

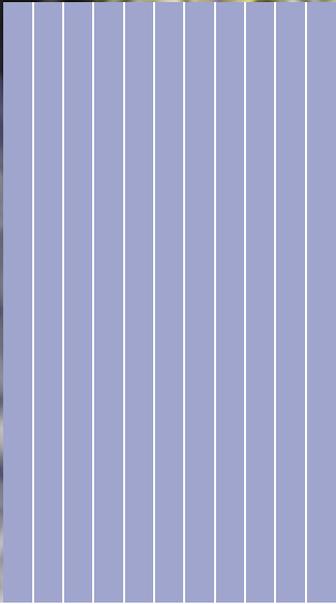


Australian Government

National Health and Medical Research Council

Hormone Replacement Therapy: Exploring the Options for Women

INVESTING IN AUSTRALIA'S HEALTH





Australian Government

National Health and Medical Research Council

Hormone Replacement Therapy:

Exploring the Options for Women

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CONTENTS

Introduction	1
Key Messages	2
Menopause	3
What is menopause?.....	3
What symptoms might I have around the time of menopause?	3
How long will symptoms last?	4
What are the options for managing menopause symptoms?.....	4
How bad should symptoms be before I ask for help?	5
Who should I ask for help?.....	5
Will menopause affect my sex life?.....	5
Hormone Replacement Therapy	6
What is hormone replacement therapy?.....	6
What is 'natural' HRT?	7
Making decisions about HRT	7
What symptoms does HRT help with?.....	8
What are the possible side effects?	9
What are the health risks and benefits?	9
Cancers and HRT	11
The heart and blood vessels and HRT	14
Thinning of the bones and HRT	16
Other conditions and HRT	17
What about HRT after early or premature menopause?	17
Can I take HRT if I have other health conditions?	18

If I Decide to Use HRT	19
What sort of HRT should I use?.....	19
How long should I use HRT?.....	19
How will I know when my menopause and its symptoms have finished?	19
What’s the best way to stop using HRT? Will the symptoms return?	20
What about the HRT risks? Do they continue when I stop using it?	20
Is HRT a form of contraception?.....	20
 Other Ways to Stay Healthy and Relieve Symptoms	
Around Menopause	21
A healthy lifestyle.....	21
Regular health checks	22
Do I need extra calcium?	23
What about over-the-counter remedies?.....	24
 Finding Reliable Information	25
How do I know if a treatment will really work?	25
How and why have the answers changed over recent years?.....	25
Understanding risk	26
Where can I get further information?.....	28
Contact details: menopause clinics and other relevant services for women.....	32
 Glossary	34
 Appendix 1: Working Party Membership	37
 Appendix 2: Process Report	39

INTRODUCTION

This booklet provides information for you about menopause and ways to manage menopausal symptoms. In particular, it aims to help you make decisions about whether or not hormone replacement therapy (HRT—also known as hormone therapy, or HT) would be a good option for you. The booklet also discusses other steps you can take to maintain good health during and after menopause. The Glossary (page 34) explains many of the terms used in the booklet.

Doctors and women’s health nurses may also find the booklet useful. It offers a common ground to discuss with you the issues of menopause and HRT.

There has been much research on women’s health over recent years. While many questions remain unanswered, we know a lot more than we did a few years ago. This booklet summarises what we know about HRT—its place in relieving menopausal symptoms, its unwanted side effects, the other health risks and possible benefits associated with HRT, and questions that remain unanswered.

The booklet has been developed by an expert working party of the National Health and Medical Research Council (NHMRC). It is based on a wide-ranging review of the scientific research evidence, together with professional expertise and consumer consultation. Where the booklet provides research findings about HRT, it shows the strength of the evidence for those findings. The evidence ratings box sets out how these levels are defined, based on the NHMRC’s levels of evidence.

Evidence Ratings

Level I evidence

The highest level of evidence, is from a systematic review of all relevant randomised controlled trials.

Level II evidence

Is obtained from at least one randomised controlled trial.

Level III evidence

Comes from other types of trials or studies that use a control or ‘comparison’ group.

Other NHMRC resources to support this decision making are:

Making Decisions: Should I use hormone replacement therapy? (HRT), a resource to help the individual woman weigh up the pros and cons of this therapy for her; and

Hormone Replacement Therapy: A Summary of the Evidence for General Practitioners and other Health Professionals, this summary sets out the risks and benefits associated with use of hormone replacement therapy.

KEY MESSAGES

- HRT has been proven to work very well in controlling hot flushes and some other menopause symptoms.
HRT should be used, however, only where symptoms are troublesome and women have made an informed decision about the risks and benefits.
- HRT reduces the incidence of bone fracture due to osteoporosis (thinning of the bones). After stopping HRT, this benefit wanes and the incidence of fracture returns to non-HRT levels over about five years.
- There is strong evidence that combined HRT* increases the incidence of breast cancer. With HRT using oestrogen-alone*, current evidence shows little or no increase in incidence. Tibolone is a drug which acts like an oestrogen on some parts of the body and as a progestogen on other parts of the body. There is insufficient evidence at this time that indicates that Tibolone increases the incidence of breast cancer. HRT does not appear to protect women against heart disease, as previously thought.
- There is strong evidence that combined HRT increases the incidence of blood clotting (deep vein thrombosis, blood clots in the lungs).
- There is evidence that HRT* increases the incidence of stroke.
- Although some women find benefit from complementary or alternative therapies the limited information available from scientific studies indicates that those that have been researched are not effective in controlling symptoms.

*For a discussion of these different types of HRT, see page 6

MENOPAUSE

What is menopause?

Menopause is the time in a your life when you stop having periods, because your ovaries have run out of eggs. Technically, it means the last natural period. The time around this, when you may experience the symptoms of menopause, is known as the *climacteric*, or *peri-menopause*.

