

Making Choices

For women at moderate risk deciding on whether to take tamoxifen for prevention of breast cancer



This decision aid booklet was developed by the breast cancer prevention research team from the Nightingale and Genesis Breast Cancer Prevention Centre at the University Hospital of South Manchester (UHSM) in collaboration with the Centre for Medical Psychology & Evidence-based Decision-Making (CeMPED) at the University of Sydney, Australia.

For further details, please contact:

Family History
Nightingale & Genesis Prevention Centre
University Hospital of South Manchester
Southmoor Road
Manchester
M23 9LT.

Telephone: 0161 291 4480

Version 1.0 - 22.09.14

Contents

	Page
Introduction	4
Understanding breast cancer risk	5
Increased risk of breast cancer	5
General population breast cancer risk	5
What is your risk of developing breast cancer in the future?	6
What can you do to reduce your risk of future breast cancer?	7
Option 1 - Standard care	8
Option 2 - Standard care + tamoxifen	9
Tamoxifen	
How does it work?	10
Potential benefits	12
Effectiveness of tamoxifen	13
Potential side effects and risks	14
Summary of main advantages & disadvantages	19

Contents

	Page
Arriving at a treatment decision	20
Worksheets	21
Examples:	
Anna's worksheet	23
Dianne's worksheet	24
Your worksheet	25
Further contacts	26
Glossary of terms	27
Your notes	29

Introduction

A substantial number of women are at increased risk of developing breast cancer.

This booklet is designed to assist you in deciding whether or not to take **tamoxifen** as one of your risk management options.

At the back of the booklet (page 29) you will find a page labelled “Your notes”, where you can write down any questions that you may like to ask your doctor. A glossary of medical terms is also included.

We would like to encourage you to pay particular attention to the sections on the potential benefits and risks of each of the options. The diagrams are included to complement the text. It is not necessary to read both. The worksheets at the end of this booklet are optional; you do not have to complete them.

Understanding breast cancer risk

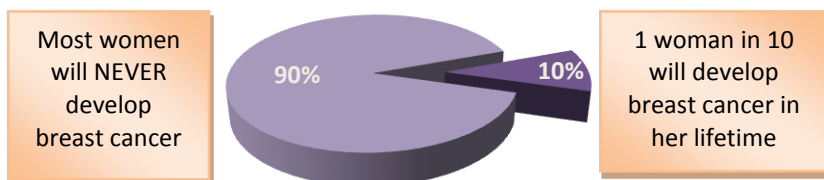
In this booklet, we use the term “**risk**” to mean the chance of developing breast cancer in the future. Everyone, including men, has some chance of developing breast cancer in their life.

Increased risk of breast cancer

Some people are more likely than others to develop breast cancer for various reasons. These people are said to be at an increased risk. *Having a family history of breast cancer* is a major factor.

General population breast cancer risk

In developed countries, close to 1 out of 10 women develop breast cancer at some point in their life.



What is your risk of developing breast cancer in the future?

Your risk is at least twice that of the general population. Your precise risk will depend on the number and degree of risk factors that apply to you. Your doctor can tell you more about your precise risk.

Most women at **increased** risk will **NEVER** develop breast cancer



At least 2 women in 10 will develop breast cancer in their lifetime if they have risk factors

If breast cancer develops, there is an excellent chance that this can be detected early. Effective treatment means that the majority of women can be cured and return to their normal life.

Other risk factors include:

- Never having had children
- Being 30 years or older at the birth of your first child
- Going through menopause after the age of 55
- Starting your periods at an early age

What can you do to reduce your risk of breast cancer?

Since you are at increased risk of developing breast cancer, you may wish to consider options to minimise the risk. The following pages will explore the advantages and disadvantages of two options.

Option 1

STANDARD CARE

(mammograms)

Option 2

STANDARD CARE

(mammograms)

+

Tamoxifen

OPTION 1: Standard care

You may choose to continue with standard risk management, which includes breast screening (breast screening). This helps to ensure that any potential problems are identified as early as possible. In addition, other strategies include weight management and exercise.

Advantages	Disadvantages
<ul style="list-style-type: none">▪ Mammography gives you a good chance of detecting any changes in breast tissue early.▪ You would not have the potential side effects that can occur when taking medication.▪ You would not have the daily reminder of cancer that bothers some women when taking medication to prevent breast cancer.	<ul style="list-style-type: none">▪ Mammograms may alert you and your doctor to the fact that there is something wrong, but they do not prevent or reduce the risk of developing breast cancer.▪ You may feel you have not done enough to maximise your chance of preventing breast cancer.▪ You may not have the reassurance of taking daily medication to prevent breast cancer.

