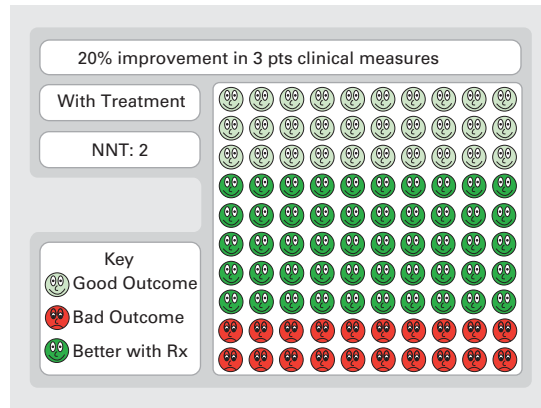
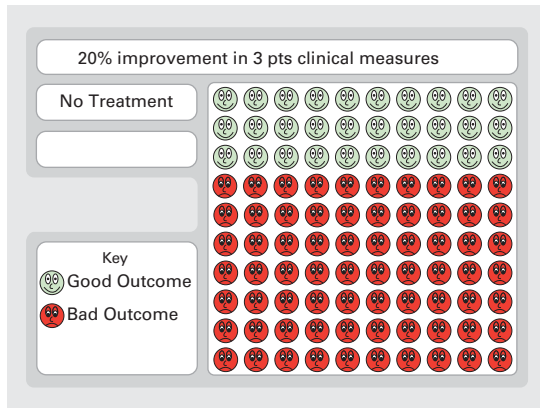


Table 11.4 Number needed to treat for etanercept versus placebo (Gorman, 2002)²⁸

Outcome	Improved with placebo	Improved with etanercept	Relative risk of improvement with etanercept (95% CI)	Absolute benefit increase (95% CI)	NNT (95% CI)
> 20% improvement in 3 of 5 clinical measures	6/20 (30%)	16/20 (80%)	2.67 (1.32–5.39)	50% (20, 70)	2 (2, 6)

*The endpoint reported in this table is the primary endpoint of the study. Also most secondary endpoints were significantly different between treatment groups.

Visual Rx Faces 11.1 NNT for etanercept versus placebo



Ankylosing spondylitis and
biologic agents
Summaries and decision aid

How well do biologic agents, such as infliximab or etanercept, work for treating ankylosing spondylitis and are they safe?

To answer this question, scientists found and analysed 3 high quality studies testing over 130 people who had ankylosing spondylitis. People received either injections of infliximab, etanercept or placebo (water) injections. These studies provide the best evidence we have today.

What is ankylosing spondylitis and how can biologic agents help?

Ankylosing spondylitis (AS) is a type of arthritis, usually in the joints and ligaments of the spine. It may also affect the shoulders, hips, or other joints and cause tendinitis. Pain and stiffness occurs and limits movement in the back and affected joints. It can come and go, last for long periods, and be quite severe. Infliximab (Remicade) and etanercept (Enbrel) are “biologic agents” that are injected into the body under the skin or infused into veins (IV). In the body they block chemicals that cause pain and swelling and may control AS, slow its progress and stop damage.

How well did infliximab or etanercept work?

Two different studies showed that more people receiving etanercept (for 4 or 10 months) or infliximab (for 12 weeks) improved by 20% compared to people receiving a placebo. People had, for example, less pain, morning stiffness, swelling, back pain or disease activity; better ability to function; or felt better overall. Another study showed that infliximab for 12 weeks improved morning stiffness and disease activity, but not ability to function.

What side effects occurred with the biologic agents?

Minor side effects, such as the common cold, diarrhoea, and headache occurred. Reactions where etanercept was injected and flu-like symptoms when infliximab is infused can occur. Rare side effects such as tuberculosis (TB) and low white blood cells occurred in a small number of people and they stopped taking the medication. Other studies that tested biologic agents in other conditions found that TB, fungal infections, and other serious infections (which may cause death) occurred in people taking biologic agents.

What is the bottom line?

There is “Silver” level evidence that in patients with ankylosing spondylitis, biologic agents, such as infliximab and etanercept, improve pain, stiffness, function and well-being. It is not known if biologic agents stop long term damage in the spine or improve the ability to move the spine.

Side effects such as common colds, diarrhoea, and headache can occur. Side effects that cause people to stop the treatment may occur more often with infliximab than with etanercept. Longer studies are needed before rare and late side effects are known. Tuberculosis (TB) has been reported in some studies and it is important to test for TB before starting a biologic.

