When painkillers are not working well enough....

Should you take traditional non-steroidal anti-inflammatory drugs (NSAIDS) or cox2 inhibitors (Coxibs) for osteoarthritis?

A decision aid for <u>women 65 years of age or older</u> to prepare you to discuss options with your doctor

Dr Peter Tugwell and others <u>more about the authors in Appendix A</u> 2006

Format is adapted from the Ottawa Personal Decision Guide http://www.ohri.ca/decisionaid

This decision aid is for you if:

- Your doctor has told you that you have 'osteoarthritis'
- You are a woman who is 65 years of age or older
- Your pain is not controlled with painkillers such as acetaminophen
- Your doctor has offered you the options of traditional NSAIDS or cox2 inhibitors

What is osteoarthritis?

It is the most common form of arthritis and affects any joint such as hands, hips, shoulders, and knees. The cartilage that protects the ends of the bones breaks down and causes pain, stiffness, and swelling. This pain and damage limits a person from doing daily routines at home and work. It may also affect a person's well being. Most of the time the pain, stiffness, and swelling come on slowly. If the disease is not treated, it may result: lasting damage to the joints; crooked joints; problems doing daily routines, need for surgery.

more facts in Glossary

How is osteoarthritis managed?

Self care tips: keep fit; hot or cold packs; rest and relax; have a healthy body weight. Several kinds of treatment may be used alone or together: pain medicines, corticosteroid injections, viscosupplementation, specific anti-osteoarthritic drugs, physiotherapy and others.

more facts in Glossary

What are your options?

- Traditional non-steroidal anti-inflammatory drugs (NSAIDs) such as Apo-Diclo, Advil, Motrin, Indocid, Novo-Keto, Mobicox, Naprosyn, Novo-Pirocam, Mobiflex, Apo-Sulin
- Cox-2 inhibitors (Coxibs) such as Celebrex, Ultradol

more facts in Glossary

Working through the 5 steps of this decision aid will help you decide.

Step 1: Be clear about the decision Step 2: Think about the benefits and risks Step 3: Choose the role you prefer in decision making Step 4: Find out what else you need to prepare for decision making Step 5: Plan the next steps

Note: Medical terms are explained in the <u>Glossary</u> at the end.

This information is not intended to replace the advice of a doctor. The authors disclaim any liability for the decisions you make based solely on this information.

Step 1: Be clear about the decision.

What are the options?

- Continue taking Acetaminophen
- Switch to Traditional NSAIDS
- Switch to Coxibs

All drugs involve taking pills every day

When does this decision have to be made? Check I one.

□ Within days □ Within weeks □ Within months

How far along are you in deciding? Check ☑ one.

- □ You have not thought about it yet
- □ You are thinking about the choices
- □ You are close to making a choice
- □ You have made a choice

Are you leaning toward a certain option? Check ☑ one.

- □ No, I am unsure
- □ Acetaminophen
- □ Traditional NSAIDS
- Coxibs
- Other ____

Do you have other health risks that may affect your choice?

Check *I* if any of these apply or place a question mark [?] if you are not sure.

Heart Disease

- □ angina/previous heart attack
- diabetes
- □ smoker
- \Box age greater than 65

Stomach Ulcers (sores)

- □ previous stomach ulcer within the last 2 years
- ☑ age greater than 60
- □ taking corticosteroids
- L taking blood thinners (anticoagulants), such as acetylsalicylic acid (aspirin) or warfarin

Liver Disease

□ have or had problems with my liver
 □ take 4 to 5 drinks of alcohol per day

About your pain from osteoarthritis

How would you feel if the pain you have now stayed the same as it is for the rest of your life? Check \square one.

- □ terrible
- unhappy
- mostly dissatisfied
- mixed; neither satisfied nor dissatisfied
- mostly satisfied
- □ pleased
- delighted

Format based on Foundation for Informed Medical Decision Making Question

Discuss your answers with your doctor to learn how they affect your options, benefits, and risks.

- □ family history of heart disease before 65
- □ high blood pressure
- □ high cholesterol

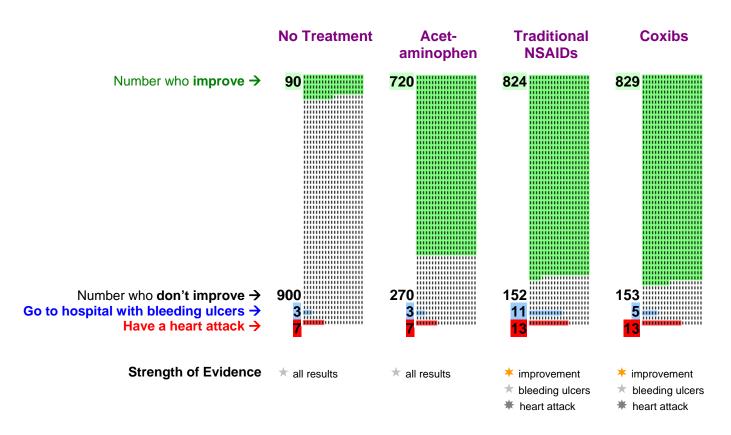
Step 2: Think about the benefits and risks.