Around the time of menopause, your ovaries gradually stop making *oestrogen* and *progesterone*, the hormones that prepare the body for pregnancy. Periods may get heavier or lighter, and they may become more or less frequent, until they stop altogether. Often this happens gradually, but some women's periods stop without warning.

Menopause generally occurs between the ages of 40 and 57, occasionally later. The average age in Australia is 50-51 years. Sometimes it occurs much earlier than 40. This is known as 'premature menopause', and is discussed further on page 17.

What symptoms might I have around the time of menopause?

Symptoms vary from woman to woman. Some have no symptoms and actually feel better, with less breast tenderness and the freedom of having no monthly periods. Some have symptoms but are not bothered by them, and some have symptoms they find troubling.

Symptoms that women report include:

- unpredictable menstrual periods—sometimes light or irregular, sometimes heavy and prolonged
- hot flushes, often accompanied by sweats, day or night
- disturbed sleep
- a dry vagina, making sex uncomfortable
- less desire for sex (loss of libido)
- more frequent and urgent need to pass urine
- joint and muscle pain
- headaches, migraine

- dry skin or a crawling sensation or itchiness in the skin
- uncharacteristic tiredness, anxiety or irritability
- memory loss, forgetfulness, difficulty concentrating
- depression, feeling ‘down’, mood swings.

Few women have all these symptoms, and they don’t occur all at once. Hot flushes are the most common—often they cause only mild discomfort, but up to one in four women has severe or frequent hot flushes.

Some of the symptoms may not actually be *caused* by menopause, but just happen to occur at the same time. Many fall within the normal range experienced by women at other times of life.

How long will symptoms last?

Some women notice symptoms for only a few months, if at all. For others, symptoms may last for years, starting three or four years before their periods stop and continuing for up to ten years or more.

What are the options for managing menopause symptoms?

Some women choose no treatment. Their symptoms may be mild, or they may prefer to concentrate on their general health through, for example, diet and exercise, stress management and relaxation (see ‘Other Ways to Stay Healthy and Relieve Symptoms Around Menopause’, page 21).

Hormone replacement therapy is very effective in relieving hot flushes, night sweats and some other symptoms of menopause, but there are some incidences associated with it (see page 8 onwards).

SSRIs (selective serotonin re-uptake inhibitors) are an antidepressant medication that require a doctor’s prescription. Some SSRIs have been found to reduce hot flushes. They can also help with mood swings, anxiety, depression and insomnia. Some women find counselling helpful in dealing with these symptoms.

You may choose to use ***complementary or alternative remedies*** with or instead of HRT. Approaches used include: phytoestrogens (plant oestrogens) in the diet or as supplements, herbal remedies, naturopathic and homeopathic remedies, acupuncture, meditation and massage. While some women find benefit, many of these approaches have not been studied or tested to the same standards as conventional

therapies, so there is little high quality evidence about whether or not they work, and about their safety. There may also be problems with quality control in the manufacture of some preparations. If you choose one of these therapies, do tell your GP what you are taking, as it could interact with other medications. (See also the discussion of ‘Over-the-counter remedies’ on page 24.)

How bad should symptoms be before I ask for help?

There is no single ‘right time’ to ask for help. Many women choose to seek help if they have symptoms that worry them in some way, or affect their quality of life.

Who should I ask for help?

Doctors, women’s health nurses and women’s health centres and clinics can all offer help to women around the time of menopause. A trusted GP is an excellent starting point. Menopause clinics specialise in the area, and some doctors (GPs and specialists) have a special interest in menopause. You will find a list of resources at the back of this booklet (page 32).

Will menopause affect my sex life?

This varies from woman to woman. The most important thing influencing your sex life is the quality of your relationship with your partner.

Some women notice no change in their sex life with menopause, and some enjoy having no periods and no need for contraception. Sex may be influenced by physical symptoms such as tiredness, heavy or erratic bleeding, vaginal dryness, hot flushes and sweats. Levels of the hormone testosterone fall around menopause and with age, and this may reduce some women’s desire for sex. This is particularly common in women who have a surgical or premature menopause. Anxiety or depression can also reduce a woman’s interest in sex. Men may also have changes in libido due to anxiety, depression, medical problems or medication.

Help is available for both you and your partner in this area. Talk to your GP or local menopause or women’s clinic for information on services in your area.

HORMONE REPLACEMENT THERAPY

What is hormone replacement therapy?

Hormone replacement therapy—HRT (also known as hormone therapy, or HT)—replaces the hormones that a woman’s ovaries stop producing at menopause. HRT must be prescribed by a doctor; it is not available over the counter.

HRT comes in various forms and combinations of hormones:

- *Unopposed oestrogen* (oestrogen-alone)—is normally prescribed only for women who have had a hysterectomy.

When oestrogen and progestogen* are used together, this is known as *combined HRT*. It comes in two forms:

- *Cyclical oestrogen and progestogen* (sequential HRT)—involves taking oestrogen every day and adding progestogen for 10 to 14 days each month. Many women have a regular monthly bleed with this treatment.
- *Daily oestrogen and progestogen* (continuous combined HRT)—is usually prescribed for women who have had no period for at least 12 months. Up to half the women on this treatment have some irregular bleeding or spotting at first, but it usually stops after 6 to 8 months.

In addition:

- *High dose progestogen alone* is sometimes used for women who have had breast cancer, if they have troublesome hot flushes. No studies have looked at the effects of this HRT in the long term.
- *Testosterone* is sometimes used with these therapies for loss of libido (sex drive). It may be used as implants, patches, or in other forms. Very few studies have looked at its use or long-term effects.
- *Tibolone* is a drug which acts like an oestrogen on some parts of the body and as a progestogen on other parts of the body. For example, tibolone is thought to affect breast tissue less than HRT. Few studies have looked at the effects of tibolone in the long term.