OPTION 2: Standard care + tamoxifen

The second option is to continue with standard risk management, but also to take preventative treatment in the form of a medication called tamoxifen.

What is tamoxifen?

Tamoxifen is a tablet whose effectiveness in treating early and advanced stages of breast cancer **has been consistently proven and monitored for almost 40 years**. In women at moderate risk of developing breast cancer, tamoxifen is known to reduce the chance of developing this. Recently, four large studies have explored the use of tamoxifen in women at increased risk. The results indicate that tamoxifen may be effective in reducing breast cancer risk and benign breast disease by up to 40%.

How is tamoxifen taken?

Tamoxifen is taken as a tablet once a day for 5 years. Tamoxifen is also taken in this way for the treatment of women who have already developed breast cancer.

Tamoxifen: how does it work?

Tamoxifen is a drug which blocks the action of oestrogen (sometimes called an anti-oestrogen). **Oestrogen** is a female hormone which is produced mainly by the ovaries in women before menopause. After menopause, low levels of oestrogen continue to be produced in fat, liver, muscle and breast tissue itself. Oestrogen stimulates the growth of breast tissue. Should this tissue contain cancerous cells then it will stimulate the growth of the cancerous tissue.

Some breast cells have molecules within them called **oestrogen receptors**. These molecules attach to oestrogen, starting a chain reaction which causes the cell to multiply and grow. Breast cancer cells sensitive to oestrogen are called “oestrogen receptor positive” (ER positive or ER+) and those that are not sensitive are called “oestrogen receptor negative” (ER negative or ER-).

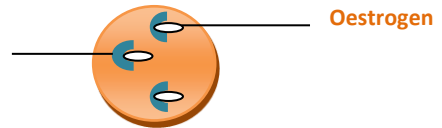
Tamoxifen is a drug that can mimic oestrogen. The easiest way to understand the way tamoxifen works is to liken the process to that of a lock and key. The oestrogen receptor is the lock and oestrogen is the key. When oestrogen comes into contact with the receptors, they unlock or activate the breast cell to multiply, and growth

increases. Tamoxifen imitates the action of the oestrogen and fits into the lock, but the key does not turn and the cells do not multiply. The tamoxifen key remains in place and prevents the oestrogen from reaching the cancer cells. The cells either grow more slowly or stop growing altogether.

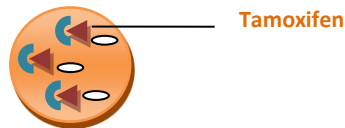
Tamoxifen is only effective against breast cells that are ER positive (ER+). We know that many cells in the breast as well as abnormal early growths contain oestrogen receptors.

Oestrogen enters the cell, binds with the receptors and
→ encourages breast cell growth

Oestrogen receptors (ER)



Tamoxifen covers the receptor (ER), preventing oestrogen from binding with the receptor and
→ stops or slows breast cell growth



Potential benefits

Prevents breast cancer

The previous page explains how tamoxifen prevents breast cancer.

Reduces breast complaints

By blocking the effect of oestrogen on breast tissue tamoxifen appears to reduce breast complaints such as cysts, non-cancerous (benign) breast disease, soreness and tenderness. Around 40% fewer women have breast problems when taking tamoxifen.

Lowers cholesterol levels

Tamoxifen can lower the level of cholesterol in the blood.

Reduces breast tissue density

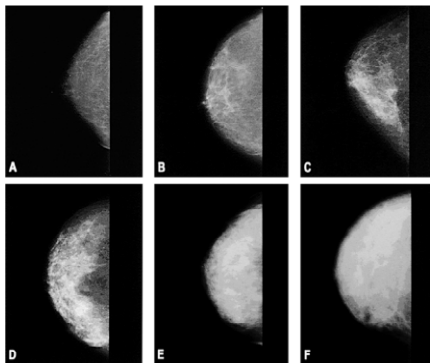
Dense breasts may appear white on a mammogram, making this test less sensitive for detecting breast cancer. Tamoxifen has been shown to reduce breast density. Hence, taking tamoxifen may make the mammogram a more sensitive test, allowing breast cancer to be seen more easily and detected earlier.

Reduces risk of recurrence

Tamoxifen is known to reduce the risk of breast cancer coming back.

Non-dense
mammograms

Dense
mammograms



Dense
mammograms
are white.

Since a cancer
also shows as
white it can be
difficult to see.

