KEY**

- Person who lives.
- Person who dies.
- Person who avoids death.

- 4-5 min to consultation time
- Improved knowledge & risk estimate
- No change in comfort or trust
- High-levels of patient involvement
- Increased satisfaction
Adherence to Medications

<table>
<thead>
<tr>
<th></th>
<th>Decision Aid</th>
<th>Usual Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statins</td>
<td>79%</td>
<td>72%</td>
</tr>
<tr>
<td>All Medications</td>
<td>78%</td>
<td>73%</td>
</tr>
</tbody>
</table>
A Case Study

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

No ischemic changes on ECG; serial cardiac troponins were negative

PMH: Hypertension, Migraines, Breast cancer
Former smoker

What would you want to do if you were her?
Hospital or ED Observation Unit Admission

- Canada 1
- Canada 2
- US
What’s Next?

Prepared for: ______________

1. Your Chest Pain Diagnosis
   Our initial evaluation has NOT shown any evidence of a heart attack. This conclusion is based on a blood test (to look for troponins — enzymes that are released when the heart muscle is damaged) and an electrocardiogram (to check that your heart is getting enough oxygen and blood). Over the next five hours, two additional blood tests (troponins) will be taken to definitively rule out a heart attack.
   However, even if these tests do confirm our diagnosis, your chest pain may indicate possible warning signs of a FUTURE heart attack.

2. Further Tests
   A STRESS TEST EVALUATION may more precisely determine if your heart is functioning correctly by viewing blood flow to your heart while at rest and under stress.
   Examining your risk will help you to determine whether you would like to have a stress test now or would like assistance in making a clinic appointment.

3. Your Personal Risk Evaluation
   Your risk of having a heart attack or of having a pre-heart attack diagnosis within the next 45 days can be determined by comparing you to people with similar factors who also came to the Emergency Department with chest pain.
   Of every 100 people with factors like yours who came to the emergency department with chest pain...

   3. had a heart attack or a pre-heart attack diagnosis within 45 days of their emergency department visit, 97 did not.

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

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

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Hess et. al Circ CQO 2012
Summary of Findings: Chest Pain Choice

Improved knowledge

Comfort with the decision

Greater level of engagement

High levels of satisfaction
## Evidence Synthesis

<table>
<thead>
<tr>
<th>BENEFITS</th>
<th>COSTS</th>
<th>SEXUAL PROBLEMS</th>
<th>SLEEP</th>
<th>WEIGHT CHANGE</th>
<th>DISCONTINUATION SYNDROME</th>
<th>GASTRO-INTESTINAL PROBLEMS</th>
<th>CONSIDERATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tricyclic Antidepressants (TCAs)</td>
<td>$4 / month Supreparin</td>
<td>Less Likely</td>
<td>More Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
</tr>
<tr>
<td>Amifitryptiline or Noramitryptiline</td>
<td>$4 / month Supreparin</td>
<td>Less Likely</td>
<td>More Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
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<tr>
<td>Mirtazapine</td>
<td>$85 / month</td>
<td>Less Likely</td>
<td>More Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
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<tr>
<td>Venlafaxine</td>
<td>$100 / month</td>
<td>Less Likely</td>
<td>More Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
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<tr>
<td>Duloxetine</td>
<td>$150 / month</td>
<td>Less Likely</td>
<td>More Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
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<tr>
<td>Ectalolaniol</td>
<td>$55 / month</td>
<td>Less Likely</td>
<td>More Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>$60 / month</td>
<td>Less Likely</td>
<td>More Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
</tr>
<tr>
<td>Paroxetine</td>
<td>$60 / month</td>
<td>Less Likely</td>
<td>More Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
</tr>
<tr>
<td>SNRIs</td>
<td>$230 / month</td>
<td>Less Likely</td>
<td>More Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
</tr>
<tr>
<td>Others</td>
<td>$1500 / month</td>
<td>Less Likely</td>
<td>More Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
<td>Less Likely</td>
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*TCAs are not included in the AHRO report.
The Depression Choice Decision Aid

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.
- 4 out of 10 people will have to try other antidepressants before they find the one that is right for them.

How long before I feel better?
- Most people need to take antidepressants regularly for at least 6 weeks to begin to feel the full effect.

Understanding side effects
- Many people using antidepressants have a loss of one side effect.
- Many side effects go away after a few weeks, but some only go away after you stop the medicine.

Sexual Issues

Some people may experience loss of sexual desire (loss of interest or ability to reach orgasm) because of the antidepressants.