* Progestogen is the synthetic form of the hormone progesterone. You may also hear the term ‘progestin’ – this is the US name for progestogen

HRT is most often taken as *tablets*. *Skin patches*, *gels* and *slow-release pellets* (implanted under the skin) are also widely used, and a *nasal spray* is also available. Where symptoms are mainly vaginal or urinary, *vaginal tablets* or *creams* are an option.

What is ‘natural’ HRT?

Hormone preparations described as ‘natural’ or ‘bio-identical’ hormones are prescribed by some doctors and manufactured by compounding chemists or pharmacists. They are commonly sold as troches (lozenges) or creams.

There are no large, good quality studies on these ‘natural’ hormone preparations to show whether they are effective in treating menopausal symptoms, and whether they carry health risks. However, many of these preparations contain oestrogen and are likely to carry the same risks as other types of HRT.

These preparations are not approved by the Therapeutic Goods Administration (TGA)—the national body that assesses and approves pharmaceutical preparations for use in Australia.

Making decisions about HRT

Deciding whether or not to use HRT involves weighing up the benefits, the known health risks, and the uncertainties, in the light of your particular needs and circumstances. You should talk to your family doctor, or seek out a doctor with an interest in menopause, and discuss:

- the benefits, risks and side effects of HRT
- the types of HRT available, and the options suitable for you
- the way your treatment will be monitored
- how long you might use HRT
- other available options.

For women thinking about using combined HRT, the NHMRC has produced *Making Decisions: Should I use hormone replacement therapy? (HRT)* to help you make the best decision for your particular situation, in the light of the benefits, risks and uncertainties of HRT.

What symptoms does HRT help with?

Hot flushes, sweats and sleep

HRT (including Tibolone) is very successful in relieving hot flushes and night sweats, and it often improves disturbed sleep.

Level I evidence

For hot flushes and night sweats

Level II evidence

For disturbed sleep

Vaginal and urinary symptoms

Many women around menopause notice that they need to pass urine more often and more urgently. Urinary infections and incontinence (leaking) can be a problem. Vaginal dryness may make sex uncomfortable or painful, and this may lead to a loss of interest in sex. Using a vaginal lubricant for sex may be a solution (several brands are available in the pharmacy). On the other hand, vaginal oestrogen creams or pessaries are often used and studies have shown these to be at least as effective as other forms of HRT in relieving these symptoms. Oestrogen used in this way is not absorbed as much into other parts of the body, so can be used even if there are reasons not to use HRT. You need a doctor's prescription for vaginal oestrogens (as for other forms of HRT).

Level I & II evidence

Other symptoms

Women often report improvements in a range of other symptoms, but the scientific evidence is unclear about whether HRT is responsible for these improvements. Many of the symptoms, and the changes in them, fall within the normal range that women experience at other times of life.

What are the possible side effects?

Side effects of HRT might include a return of monthly bleeding, other bleeding, and sometimes tender breasts. These side effects are less likely with lower dose HRT or with tibolone.

HRT does not cause women to gain weight. Some women gain some weight in the years before and after menopause, whether or not they are on HRT—probably because their metabolism slows with age.

The research also suggests that HRT does not cause migraine or fluid retention.

Level I & Level II evidence

What are the health risks and benefits?

There is now clear evidence that HRT increases the incidence of blood clots (deep vein thrombosis, pulmonary embolism) and breast cancer. On the positive side, it reduces the incidence of some bone fractures.

Level I, II & III evidence

For DVT

Level I, II & III evidence

For breast cancer

Level I, II & III evidence

For bone fractures

A number of other possible health risks and benefits have been talked about, but the evidence on these is less clear. For some conditions, the answers have changed over recent years with larger, better designed studies (see the section, ‘How and why have the answers changed over recent years?’, on page 25).

The risks, benefits and uncertainties are summarised in the table below and discussed in the following pages.

IN SUMMARY

		EVIDENCE RATINGS
CANCERS		
Breast cancer	↑	Combined HRT increases the incidence. Level I, II & III
	↔	Oestrogen-only HRT shows little or no increased incidence. Level I, II & III
Cancer of the uterus (womb)	↑	Oestrogen-only HRT increases the incidence. Level I, II & III
	↔	Combined HRT shows little or no increased incidence. Level II & III
Ovarian cancer	↑	Oestrogen-only HRT slightly increases the incidence. Level III
	?	For combined HRT, there is not enough evidence to say. Level II & III
Bowel cancer	↓	Combined HRT reduces the incidence. Level II
	↔	No change with oestrogen only Level II
THE HEART AND BLOOD VESSELS		
Blood clots in veins & lungs	↑	Combined HRT increases the incidence. Level I, II & III
	?	For oestrogen-only HRT, there is not enough evidence to say. Level II
Stroke	↑	HRT increases the incidence. Level II & III
Heart disease	↔	HRT <i>does not</i> appear to protect women against heart disease, as was previously thought. Level II & III
THINNING OF THE BONES		
Osteoporosis and fracture	↓	HRT reduces the incidence. Level I, II & III
OTHER CONDITIONS		
Gall bladder disease	↔	HRT increases the incidence only very slightly, if at all. Level II
Cognition and dementia	↔	There is not enough evidence to say whether HRT helps to preserve thinking skills or prevent dementia. Level I, II & III

It should be noted that the effect of tibolone on the conditions above is unknown.

Key: ↑ incidence increased ↓ incidence decreased
 ↔ incidence unchanged ? insufficient evidence

Cancers and HRT

Breast cancer

Combined HRT increases the incidence of breast cancer.

How much is the incidence increased? For Australian women in their fifties, we know that eleven in every thousand are likely to develop breast cancer over a five-year period. If a thousand women of this age should decide to use combined HRT for five years, we estimate that fifteen of these women are likely to develop breast cancer. In other words, use of combined HRT could cause breast cancer in four women for every thousand who use it for five years.