Effectiveness of tamoxifen

Tamoxifen can reduce ER+ breast cancer risk by up to 40%. Out of 1,000 women at moderate risk, we would expect to see:

Number of ER+ breast cancers we expect to see	Without taking tamoxifen	With tamoxifen	Number breast cancers prevented
In 10 years	50	30	20
In 20 years	100	60	40

Potential side effects and risks

Tamoxifen, like most medications, may cause unwanted side effects in some women. Each woman responds differently to this treatment; many have very few or no side effects. Whilst you are taking tamoxifen you may also experience symptoms by chance which are unrelated to the drug. The best way to work out if symptoms are related to tamoxifen is to see if they begin soon after you start taking the drug. We have learned a lot about the true risks and benefits of tamoxifen by comparing the side effects in women taking tamoxifen and those taking a placebo (a pill with no active ingredients).

A recent study of over 340 women taking either tamoxifen or a placebo documented the occurrence of 41 possible side effects. For most side effects, taking tamoxifen made no difference, but tamoxifen did increase the chance of experiencing some side effects, which are described on the following pages.

If you experience side effects and decide to take a break from taking tamoxifen, it is likely that the side effects will reappear once you start taking the drug again.

Side effects

Common side effects

Night sweats, hot flushes and cold sweats

Menopausal-like symptoms are fairly common but are usually mild and disappear when tamoxifen is no longer taken.

There are a number of ways to help reduce or control hot flushes and sweats. Some women find it helpful to avoid or cut down on tea, coffee, nicotine and alcohol. Others find that regular exercise helps. Complementary therapies to ease these side effects may also be helpful (e.g. herbal medication).

Less common side effects

Vaginal discharge

Vaginal discharge may also occur for women taking tamoxifen.

Some women find that wearing cotton underwear that can breathe is helpful as well as cleaning yourself with gentle soaps.

What do we mean by common?

The following diagrams represent 100 women taking tamoxifen for five years. The area shaded in pink shows the number of women likely to develop each side effect. The area shaded in purple shows the number of **additional** women likely to develop each side effect over five years because they are taking tamoxifen.

Night sweats

Out of 100 women at increased risk of breast cancer, 29 women will experience night sweats.

If the same 100 women take tamoxifen, an **additional** 14 women will experience night sweats.





Hot Flashes

Out of 100 women at increased risk of breast cancer, 29 women will experience hot flashes.

If the same 100 women take tamoxifen, an additional 13 women will experience hot flashes.

Vaginal discharge

Out of 100 women at increased risk of breast cancer, 10 women will experience vaginal discharge.

If the same 100 women take tamoxifen, an additional 8 women will experience vaginal discharge.



Rare but potentially serious risks (only about 1-2 in 1,000 women experience these)

Endometrial cancer (cancer of the womb)

The uterus (womb), like breast tissue, is also sensitive to stimulation by oestrogen. Tamoxifen may stimulate the uterus and cause cancer of the lining of the uterus, known as endometrial cancer.

Blood clots (thrombosis)

Tamoxifen may cause a two-fold increase in the risk of blood clots, particularly in the veins of the legs. In a previous study, 42% of these blood clots developed after major surgery or if the woman was immobile for a long period of time. If these clots break loose, they can block smaller vessels in the heart, lungs and brain (stroke).

Clots can be prevented to some extent by exercise and treatments prescribed by your doctor. Clots are most common at times when you are immobilised, such as after an operation or a leg fracture. Talk to your doctor about stopping tamoxifen temporarily in these circumstances.

Tamoxifen: Summary of main advantages & disadvantages

Advantages	Disadvantages
<ul style="list-style-type: none"> ▪ Known to prevent or delay breast cancer developing for the first time ▪ Reduces the risk of breast complaints ▪ Known to reduce the level of cholesterol in the blood ▪ May reduce breast density which could allow breast cancer to be detected earlier ▪ Known to reduce the risk of breast cancer coming back 	<p>Increased risk of:</p> <ul style="list-style-type: none"> ▪ Night sweats ▪ Hot flushes & cold sweats ▪ Vaginal discharge ▪ Uterine problems ▪ Blood clots

Arriving at a treatment decision

The previous pages have outlined the main risk management options available to you now. The following steps may help you to make the decision whether or not to take tamoxifen for the prevention of breast cancer. The decision-making process can be helped by following these six steps.

1. Understand your future risk of breast cancer as fully as you can.
2. Understand your options for further management and the risks and benefits of these options.
3. Review the advantages and disadvantages of those options.
-
4. Assess the importance to you of the advantages and disadvantages.
5. Prioritise the advantages and disadvantages of tamoxifen for you and your family.
6. Get more information or clarification for any uncertain areas.