Sleep

Some people may experience sleepiness or insomnia because of the antidepressants.

Weight Change

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

Stopping Approach

Getting your medicine off is a step that can take you few years, as if you had the flu, for example, headaches, dizziness, light-headedness, nausea or shakiness.

Cost

These figures are estimates only and can change. Actual out-of-pocket costs vary by insurance plan and pharmacy. We have also not accounted for changes in preparation and dispensing.

Considerations

All of the following depression medications may cause:
- increased appetite, weight gain
- sex problems, including decreased sexual desire, reduced ability to have sex
- heart problems, including heart attack and stroke
- possible withdrawal symptoms

Additional considerations
- When you start treatment, you may need to take the medicine every day to achieve the maximum benefit.
- If you stop taking the medicine, your doctor may advise you to taper off gradually to avoid withdrawal symptoms.
- If you have a history of depression or if you are taking other medications that can affect the brain, you may be more at risk for withdrawal symptoms.
LESS IS MORE

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

Meta-analysis of Randomized Controlled Trials

Kathleen Stergiopoulos, MD, PhD; David L. Brown, MD
Coronary artery disease is a CHRONIC disease.

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

**MEDICINES**

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

**MEDICINES + STENTS**

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

Based upon this shared information...

What is most important to you?

**Did you know...**

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

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**Benefits**

**Improvement of symptoms in 100 people like you after treatment:**

- **Medicines alone**
  - One month: 85% feel better
  - Six months: 78% feel better
  - One year: 68% feel better

- **Medicines plus stents**
  - One month: 24% feel better
  - Six months: 48% feel better
  - One year: 69% feel better

**Risks**

**During stent procedure**

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

**Bleeding and clotting within one year**

- **In 100 people like you:**
  - **THREE** will have a bleeding event from the additional blood thinner needed with a stent, **97** will not.
  - **TWO** will develop a clot that forms in the stent leading to a heart attack, **98** will not.
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Success of the decision aid
Fidelity

20%
Create a conversation

17%
Adherence

Adherence to medication at 6 months
Implementation
Generic Disease Management System

Summary for diseases and preventive services

Patient summary

Labs for past 5 years

Recommended actions

MayoExpert

1. What goes into figuring out my risk of having a heart attack in the next 10 years?
   
   This tool uses data from the Framingham Heart Study to estimate 10-year risk for myocardial infarction for people like you. The risk shown does not take into account strategies you are currently using to reduce this risk (healthy lifestyles, other medicines).

   Age: 74 years
   Gender: Male
   Total cholesterol: 190 mg/dL
   HDL cholesterol: 61 mg/dL
   Smoker: No
   Diabetic: No
   Blood pressure: 148/73 mm Hg
   History of coronary disease: No

   For Physicians: AskMayoExpert

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

   The risk for 100 people like you who DO NOT take statins
   NO STATIN
   - 69 people DO NOT have a heart attack
   - 31 people DO have a heart attack

   The risk for 100 people like you who DO take statins
   YES STATIN
   - 69 people DO NOT have a heart attack
   - 23 people still DO have a heart attack
   - 8 people AVOIDED a heart attack
   - 92 people experienced NO BENEFIT from taking statins.

3. What are the downsides of taking statins (cholesterol pills)?
Statin Choice
Decision Aid

Benefits vs Downsides according to my personal health information
Using UKPDS Risk Calculator

Your current risk
The risk for 100 people like you who do not take statins:

Cost
Std. dose statins: about $4/month

Side Effects
Common side effects
- Nausea, diarrhea, constipation (most patients can tolerate)
- Muscle aching/stiffness
  - 5 in 100 patient
  - (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)

Your risk by taking statins
The risk for 100 people like you who do take statins on standard dose:

Over 10 years:
- 15 people will have a heart attack;
- 85 people will have no heart attack;
- 5 people will be saved from a heart attack.

Daily Routine
Statins need to be taken every day for a long time.
(maybe forever)

Other Benefits
Decreases risk of stroke by about 19%

Notes
Lessons learnt

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

Challenges with evidence synthesis and changing evidence

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

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

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

The impact on improving adherence to medications is mixed.

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

Better understanding of the level of evidence necessary to embed into practice

Challenges of broad implementation into routine practice and repeated use

Right place and time to engage patients with chronic conditions
For copies of the slides from today’s presentation please visit: 
www.ucdenver.edu/implementation
or contact Katherine Gechter at katherine.gechter@ucdenver.edu