Based on Van der Linden S, van Tubergen A, Boonen A, Mihai C, Ottawa Methods Group. Spondyloarthropathies. In *Evidence-based Rheumatology*. London: BMJ Books, 2003.

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Infliximab (Remicade) and etanercept (Enbrel) are “biologic agents” or “biological response modifiers”. These new biologic agents are injected into the body under the skin or infused into veins (IV). In the body, biologic agents clamp onto a chemical in the body called tumour necrosis factor alpha (TNF-alpha). TNF-alpha is thought to start a chain reaction in the body that causes swelling, pain, and damage in the body's joints. When clamping onto TNF-alpha, the biologic agents stop the chain reaction, which may decrease pain and swelling in the joints. Blocking TNF-alpha from working may control ankylosing spondylitis, slow the progress of the disease and stop permanent damage.

How did the scientists find the information and analyse it?

The scientists searched for studies testing infliximab or etanercept in patients with ankylosing spondylitis. Not all studies found were of a high quality and so only those studies that met high standards were selected.

The high quality studies had to be randomised controlled trials – where a group of patients receiving infliximab or etanercept were compared to a group of patients receiving a placebo (water injection). The studies also had to measure pain, function, stiffness, well-being, and joint swelling using agreed upon scales.

Which studies were included in the summary?

There were 3 studies included in this summary. The studies examined 131 patients with ankylosing spondylitis for 6 weeks to 10 months:

- a 4 month study tested 40 patients (20 received etanercept injections and 20 received a placebo injection); 37 of these patients were followed for another 6 months (all patients received etanercept for the next 6 months)
- a 12 week study tested 70 patients (35 received IV infliximab and 35 received IV placebo)
- another 12 week study tested 40 patients, 21 of whom had ankylosing spondylitis (9 received IV infliximab and 12 received IV placebo).

Infliximab is given by IV for about 2 hours. After the first dose, it is given 2 weeks later, then another 4 weeks later, and then every 6 weeks. Etanercept is given as an injection two times per week and can be given at home by the patient.

How well did infliximab or etanercept work to treat ankylosing spondylitis?

Etanercept: After 4 and 10 months, 80 out of 100 patients receiving etanercept improved by 20% compared to 30 out of 100 patients receiving placebo. A 20% improvement in this study meant that patients improved in at least three of the following five measures: pain, function, morning stiffness, swelling, overall wellbeing. This improvement happened quickly. But the improvement in movement of the spine was small.

Infliximab: After 12 weeks, the one study testing 70 patients showed that 53 out of 100 patients receiving infliximab improved by 50% in disease activity (pain and stiffness) compared to 9 out of 100 patients receiving placebo. The differences in improvement between the two groups of patients occurred after 2 weeks. The study also noted that the effect of infliximab on movement of the spine was good.

After 12 weeks, the other study showed that more patients receiving infliximab had less stiffness, back pain, and disease activity and better function than patients receiving a placebo. But receiving infliximab or a placebo did not make a difference in their ability to move their spine. Improvements with infliximab occurred within 2 weeks.

What side effects occurred with the biologic agents?

Etanercept: After 4, 6, and 10 months minor side effects occurred just as often in patients receiving etanercept as placebo. Minor side effects were:

- lung infections (in 50 out of 100 patients receiving etanercept and 60 out of 100 receiving placebo)
- diarrhoea (in 15 out of 100 receiving etanercept and 5 out of 100 receiving a placebo)
- reactions and redness where the injection was (in 20 out of 100 patients receiving etanercept and in 5 out of 100 patients receiving placebo)
- headaches (in 10 out of 100 patients receiving etanercept).

Infliximab: In the 12 week study with 70 patients:

- common colds and respiratory tract (lung) infections occurred about equally in patients receiving infliximab or a placebo (51 out of 100 patients receiving infliximab and 35 out of 100 receiving placebo)
- diarrhoea occurred in 15 out of 100 receiving infliximab and 5 out of 100 receiving a placebo
- 3 out of the 35 patients (or 9 out of 100) stopped receiving infliximab because 1 had tuberculosis, 1 had an allergic reaction that affected the lungs and 1 had low white blood cells.

In the other 12 week study, side effects such as the common cold, itching, fatigue, and headache occurred in about the same number of patients receiving infliximab as placebo. Two out of the 40 patients receiving infliximab stopped taking infliximab because 1 had tuberculosis and 1 may have had an infection.

Other studies that tested biologic agents in other conditions found that tuberculosis (TB), fungal infections, and other serious infections occurred in people taking biologic agents. Some of these infections caused death. Patients are now tested for previous contact with TB before they start a biologic and are told to call their doctor if they think they have an infection.