You have already gone through steps 1-3. To help you complete steps 4-6 and come to the decision that suits you best, we have included examples of how some women reached their decision.

Worksheets

This section starts with examples of how some women view the advantages and disadvantages of the standard treatment plus tamoxifen. This is followed by your own worksheet, where we invite you to list the advantages and disadvantages of the statements in the boxes and rate how important these are to you.

Each statement has three options underneath it, each describing a level of importance. By circling one of the options, you can indicate and see at a glance how important each issue is to you:

- | | |
|------------------------------------|---|
| Circling not important | ➡ indicates that the issue is of no concern to you |
| Circling somewhat important | ➡ indicates that the issue is a small concern to you |
| Circling very important | ➡ indicates that the issue is a big concern to you |

The scales with more “very important” options circled may indicate that you are more inclined to choose that option. There is also space for you to add your own advantages and disadvantages and rate their importance.

Example:

One of the disadvantages is the side effects of tamoxifen. If the woman using the worksheet feels that she will be able to handle this, she would circle “somewhat important” for this statement because side effects are a small concern to her.

Side effects from tamoxifen	'I think I'll be able to handle that'		
	Not important	Somewhat important	Very important

At the bottom of the worksheet you can indicate (by circling one of the 1-7 stars) which way you are leaning towards in your decision:

Not participating in the study	★ ★ ★ ★ ★ ★ ★	Participating in the study
-----------------------------------	---------------	-------------------------------

By circling the 4th (middle) star, this person is still unsure whether or not to take tamoxifen. In this case, they may need to find out more information and discuss their options with their doctor.

WORKSHEET: EXAMPLE 1

Anna's thoughts: "Will taking tamoxifen for prevention suit me?"

I will have to take tamoxifen every day for 5 years .
"I'm prepared to do that"

<input checked="" type="radio"/> Not Important	<input type="radio"/> Somewhat Important	<input type="radio"/> Very Important
--	--	--------------------------------------

Tamoxifen may not be effective for me in preventing breast cancer.
"But I won't know if I don't try"

<input checked="" type="radio"/> Not Important	<input type="radio"/> Somewhat Important	<input type="radio"/> Very Important
--	--	--------------------------------------

I may experience side effects and other risks.
"I think I'll be able to handle that"

<input type="radio"/> Not Important	<input checked="" type="radio"/> Somewhat Important	<input type="radio"/> Very Important
-------------------------------------	---	--------------------------------------

Other:

<input type="radio"/> Not Important	<input type="radio"/> Somewhat Important	<input type="radio"/> Very Important
-------------------------------------	--	--------------------------------------

AGAINST

I feel that I am doing something to reduce my risk.
"I can make a difference, and my daughter may benefit"

<input type="radio"/> Not Important	<input type="radio"/> Somewhat Important	<input checked="" type="radio"/> Very Important
-------------------------------------	--	---

I will get excellent care whilst I'm taking tamoxifen.
"It's good to know I'm getting cutting edge care"

<input type="radio"/> Not Important	<input checked="" type="radio"/> Somewhat Important	<input type="radio"/> Very Important
-------------------------------------	---	--------------------------------------

I will get access to a drug that could reduce my risk of breast cancer.
"Reducing the risk is important to me"

<input type="radio"/> Not Important	<input type="radio"/> Somewhat Important	<input checked="" type="radio"/> Very Important
-------------------------------------	--	---

Other:

<input type="radio"/> Not Important	<input type="radio"/> Somewhat Important	<input type="radio"/> Very Important
-------------------------------------	--	--------------------------------------

FOR

Any further questions? *"Can I continue taking the drugs when the 5 year treatment period is over?"*

Which way is Anna leaning?

Not taking tamoxifen

★ ★ ★ ★ ★ ☒

Taking tamoxifen

WORKSHEET: EXAMPLE 2

Dianne's thoughts: "Will taking tamoxifen for prevention suit me?"