Incidence

Increases with combined HRT

Level I, II & III evidence

Oestrogen-only HRT appears to increase the incidence of breast cancer very little, if at all.

Incidence

Little or no change with oestrogen-only HRT

Level I, II & III evidence

Tibolone is thought to have less effect on breast tissue than other HRT, but there is not yet enough evidence to know whether it has an impact on breast cancer incidence.

Will HRT make my breast cancer return?

Recent evidence¹ suggests that HRT may increase the incidence that breast cancer will recur.

Incidence

Increases with HRT

Level II & III evidence

1 Holmberg L, Anderson H. 2004. 'HABITS (hormonal replacement therapy after breast cancer – is it safe?), a randomised comparison: trial stopped', *The Lancet*, published online February 3. <http://image.thelancet.com/extras/03let12260web.pdf>

Mammography and HRT

More women who are on HRT, or who have taken it recently, are asked to return for further tests after a screening mammogram. These tests are needed for some types of breast changes that are probably not breast cancer, or when it's uncertain whether or not the mammogram shows breast changes. These extra tests almost always confirm there is no breast cancer. However, being asked to come back for more tests makes some women anxious, even though no breast cancer is found and makes it less likely that they will come back for screening in the future.

Cancer of the uterus (or womb)

Oestrogen-only HRT increases the incidence of cancer of the uterus or womb—known as endometrial cancer (the endometrium is the lining of the uterus). When women stop this type of HRT, the incidence may lessen over time, but it probably never returns to non-HRT levels.

Incidence

Increases with oestrogen-only HRT

Level I, II & III evidence

Progestogen is now prescribed along with oestrogen for women who have their uterus (ie those who have not had a hysterectomy). Most studies show no increased incidence of cancer of the uterus with combined HRT. Some small studies suggest a slight increase in incidence with cyclical (also known as 'sequential' or 'intermittent') oestrogen and progestogen, and this risk may continue to increase as long as the woman is on HRT. However, any risk on combined HRT is far less than the risk with oestrogen-alone HRT.

Incidence

No change with combined HRT

Level II & III evidence

Ovarian cancer

Studies have shown that oestrogen-alone HRT slightly increases the incidence of cancer of the ovaries.

Incidence

Increases with oestrogen-only HRT

Level III evidence

We do not have enough evidence (Level II & III) to know whether this is the case for combined HRT.

Bowel cancer

The research shows that combined HRT reduces the incidence of bowel cancer (also known as ‘colorectal cancer’).

How much is the incidence reduced? For Australian women in their fifties, we know that three in every thousand are likely to develop bowel cancer over a five-year period. If a thousand women of this age should decide to use combined HRT for five years, only two are likely to develop bowel cancer—in other words, combined HRT is likely to prevent bowel cancer in one woman in every thousand who use this HRT for five years.

Incidence

Reduces with combined HRT

Level II evidence

This benefit does not occur with oestrogen-only HRT, which appears to have no effect on the incidence of bowel cancer.

Incidence

No change with oestrogen-only HRT

Level II & III evidence

The heart and blood vessels and HRT

Blood clots

Women using combined HRT are at substantially increased risk of forming blood clots—either deep vein thrombosis (DVT) or clots in the lungs (pulmonary embolism). If a woman is going to develop a clot as a result of using HRT, it appears to happen more commonly in the first year on HRT.

Incidence

Increases with combined HRT

Level I, II & III evidence

How much is the risk increased? For Australian women in their fifties, we know that three in every thousand may develop serious blood clots over a five-year period. If a thousand women of this age should decide to use combined HRT for five years, we estimate that eight are likely to develop serious blood clots. In other words, use of combined HRT could cause serious blood clots in five women in every thousand who use this HRT for five years. This risk may have implications for women having surgery, or undertaking long flights. Women should talk this over with their doctor.

For women on oestrogen-only HRT, it is not clear whether or not their risk is increased—there is not enough high quality evidence (Level II) to be sure.

At present, it is not clear whether the risk is influenced by the different ways in which HRT can be taken (eg tablets versus skin patches).

Stroke

HRT (both combined and oestrogen-only) increases the incidence of stroke. There is some evidence that the incidence is higher with higher doses of oestrogen.

How much is the risk increased? For Australian women in their fifties, we know that four in every thousand are likely to have a stroke over a five-year period. If a thousand women of this age should decide to use HRT for five years, we estimate that six are likely to have a stroke. In other words, use of HRT could cause strokes in two women in every thousand who use it for five years.

Incidence

Increases with HRT

Level II & III evidence

Strokes may be due to a blood clot or to bleeding (haemorrhage) in the brain, but the evidence on HRT and stroke does not distinguish between these two types.

Heart disease

It was thought in the past that HRT helped to protect women against heart disease, but recent large studies have found that this is not the case. The best evidence we have to date is that HRT does not provide any protection against heart disease (eg angina or atrial fibrillation) or heart attack. Nor does it help to protect women who have already had a heart attack.

Incidence

No change with HRT

Level II & III evidence

One recent study suggests that incidence of heart disease is slightly increased with HRT. Overall, the evidence on this remains unclear, but we cannot rule out the possibility of increased incidence.

Thinning of the bones and HRT

Osteopenia and osteoporosis

Many women, as they get older, lose calcium from their bones. This is known as ‘bone mineral density loss’ and it results in ‘osteopenia’—the milder form—and ‘osteoporosis’, which is more severe and less common.

Before menopause, oestrogen prevents the loss of calcium from bones. After menopause, this protection is lost, and the bones may gradually become thinner and break more easily, especially at the wrist, spine and hip.

Most studies show that HRT reduces the incidence of bone fracture for women using it for more than two years. This protection gradually wanes when the woman stops using HRT, and the risk returns to non-HRT levels over about five years.

Incidence

Reduces with HRT

Level I, II, & III evidence

Should I consider HRT to prevent osteoporosis?