What is the bottom line?

There is “Silver” level evidence that in patients with ankylosing spondylitis, biologic agents, such as infliximab and etanercept, improve pain, stiffness, function, and well-being . It is not known if biologic agents stop long term damage in the spine or improve the ability to move the spine.

Side effects such as common colds, diarrhoea, and headache can occur. Side effects that cause people to stop taking the treatment may occur more often with infliximab than with etanercept.

Longer studies are needed before rare and late side effects are known. Tuberculosis (TB) has been reported in some studies, and it is important to test for TB before starting a biologic.

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Information about ankylosing spondylitis treatment

What is ankylosing spondylitis (AS)?

Ankylosing spondylitis (AS) is a type of arthritis, usually in the joints and ligaments of the spine. AS also affects the shoulders, hips, or other joints and can cause tendonitis. AS causes pain and stiffness, and can limit movement in the back and affected joints. Over time the joints of the back may fuse together and lead to bent posture and reduced mobility. The pain and damage from AS can limit a person's ability to carry out daily activities at home and work and affects their well-being.

The pain and stiffness can come and go, last for long periods, and be quite severe. If it is not treated, it may result in:

- limited daily activities
- bent posture
- fused joints
- need for surgery

What can I do on my own to manage my disease?

- ✓ Relaxation and regular rest
- ✓ Hot/cold packs
- ✓ Regular daily exercise
- ✓ Activity that puts less stress on joints (such as swimming or walking)
- ✓ Spa therapy (available at a spa-resort)

What treatments are used for ankylosing spondylitis?

Four kinds of treatment may be used alone or together. The common (generic) names of treatment are shown below.

Treatments to control short-term symptoms (pain and stiffness):

1. *Pain medicines*
 - Acetaminophen
2. *Non-steroidal anti-inflammatory drugs (NSAIDs), some of which are listed below*
 - Acetylsalicylic acid
 - Celecoxib
 - Diclofenac
 - Ibuprofen
 - Indomethacin
 - Meloxicam
 - Nabumetone
 - Naproxen
 - Piroxicam
 - Rofecoxib
 - Sulindac

Treatments to limit the long term symptoms and the damage

3. *Disease modifying anti-rheumatic drugs (DMARDs)*
 - Methotrexate
 - Pamidronate
 - Sulphasalazine
4. *Biologic agents*
 - Etanercept
 - Infliximab

What about other treatments I have heard about?

There is not enough evidence about the effects of some treatments. Other treatments do not work. For example:

- Azathioprine
- D-penicillamine
- Thalidomide
- Prednisone

What are my choices? How can I decide?

Treatment for your disease will depend on your condition. You need to know the good points (pros) and bad points (cons) about each treatment before you can decide.

Ankylosing spondylitis decision aid

Should I take biologic agents, such as infliximab or etanercept?

This guide can help you make decisions about the treatment your doctor is asking you to consider.

It will help you to:

1. Clarify what you need to decide.
2. Consider the pros and cons of different choices.
3. Decide what role you want to have in choosing your treatment.
4. Identify what you need to help you make the decision.
5. Plan the next steps.
6. Share your thinking with your doctor.

Step 1. Clarify what you need to decide

What is the decision?

Should I start taking biologic agents when non-steroidal anti-inflammatory drugs (NSAIDs, see some examples on previous page) are not working enough to control ankylosing spondylitis?

Biologic agents are injections (given under the skin or intravenously) at pre-set times (at home or infusion center).

When does this decision have to be made? Check ✓ one

- within days within weeks within months

How far along are you with this decision? Check ✓ one

- I have not thought about it yet
- I am considering the choices
- I am close to making a choice
- I have already made a choice

Step 2: Consider the pros and cons of different choices

What does the research show?

Biologic agents are classified as: **Trade-off between benefits and harms**

There is “Silver” level evidence from 3 studies of biologic agents in 131 people. The studies lasted up to 10 months. These studies found pros and cons that are listed in the chart below.

What do I think of the pros and cons of biologic agents?

1. Review the common pros and cons.
2. Add any other pros and cons that are important to you.
3. Show how important each pro and con is to you by circling from one (*) star if it is a little important to you, to up to five (*****) stars if it is very important to you.