AGAINST		FOR	
<p>I will have to take tamoxifen every day for 5 years and get extra tests. <i>"It sounds like a big commitment"</i></p> <p>Not Important Somewhat Important Very Important</p> <p>Tamoxifen may not be effective for me in preventing breast cancer. <i>"it's not foolproof"</i></p> <p>Not Important Somewhat Important Very Important</p> <p>I may experience side effects and other risks. <i>"I don't want to get hot flushes"</i></p> <p>Not Important Somewhat Important Very Important</p> <p>Other: <i>"I don't want to have night sweats"</i></p> <p>Not Important Somewhat Important Very Important</p>	<p>I feel that I am doing something to reduce my risk. <i>"But it will affect my life too much"</i></p> <p>Not Important Somewhat Important Very Important</p> <p>I will get excellent care whilst taking tamoxifen. <i>"I get excellent care from my doctor now"</i></p> <p>Not Important Somewhat Important Very Important</p> <p>I will get access to a drug that could reduce my risk of breast cancer. <i>"But it might not work for me"</i></p> <p>Not Important Somewhat Important Very Important</p> <p>Other:</p> <p>Not Important Somewhat Important Very Important</p>		

Any further questions? *"Can tamoxifen interfere with other medication?"*

Which way is Dianne leaning?

Not taking tamoxifen

★ ★ ★ ★ ★

Taking tamoxifen

YOUR WORKSHEET

YOUR thoughts: "Will taking tamoxifen for prevention suit me?"

AGAINST	FOR
<p>I will have to take tamoxifen every day for 5 years.</p> <p>Not Important Somewhat Important Very Important</p>	<p>I feel that I am doing something to reduce my risk.</p> <p>Not Important Somewhat Important Very Important</p>
<p>Tamoxifen may not be effective for me in preventing breast cancer.</p> <p>Not Important Somewhat Important Very Important</p>	<p>I will get excellent care whilst taking tamoxifen.</p> <p>Not Important Somewhat Important Very Important</p>
<p>I may experience side effects and other risks.</p> <p>Not Important Somewhat Important Very Important</p>	<p>I will get access to a drug that could reduce my risk of breast cancer</p> <p>Not Important Somewhat Important Very Important</p>
<p>Other:</p> <p>Not Important Somewhat Important Very Important</p>	<p>Other:</p> <p>Not Important Somewhat Important Very Important</p>

Any further questions?

Which way are YOU leaning towards? *(Circle one star only)*

Not taking tamoxifen

★ ★ ★ ★ ★ ★ ★

Taking tamoxifen

Further contacts

Many women seek information on the internet about breast cancer treatments, research, clinical trials and support services. However, not all information reported is accurate or reliable.

Listed below are a number of websites that are prepared by cancer organisations. As the information can only be general and not specific to your situation, it is important to discuss any questions you have with your doctor.

Websites about breast cancer	
Genesis Breast Cancer Prevention Appeal	www.genesisuk.org
Cancer Research UK	www.cancerresearchuk.org
Breast Cancer UK	www.breastcanceruk.org.uk
Macmillan Cancer Support	www.macmillan.org.uk
Breast Cancer Care UK	www.breastcancercare.org.uk
Breakthrough Breast Cancer	www.breakthrough.org.uk/
Breast Cancer Campaign	www.breastcancercampaign.org

Glossary of terms you may come across

A

Advanced breast cancer: Cancer cells have spread past the breast and armpit to other parts or organs of the body.

B

Body composition: The relative amounts of bone, muscle and fat in your body.

Bone mineral density test: An X-ray test to determine the amount of calcium and other minerals in the bone, used to diagnose osteoporosis.

C

Cancer: A group of diseases in which malignant cells grow out of control and may spread to other parts of the body.

Cholesterol: A substance found in fats in the bloodstream.

Clinical trial: A scientific test of the effectiveness and safety of a drug using consenting human participants.

Cysts: An accumulation of fluid or semisolid material within a sac in the breast.

D

Diagnosis: Process of identifying a disease from symptoms & tests.

E

Endometrial cancer: A cancer of the lining of the uterus.

ER: Oestrogen receptor. Molecules inside the cells that allow oestrogen to enter.

G

Gynaecological problems: Problems affecting the female reproductive organs.

H

Hysterectomy: Surgical operation for removing the uterus.

I

Invasive breast cancer: Breast cancer which has spread beyond the tissue in which it developed and is growing into surrounding, healthy tissues.

M

Mammogram: A low-dose X-ray of the breast to check for any abnormal tissue in the breasts.

O

Oestrogen: Female sex hormones produced primarily by the ovaries.

Osteoporosis: A condition that makes bones prone to fracture.

P

Pre-menopausal: The time in a woman's life when they have menstrual periods.

S

Standard risk management: The current way to minimise your risk of breast cancer.

T

Tamoxifen: A current treatment for breast cancer which stops the action of oestrogen.

Treatment holiday: Stopping the treatment for a period of time.

Your notes