HRT is not a first line treatment for osteoporosis. You need to discuss this with your doctor. You may decide to have your bone density measured at or around the time of menopause, especially if you have risk factors for osteoporosis (see below).

As discussed above, HRT has been shown to reduce the incidence of osteoporotic fracture. However, calcium, Vitamin D and exercise also have a role in keeping bones strong (ie maintaining bone density) and preventing osteoporosis. These lifestyle approaches are discussed on page 21.

INCIDENCE FACTORS FOR OSTEOPOROSIS:

family history of osteoporosis	early menopause
smoking	not much exercise
too much alcohol	not enough calcium in the diet
Vitamin D deficiency	small body frame
taking cortisone	

Other conditions and HRT

Gall bladder disease

Evidence from earlier studies suggested some increase in incidence of gall bladder disease for women on combined HRT, but recent large studies show that any increase in risk, if it exists at all, is very small.

Incidence

No change with HRT

Level II evidence

There is not enough evidence to show whether there is any incidence of gall bladder disease for women on oestrogen-only HRT.

Cognition and dementia

It has been suggested that women on HRT may be more likely to retain their cognitive skills (thinking, learning, problem solving and memory) and that HRT might help to prevent or slow down dementia.

The evidence (I, II & III), however, is very unclear—the research is inconsistent and contradictory, and we can draw no conclusions.

What about HRT after early or premature menopause?

Some women reach menopause long before the average age of the early 50s. A small percentage of these women have a family history of early menopause. Others may have a surgical menopause (removal of the ovaries) at a young age, and some will have menopause brought on by chemotherapy, radiotherapy near the ovaries, or a medical condition. Sometimes there is no obvious cause.

The younger a woman is at menopause, the more concerns doctors have about the possible consequences for her future health. For the woman herself, a central concern may be the loss of her fertility.

When the ovaries stop producing oestrogen at an early age, there could be an increased chance of developing osteoporosis. In addition, women who have a surgical menopause may sometimes have more severe symptoms of menopause.

The decision about whether to use HRT (or the oral contraceptive pill, which can also provide effective hormone replacement), and for how long, will be up to the individual woman in consultation with her doctor.

Can I take HRT if I have other health conditions?

Making decisions about HRT always involves weighing up the pros and cons for you—and it's always best to discuss this with your doctor. The following health conditions may influence your decision about HRT: (See pages 11-17)

- **Breast cancer:** For women who have had breast cancer, recent evidence suggests that HRT may increase the incidence of recurrence, although we need more evidence to be sure of this.
- **Liver disease:** HRT is metabolised in the liver. Severe liver disease may slow this down and the woman may have more side effects from HRT.
- **Thrombosis (blood clots):** Combined HRT increases the incidence of thrombosis. Women who have had a thrombosis, or have a strong family history of thrombosis, may need blood tests before using HRT to assess their risk of blood clots. Women who have had a thrombosis should generally not use HRT unless their potential risk has been medically assessed.
- **Stroke:** The evidence we have shows an increase in the incidence of stroke. We know that HRT increases the incidence of blood clots in other parts of the body (deep vein thrombosis and clots in the lungs), so doctors generally advise that women who have had a stroke, or have a strong family history of stroke, may need blood tests before using HRT, to assess their risk of blood clots.
- **Epilepsy, large fibroids:** HRT may aggravate these conditions. If it is used, it needs careful monitoring.

If you have any of these health conditions, and you have severe menopausal symptoms, it is best to seek specialist advice from a menopause clinic or specialist physician. If you use HRT, you need to see your doctor for regular check-ups and monitoring.

IF I DECIDE TO USE HRT

What sort of HRT should I use?

This will depend on your circumstances and preference. Most women start on tablets, but patches, gels, implants or nasal spray may be more suitable for some. If your symptoms are mainly vaginal or urinary, vaginal tablets or creams are an option.

It may take a few months to find the HRT dose that is best for you. If it causes you any side effects, your doctor may change the dose or prescribe a different type of HRT. Some women respond best to tablets, others to patches or implants. Some women need to try more than one type or dose of HRT to find the one that suits them best.

How long should I use HRT?

There is no one right answer to this—it is something you should discuss and review regularly with your doctor, weighing up the risks, benefits and preferences in your own situation.

The Australian Drug Evaluation Committee (ADEC) recommends that women should see their doctor at least every six months to review their HRT and general health (page 22 sets out the regular health checks recommended for women). You can then decide with your doctor when you are ready to try weaning off HRT.

Most women use HRT for between one and five years. Some, however, find that symptoms persist for much longer than five years, and if other therapies don't provide relief, some women may decide to use HRT for a longer time, recognising the importance of quality of life.

How will I know when my menopause and its symptoms have finished?

The only way to know is to try reducing your HRT dose and see whether your symptoms return.

What's the best way to stop using HRT? Will the symptoms return?

There is no good research evidence on this, but it is generally accepted that the best way to stop HRT is to reduce it gradually over a few weeks or months (unless there is a good health reason for stopping suddenly on your doctor's advice). Hot flushes often return after stopping HRT, sometimes immediately, sometimes after a few months, and weaning off gradually is the best way to adjust to and manage this.

Talk with your doctor before stopping or reducing your HRT.

Some women move to a lower dose after a while, and find that this is satisfactory to control symptoms. Later you may reduce the dose further by taking tablets every second or third day, or cutting your patch in half (this can only be done with a matrix patch). If symptoms return, you can go back onto HRT and try reducing it again later. Eventually your symptoms will lessen—how long this takes varies from woman to woman.

What about the HRT risks? Do they continue when I stop using it?

We do not know. The evidence to date is not clear on this except for breast cancer where evidence confirms that the risk returns to that of non users within five years.

Is HRT a form of contraception?

No. HRT should not be confused with birth control pills. HRT uses much lower doses of different hormones and will not stop a woman from becoming pregnant. The contraceptive pill, however, can provide a form of HRT.