A) What does the research show?

Blocks of 1000 dots (.) show the 'best estimate' of what happens to **1000 WOMEN 65 years** of age or older with osteoarthritis of the knee if they try an option for one year.

Each dot (,) stands for one woman.

There is no way of knowing what will happen to you.



Stronger study results are shown as * Platinum or * Gold. Weaker study results are shown as * Silver or * Bronze.

B) What do you think of the benefits and risks?

- 1. Review the common reasons to choose each option.
- 2. Add any other reasons that matter to you.
- 3. Show how much each reason matters to you. Circle one (★) star if it matters a little and up to five (★★★★) stars if it matters a lot. Circle no stars if it does not matter.

		Rea	asons to Ch	oose			
Acetaminophen	How much does it matter to you?		ditional SAIDS	How much does it matter to you?	Co	xibs	How much does it matter to you?
You have a <u>bigger</u> chance of pain relief compared to no treatment but not as high as the other options You avoid the	****	chance	mpared to	****	chance o relief con Acetamir	npared to	****
 bigger risks of NSAIDS and Coxibs bleeding stomach ulcers heart attacks having to start heart or blood pressure pills 	****				chance o ulcers co traditiona	of bleeding mpared to al NSAIDS s small as	
Your other reasons to choose this option are:	****	Your oth to choos option a	· -	****	Your othe to choose option ar		****

Which option do you prefer? Check \square all that apply.

□ I am not sure

- Traditional NSAIDs
- □ Acetaminophen
- Coxibs

□ I prefer no treatment at all

Other, I prefer _

Step 3: Choose the role you prefer in decision making.

Check ☑ one.

- □ You prefer to choose on your own after hearing the views of others
- □ You prefer to share the choice with:
- □ You prefer that someone else chooses for you, namely:

Step 4: Find out what else you need to prepare you for decision making.

Please answer the questions below.

If you answer 'No' to the questions, discuss them with your doctor.

		Yes	No
Knowledge	Do you know which options are available to you? Do you know <u>both</u> the benefits and risks of each option?		
Values	Are you clear about which benefits and risks matter most to you?		
Support	Do you have enough support and advice from others to make a choice? Are you choosing without pressure from others?		
Certainty	Do you feel sure about the best choice for you?		

Decisional Conflict Scale © A O'Connor 1993, Revised 2004

Find out how well this decision aid helped you learn the key facts.

Check *I* the best answer. Answers are in <u>Appendix B</u>.

a.	Which option has the <u>biggest</u> chance of improving pain?						
b.	Which option has the <u>smallest</u> chance of having a heart attack?						
C.	Which option has the <u>biggest</u> chance of bleeding stomach ulcers?						
d.	 If 1000 women 65 years old or older with osteoarthritis take NSAIDs or Coxibs for 1 year, about how many more have a heart attack than if they had no treatment? between 1 and 10 between 11 and 25 between 26 and 50 more women 						

- □ between 51 and 100 <u>more</u> women
- □ between 101 and 500 <u>more</u> women

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Step 5: Plan the next steps

List plans, for example: show your balance scale and responses to your doctor and/or family; learn more about the options.

Appendix A: Information about the authors

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Format is based on the Ottawa Decision Guide © 2000, A O'Connor, D Stacey, University of Ottawa, Ottawa Health Research Institute.

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Appendix B: Answers to questions in Step 4

- a. Which option has the best chance of improving pain? □ Acetaminophen ☑ Traditional NSAIDS and Coxibs □ All are about equal
- b. Which option has the lowest chance of having a heart attack? ☑ Acetaminophen □ Traditional NSAIDS and Coxibs □ All are about equal
- c. Which option has the highest chance of bleeding stomach ulcers? □ Acetaminophen ☑ Traditional NSAIDS □ Coxibs □ All are about equal
- d. If 1000 women who are 65 years of age and older with osteoarthritis take NSAIDs or Coxibs for 1 year, about how many more may have a heart attack than if they had no treatment?
 - ☑ between 1 and 10 more women have heart attacks than if they had no treatment
 - □ between 11 and 25 more women
 - □ between 26 and 50 <u>more</u> women
 - □ between 51 and 100 more women
 - □ between 101 and 500 more women

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Glossary

Osteoarthritis. It is the most common form of arthritis and affects any joint such as hands, hips, shoulders, and knees. The cartilage that protects the ends of the bones breaks down and causes pain, stiffness, and swelling. This pain and damage limits a person from doing daily routines at home and work. It may also affect a person's well being. Most of the time the pain, stiffness, and swelling come on slowly. If the disease is not treated, it may result: lasting damage to the joints; crooked joints; problems doing daily routines, need for surgery.