PROS AND CONS OF BIOLOGIC AGENTS, SUCH AS INFLIXIMAB AND ETANERCEPT	
PROS (number of people affected)	How important is it to you?
Improves my pain and stiffness 80 out of 100 people receiving a biologic improve at least a little compared to 30 out of 100 patients receiving a placebo. 53 out of 100 people receiving a biologic improve a lot compared to 9 out 100 patients receiving placebo	* * * * *
Improves my ability to do daily activities	* * * * *
Works within days/weeks rather than months	* * * * *
Might improve long term damage to my spine	* * * * *
Other pros:	* * * * *
CONS (number of people affected)	How important is it to you?
Side effects: colds, headache, diarrhoea, abdominal pain	* * * * *
Reactions during or immediately after the injection include headache, nausea, and hives	* * * * *
Serious harms: tuberculosis (TB) and other serious infections Some of these infections have been fatal	* * * * *
Unsure of what effect it will have if we still want to have children	* * * * *
Personal cost of medicine	* * * * *
Unsure how easy it is to travel with this medicine Need needles and kept in the fridge	* * * * *
Other cons:	* * * * *

What do you think of biologic agents? Check one

Willing to consider this treatment
 Pros are more important to me than the Cons

Unsure

Not willing to consider this treatment
 Cons are more important to me than the Pros

Step 3: Choose the role you want to have in choosing your treatment

Check one

- I prefer to decide on my own after listening to the opinions of others
- I prefer to share the decision with: _____
- I prefer someone else to decide for me, namely: _____

Step 4: Identify what you need to help you make the decision

What I know	Do you know enough about your condition to make a choice?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Do you know which options are available to you?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Do you know the good points (pros) of each option?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Do you know the bad points (cons) of each option?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
What's important	Are you clear about which pros are most <i>important to you</i> ?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Are you clear about which cons are most <i>important to you</i> ?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
How others help	Do you have enough support from others to make a choice?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Are you choosing without pressure from others?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Do you have enough advice to make a choice?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
How sure I feel	Are you clear about the best choice for you?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Do you feel sure about what to choose?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure

If you answered No or Unsure to many of these questions, you should talk to your doctor.

Step 5: Plan the next steps

What do you need to do before you make this decision?

For example – talk to your doctor, read more about this treatment or other treatments for ankylosing spondylitis.

Step 6: Share the information on this form with your doctor

It will help your doctor understand what you think about this treatment.

Decisional Conflict Scale © A O'Connor 1993, Revised 1999.

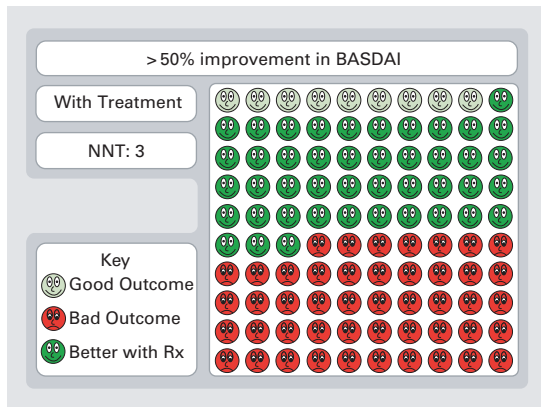
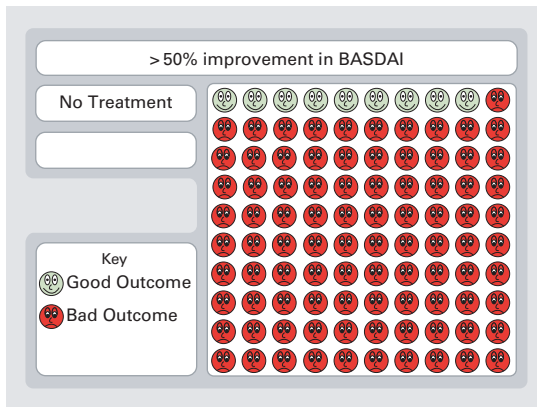
Format based on the Ottawa Personal Decision Guide © 2000, A O'Connor, D Stacey, University of Ottawa, Ottawa Health Research Institute.

Table 11.5 Number needed to treat for infliximab versus placebo (Braun *et al*, 2002)²¹

Outcome	Improved with placebo	Improved with infliximab	Relative risk of improvement with infliximab (95% CI)	Absolute benefit increase (95% CI)	NNT (95% CI)
>50% improvement in disease activity (BASDAI)	3/35 (9%)	18/34 (53%)	6.18 (2.00–19.07)	44% (23, 61)	3 (2, 5)

*The endpoint reported in this table is the primary endpoint of the study. Also most secondary endpoints were significantly different between treatment groups.

Visual Rx Faces 11.2 NNT for infliximab versus placebo



Ankylosing spondylitis and biologic agents Summaries and decision aid

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What can I do on my own to manage my disease?