Women often start using HRT before their periods stop completely, when there is still a small chance of becoming pregnant. A low dose contraceptive pill can be a good option at this stage, as it will also help to manage pre-menopausal symptoms.

If you are unsure about whether you still need contraception, speak to your doctor.

OTHER WAYS TO STAY HEALTHY AND RELIEVE SYMPTOMS AROUND MENOPAUSE

A healthy lifestyle

There are a number of things you can do to promote good health and help to prevent cancers, heart disease, stroke and osteoporosis.

- *Avoid or reduce smoking:* Smoking is linked to earlier menopause and more severe menopausal symptoms. It increases the incidence of osteoporosis, heart disease, stroke, a number of cancers and other illnesses, and it speeds up the ageing of the skin (ie causes more wrinkles).
- *If you drink alcohol, drink in moderation:* The NHMRC recommends that women drink no more than 14 standard drinks per week, with never more than 4 on any one day, and have two alcohol-free days per week. A standard drink contains 10 grams of alcohol, equal to 30mL of spirit or 100mL of table wine (a small wine glass).²
- *Exercise regularly:* Try brisk walking for 30 minutes a day, swimming, dancing, jogging, gardening, bike riding, golf, tennis or yoga. Regular exercise helps you feel well, keep your weight within a healthy range, keep your blood pressure healthy, and maintain strong bones and strong and flexible muscles.
- *Enjoy a wide variety of nutritious foods* that are low in saturated fat, especially those containing calcium, for example, low fat dairy foods. Eat plenty of fruit, vegetables, bread and cereals, and soy products, and include plenty of calcium—at least 1000 mg per day from diet and/or supplements.³
- *Do pelvic floor exercises regularly* to strengthen the muscles that support the bladder, uterus and bowel (a physiotherapist can help you with this).

2 Australian Alcohol Guidelines: Health Risks and Benefits, NHMRC 2001

3 Dietary Guidelines for Australian Adults, NHMRC 2003

Regular health checks

You should have the following routine health checks during and after menopause:

- *A Pap test every two years* to check for changes to the cells of the cervix that may lead to cervical cancer.
- *A mammogram every two years from the age of 50.* Mammography screening is the best way of detecting breast cancer at its earliest stages among women over 50 years of age. BreastScreen Australia provides free mammography, targeting women aged 50-69 years. If you have one of more close relatives affected by breast cancer, ask your doctor's advice about whether you need mammograms more often than two-yearly, or starting earlier than age 50.
- *A blood pressure check every year.*
- *Regular cholesterol checks.* Talk to your doctor about how often these should be. It will depend on your cholesterol levels and your family history.

You should also become familiar with the normal look and feel of your breasts, to help you to recognise changes that could be a sign of breast cancer. There is no one best way to do this—what's important is to be comfortable about feeling your breasts and learning what is normal for you. If you notice a change, have it checked by your doctor. You can also ask your doctor to examine your breasts;

You should also discuss with your doctor the need for *bone density testing* to check for any signs of osteoporosis.

Do I need extra calcium?

Bones owe their strength to calcium, and having plenty of calcium may help to slow down bone loss. Dairy foods are the best source of calcium, and choosing low-fat and skim milk products (which have the same calcium content) will help to limit saturated fats and keep your weight within a healthy range.

To get enough calcium, women after menopause need three or four serves of dairy food each day. Each of the following is one serve:

- a cup of low fat milk
- a small tub of yoghurt
- 40 grams of cheese—two slices
- a cup of custard

If this is difficult, try adding three tablespoons of powdered milk to each cup of ordinary milk, to make ‘double strength’ milk—two serves—and use it in custards, mornays, fricassees or puddings.^{4,5}

To make sure that you are getting enough calcium, check with a dietician or doctor. If necessary, you might consider taking a calcium supplement.

As vegans do not obtain calcium requirements from dairy products the following commonly eaten foods are examples of sources of calcium.

- dark green vegetables
- tofu processed with calcium sulfate
- tahini
- soybeans

Vitamin D helps the body to absorb calcium. To produce Vitamin D, the body needs sunlight—about 15 minutes a day, to face, hands and arms. Women who are not exposed to sunlight might need to take a Vitamin D supplement.

4 Dietary Guidelines for Australian Adults, NHMRC 2003;

5 Dietary Guidelines for Older Australians, NHMRC 1999

What about over-the-counter remedies?

There are a number of over-the-counter remedies that are advertised and sold through pharmacies or health food shops. Commonly advertised examples include phytoestrogens (plant oestrogens), red clover, dong quai, and evening primrose oil, along with a range of other herbal remedies including black cohosh. Women with a family or personal history of breast cancer should not take black cohosh without medical advice.

When a doctor or therapist prescribes HRT (or other medication) he or she should discuss with you the risks, benefits and possible side effects, explain how to use the medication and for how long, and tell you when to return for a follow-up visit.

With an over-the-counter remedy, this advice is not generally available. Your pharmacist may be able to provide some answers to your questions from his or her experience of the products. Remember that products labelled 'natural' are not necessarily better or safer than prescribed therapies, and may have side effects. Many toxic substances occur naturally. It is worth checking labels for warnings and ingredients. Be aware that contents of some products vary from batch to batch, and not all side effects may be listed.

Most over-the-counter remedies for menopause symptoms have not been tested in good quality clinical trials, and there are no long-term studies of the benefits or risks of these products. Although some women find benefit from complementary or alternative therapies the limited information available from scientific studies indicates that those that have been researched are not effective in controlling symptoms.

FINDING RELIABLE INFORMATION

How do I know if a treatment will really work?

It is important to have evidence from scientifically conducted clinical trials—especially randomised placebo-controlled trials, where a large number of women are given the drug and a similar number receive a placebo (a dummy drug). If the drug works significantly better than the placebo, this is strong evidence that the drug is effective.