It is not known why pain happens. Pain may occur because:

- Muscles and tendons work harder or in a different way when the cartilage is broken down;
- Pieces of broken cartilage inflame soft tissue around the joint; or
- Bones rub against bones.

How osteoarthritis is managed. Self care tips: keep fit; hot or cold packs; rest and relax; have a healthy body weight

Seven kinds of treatment may be used alone or together. (drug and brand names in Canada are below)

- 1. Pain medicines and Acetylsalicylic acid
 - Acetaminophen (Tylenol)
 - Acetylsalicylic acid (Aspirin)
- 2. Traditional non-steroidal anti-inflammatory drugs (NSAIDs)
 - Diclofenac (Apo-Diclo)
 - Ibuprofen (Advil, Motrin)
 - Indomethacin (Indocid)
 - Ketoprofen (Novo-Keto)
 - Meloxicam (Mobicox)
- 3. Cox-2 inhibitors (Coxibs)
 - Celecoxib (Celebrex)
 - Etodolac (Ultradol)
 - Etoricoxib (not available in Canada)
 - Lumiracoxib (not available in Canada)
- 4. Topical creams and gels
 - Diclofenac (Pennsaid)
- 5. Injections
 - Corticosteroids
- 6. Specific anti-osteoarthritic drugs
 - Glucosamine sulphate
 - Diacerein
- 7. Physiotherapy
 - Exercise (on land)
 - Shoe insoles

- Codeine
- Tramadol
- Naproxen (Naprosyn)
- Piroxicam (Novo-Pirocam)
- Tenoxicam (Novo-Pirocal
 Tenoxicam (Mobiflex)
- Sulindac (Apo-Sulin)
- Parecoxib (not available in Canada)
- Valdecoxib (Bextra) (not available)
- Rofecoxib (Vioxx) (not available)
- Capsaicin
- Viscosupplementation
- Chondroitin
- Thermotherapy (cold)
- Pain varies from person to person. When it is severe, it can limit daily routines at home and at work. Also, it can affect the way a person feels about their well-being. Pain relief or improvement means you notice that the pain you normally have when you are resting is lessened.

- **Stomach ulcers** are sores in the lining of the stomach. Ulcers cause heartburn, a burning or gnawing pain in the abdomen. This pain occurs between meals and may wake you up during the night. The pain may be relieved by eating something or taking an antacid. If ulcers **bleed**, it causes stools (bowel movements) to turn red, black or look like tar. If untreated, a bleeding ulcer can break through the wall of the stomach causing severe pain. Bleeding ulcers require urgent medical attention; some people may go to hospital and may die.
- **Heart disease** includes any disease that affects your heart. People can be born with a heart disease or develop heart disease due to their habits (smoking, eating, physical activity) or because of an infection. Heart disease can affect the heart muscle, how it pumps, the arteries that bring blood to the heart or the valves that open and shut in the heart. Heart disease can cause chest pain (angina), fatigue, and heart attacks which can lead to death. Chest pain and fatigue may limit a person's daily routines and can affect how a person feels about their well-being.
- Having to start heart or blood pressure pills. Research studies found that Traditional NSAIDS and Coxibs increased some people's blood pressure or affected the way their hearts worked. The doctors in the studies started these patients on drugs to lower blood pressure and to make the heart work better.

Strength of evidence

- **Platinum:** Results from a good review of 2 or more randomised controlled trials that had enough people in each study.
- Cold: Results from at least one well done randomised controlled trial that had enough people in each study.
- **Silver:** Results from studies that were not as well done [too few people or not well done or weaker design].
- **+** Bronze: Expert views and experiences, or cases of what happened to someone who had one of the options.
- What it means to answer 'no' to the questions in Step 4 asking about what else you need. The more 'no' answers a person has, the more likely they are to delay their decision, change their mind, be dissatisfied with their choice, express regret with the decision they made, and blame their doctors for bad outcomes. Therefore it is important to discuss your needs with your doctor and others so that you answer 'yes' to most questions.

Scientific References

For further facts and numbers behind this decision aid, go to http://decisionaid.ohri.ca/NSAID.html.

This decision aid is being tested to see if it meets the International Patient Decision Aid Standards (IPDAS) Collaboration global standards (<u>http://ipdas.ohri.ca</u>).