- ✓ Relaxation and regular rest
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- ✓ Activity that puts less stress on joints (such as swimming or walking)
- ✓ Spa therapy (available at a spa-resort)

What treatments are used for ankylosing spondylitis?

Four kinds of treatment may be used alone or together. The common (generic) names of treatment are shown below.

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 - Naproxen
 - Piroxicam
 - Rofecoxib
 - Sulindac

Treatments to limit the long term symptoms and the damage

3. *Disease modifying anti-rheumatic drugs (DMARDs)*
 - Methotrexate
 - Pamidronate
 - Sulphasalazine
4. *Biologic agents*
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 - Infliximab

What about other treatments I have heard about?

There is not enough evidence about the effects of some treatments. Other treatments do not work. For example:

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1. Clarify what you need to decide.
2. Consider the pros and cons of different choices.
3. Decide what role you want to have in choosing your treatment.
4. Identify what you need to help you make the decision.
5. Plan the next steps.
6. Share your thinking with your doctor.

Step 1. Clarify what you need to decide

What is the decision?

Should I start taking biologic agents when non-steroidal anti-inflammatory drugs (NSAIDs, see some examples on previous page) are not working enough to control ankylosing spondylitis?

Biologic agents are injections (given under the skin or intravenously) at pre-set times (at home or infusion center).

When does this decision have to be made? Check ✓ one

- within days within weeks within months

How far along are you with this decision? Check ✓ one

- I have not thought about it yet
- I am considering the choices
- I am close to making a choice
- I have already made a choice

Step 2: Consider the pros and cons of different choices

What does the research show?

Biologic agents are classified as: **Trade-off between benefits and harms**

There is “Silver” level evidence from 3 studies of biologic agents in 131 people. The studies lasted up to 10 months. These studies found pros and cons that are listed in the chart below.

What do I think of the pros and cons of biologic agents?

1. Review the common pros and cons.
2. Add any other pros and cons that are important to you.
3. Show how important each pro and con is to you by circling from one (*) star if it is a little important to you, to up to five (*****) stars if it is very important to you.

PROS AND CONS OF BIOLOGIC AGENTS, SUCH AS INFLIXIMAB AND ETANERCEPT	
PROS (number of people affected)	How important is it to you?
Improves my pain and stiffness 80 out of 100 people receiving a biologic improve at least a little compared to 30 out of 100 patients receiving a placebo. 53 out of 100 people receiving a biologic improve a lot compared to 9 out 100 patients receiving placebo	* * * * *
Improves my ability to do daily activities	* * * * *
Works within days/weeks rather than months	* * * * *
Might improve long term damage to my spine	* * * * *
Other pros:	* * * * *
CONS (number of people affected)	How important is it to you?
Side effects: colds, headache, diarrhoea, abdominal pain	* * * * *
Reactions during or immediately after the injection include headache, nausea, and hives	* * * * *
Serious harms: tuberculosis (TB) and other serious infections Some of these infections have been fatal	* * * * *
Unsure of what effect it will have if we still want to have children	* * * * *
Personal cost of medicine	* * * * *
Unsure how easy it is to travel with this medicine Need needles and kept in the fridge	* * * * *
Other cons:	* * * * *

What do you think of biologic agents? Check one

Willing to consider this treatment
Pros are more important to me than the Cons

Unsure

Not willing to consider this treatment
Cons are more important to me than the Pros

Step 3: Choose the role you want to have in choosing your treatment

Check one

- I prefer to decide on my own after listening to the opinions of others
- I prefer to share the decision with: _____
- I prefer someone else to decide for me, namely: _____

Step 4: Identify what you need to help you make the decision

What I know	Do you know enough about your condition to make a choice?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Do you know which options are available to you?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Do you know the good points (pros) of each option?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Do you know the bad points (cons) of each option?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
What's important	Are you clear about which pros are most <i>important to you</i> ?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Are you clear about which cons are most <i>important to you</i> ?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
How others help	Do you have enough support from others to make a choice?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Are you choosing without pressure from others?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Do you have enough advice to make a choice?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
How sure I feel	Are you clear about the best choice for you?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure
	Do you feel sure about what to choose?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unsure

If you answered No or Unsure to many of these questions, you should talk to your doctor.

Step 5: Plan the next steps

What do you need to do before you make this decision?

For example – talk to your doctor, read more about this treatment or other treatments for ankylosing spondylitis.

Step 6: Share the information on this form with your doctor

It will help your doctor understand what you think about this treatment.

Decisional Conflict Scale © A O'Connor 1993, Revised 1999.

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