How and why have the answers changed over recent years?

Sometimes the answers from the research evidence change over time, as the evidence builds from larger and better designed studies.

Scientific research is a slow, step-by-step process that involves asking questions and doing experiments to test for possible answers. Experiments can never provide a final answer—they are simply steps towards better understanding.

Scientific knowledge always builds on the work of others. It is always open to challenge and change from new and better research. However, as evidence builds up, we can become more and more confident in the answers.

Recent large research studies have produced new and important information on the risks and benefits associated with HRT. In particular:

- The **Women's Health Initiative (WHI)** looked at the effects of combined HRT in post-menopausal women in the general population aged 50-79.
- The **Heart and Estrogen Replacement Study (HERS)** studied HRT in women known to have heart disease.

The WHI study showed a clear, though small, increase in the incidence of breast cancer for women on combined HRT. Both studies found that HRT did not protect women against heart disease, as previously thought.

While there are still some doubts about how the data from these studies should be interpreted, both were randomised controlled trials—the gold standard for this type of research—and involved very large numbers of women over a long time. Results from earlier studies have been less clear because the studies were not of as high a quality—for example, they involved too few women or covered too short a time.

Understanding risk

Risk is a person's chance of getting a disease over a certain period of time. Some factors can increase or decrease that risk.

Most people think of risk in *absolute* terms, but researchers and health professionals—and the media—often talk about *relative* risk when they are comparing risk under different conditions (eg with and without HRT). This can often lead people to misunderstand the real size of a risk.

For example, research might show that a medication used for five years, or a particular diet, might increase the *absolute risk* of getting a disease (eg a cancer) from one per 1000 people to two in 1000—still not a high risk to the individual (though it affects a significant number of people if we consider the whole population). For another disease and another risk factor, *absolute risk* might increase from 25 to 50 per 1000 people—a much more worrying increase.

In both these situations, however, the *relative* increase is the same—the risk is doubled—that is, it increases by 100 percent. And this alarming figure is what you are likely to see reported in the media, regardless of the size of the absolute risk.

When you are looking at information about risks and benefits, it is therefore important to check whether you are looking at absolute or relative risk. It is always helpful to seek out the absolute risk figures, so you have an accurate idea of the level of risk or benefit.

The box below looks at the specific example of breast cancer and HRT.

Understanding risk – breast cancer and HRT

Breast cancer is common—it is a risk all women face. For Australian women in their fifties, we know that over five years, about 11 women in every 1000 (1.1 per cent) will be diagnosed with breast cancer. This is the *absolute risk* for women of this age, over this length of time, without HRT—a risk of 11 per 1000, or 1.1 per cent.

Research has shown that combined HRT increases this risk. For every 1000 women in their 50s who use HRT for five years, 15 (1.5 per cent) are likely to be diagnosed with breast cancer. This is four more than would be expected without HRT. Thus, the *increase in absolute risk* for women on HRT for five years is four per 1000, or 0.4 per cent.

Expressed in relative terms, these same facts sound much more dramatic. Researchers express the rise from 11 to 15 cases per 1000 as a *relative risk* of 1.26 ('RR=1.26'). The media are likely to describe it as a 26 per cent rise in risk. There is a real danger that many people will interpret this—quite wrongly—as an increase of 26 per 100. In fact, an extra four cases of breast cancer per 1000 women is a small increase in absolute risk from the individual's view point, although across the whole population it means a significant number more women with breast cancer.

Where can I get further information?

Health professionals and menopause clinics

For more information about menopause or HRT, speak to your family doctor or visit a family planning clinic, a community or women's health centre, or a menopause clinic. You may wish to ask for extra information to take home and consider in your own time. Contact details for menopause clinics and other relevant women's services are given at the end of this section (page 32).

The internet

There is a mass of information on the internet about menopause—it's a great resource, but caution is also in order. Anyone can set up a website and publish information on the web, and there is no way of regulating the quality or the accuracy of this information.

Look for:

- websites sponsored by universities, government agencies and not-for-profit organisations;
- information that has been published in recognised, peer reviewed journals—an indicator of quality and integrity.

Be wary of:

- websites that endorse particular products—advertising dressed up as information;
- websites that fail to list a company or organisation, name, physical address, phone number or contact information;
- websites that offer online consultations and prescriptions;
- claims that a product or therapy method is a 'scientific breakthrough' or 'secret ingredient'. Such language often covers up a lack of good science and research. If it sounds too good to be true, it probably is.

Websites that women may find useful include the following:

- www.healthinsite.gov.au – the website of Health*Insite*, an Australian Government initiative that aims to improve the health of Australians by providing easy access to quality information about human health. There are over 40 articles and resources on menopause at www.healthinsite.gov.au/topics/Menopause
- www.menopause.org.au – the website of the Australasian Menopause Society, which provides both professional and community information
- www.imsociety.org – the website of the International Menopause Society
- www.nhmrc.gov.au/ – the NHMRC website, which includes the HRT Literature Review which informed this booklet, *Hormone Replacement Therapy—A Summary of the Evidence for General Practitioners and other Health Professionals*, and *Making Decisions: Should I use hormone replacement therapy? (HRT)*
- www.menopause.org – the website of the North American Menopause Society. It also provides information for women and for professionals, although its strong North American perspective may not always be directly relevant to women in Australia
- www.pofsupport.org – a website for women with premature ovarian failure, which provides useful information and support for women with a specific range of menopausal issues
- www.jeanhailes.org.au – the website of the Jean Hailes Foundation, based in Melbourne, which provides information on women's health care, both for women and professionals, especially in the field of menopause. The Foundation's 'Early Menopause Australia Support Group' can be contacted by e-mail at: early_menopause_australia@hotmail.com
- www.womhealth.org.au – the website for Women's Health Queensland Wide, a not-for-profit, government-funded health, information and education centre. For menopause information, go to www.womhealth.org.au/healthinformation.html

- www.betterhealth.vic.gov.au – the website of the Better Health Channel, established by the Victorian Government. It includes a number of articles on menopause, produced in consultation with the Jean Hailes Foundation. Go to www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/hc_reproductivesystem_menopause
- www.mhcs.health.nsw.gov.au – the website of the NSW Multicultural Health Communication Services, providing multilingual information on a wide range of topics as well as links to other sites and resources. For menopause information in 10 languages, go to www.mhcs.health.nsw.gov.au/health-public-affairs/mhcs/publications/800.html
- www.fpwa-health.org.au – the website of Family Planning Western Australia, and the only Australian family planning site that provides information on menopause, at www.fpwa-health.org.au/menopause.htm. It also provides information on various other sexual health issues
- www.osteoporosis.org.au – the website for Osteoporosis Australia
- www.whv.org.au – the website of Women’s Health Victoria, a women’s health promotion, advocacy and health information service. The website includes a menopause fact sheet and list of resources on menopause. Follow the links from www.whv.org.au/health_issues/menopause.htm
- www.tased.edu.au/tasonline/twhn/ – the website of the Tasmanian Women’s Health Network
- www.phimr.monash.edu.au – the website of the Prince Henry’s Institute, at Monash Medical Centre in Melbourne. The site includes fact sheets on HRT and menopause
- www.bci.org.au – the website of the NSW Breast Institute

The media

It is easy to find information in newspapers, magazines and on television and radio. Some of this information is accurately reported and well presented; some is biased towards ‘newsmaking’ and can be misleading and alarming.

In particular, the media often present risk as relative risk—for example, reporting ‘a 50 percent increase in risk’. This can sound frightening, even if the absolute risk remains small (see the section on page 26 ‘Understanding risk’).

It is best to check information in the media with health professionals and menopause clinics to be sure about what it means for you.

Women’s networks

Other women are also an important source of information. Women’s networks, associations and support groups are often able to provide valuable information, particularly about the personal experience of women in relation to menopause and HRT.

Contact details: menopause clinics and other relevant services for women (updated July 2004)

Contact details for menopause clinics and some other relevant services in cities across Australia are listed below. You may also wish to check your telephone directory for family planning, community and women's health centres in your area.

SYDNEY

Menopause Clinic

Royal North
Shore Hospital
Pacific Highway
St Leonards NSW 2065
Phone: (02) 9926 7686
Fax: (02) 9926 8197

Sydney Menopause Centre

(various times Tues-Fri)
Royal Hospital for Women
Barker Street
Randwick NSW 2031
Phone: (02) 9382 6620/1
Fax: (02) 9382 6600

Midlink Menopause Service

(Tues afternoons only)
Level 3, 158 Marsden Street
Parramatta NSW 2150
Phone: (02) 9843 3245

Menopause Clinic

(Wed afternoons only)
Concord Hospital (6th Floor
of Medical Centre)
Hospital Road
Concord NSW 2139
Phone: (02) 9767 6747
Fax: (02) 9767 7472

Menstrual Disorders Clinic

(Wed afternoons only)
Liverpool Hospital
Cnr Goulburn &
Elizabeth Sts
Liverpool NSW 2170
Phone: (02) 9828 4191

The Menopause Service Nepean Hospital— Women's Health Clinic

Derby St
Penrith NSW 2751
Phone: (02) 4734 2427
Fax: (02) 4734 3213

CANBERRA

Menopause Centre Canberra

Level 1, 28 University Ave
Canberra City ACT 2601
Phone: (02) 6257 4591
Fax: (02) 6257 5710

MELBOURNE

Menopause Clinic

(Thurs afternoons)
Royal Women's Hospital
132 Grattan Street
Carlton VIC 3053
Phone: (03) 9344 2183
Fax: (03) 9344 2055

Menopause Clinic

(Thurs afternoons, plus Early Menopause clinic each month, & Turner's Syndrome clinic every 2 months)
Monash Medical Centre—
Outpatient Department
246 Clayton Road
Clayton VIC 3168
Phone: (03) 9594 2574
Fax: (03) 9594 6925

Menopause Clinic

(for metabolic & obesity issues relating to menopause)
Commercial Road
Prahran VIC 3181
Phone: (03) 9276 3795
Fax: (03) 9276 6932
Web: www.baker.edu.au

Osteoporosis Clinic

(Wed afternoons)
Broadmeadows
Health Service
35 Johnstone Street
Broadmeadows VIC 3047
Phone: (03) 8345 5286
Fax: (03) 8345 5637

Jean Hailes Foundation Medical Centre

173 Carinish Rd
Clayton VIC 3168
Phone: (03) 9562 7555
Fax: (03) 9562 7477
Email: clinic@jeanhailes.org.au

BRISBANE

Bone & Menopause Clinic

(Friday mornings)

Princess Alexandra Hospital
Ipswich Road

Woolloongabba QLD 4102

Phone: (07) 3240 2834

Fax: (07) 3240 5665

Menopause Clinic

(Monday afternoons)

Royal Brisbane Hospital
Herston Road

Herston QLD 4029

Phone: (07) 3636 1818

Fax: (07) 3636 5478

PERTH

Menopause Clinic

(Wed 8.30-3.30)

Centenary Building, King
Edward Memorial Hospital
Hensman Road
Subiaco WA 6008

Phone: (08) 9340 1355

Fax: (08) 9340 1095

Menopause Clinic

(Open most days at various times)

The Rosalie Gollan Centre
for Women's Health
QEII Medical Centre
Perth WA 6009

Phone: (08) 9346 4014

Fax: (08) 9346 3003

Email: rmri@wt.com.au

Mid-Life and Menopause Support Group

(Wed & Fri 10am - 4pm)

Centenary Building, King
Edward Memorial Hospital

Hensman Road

Subiaco WA 6008

Phone: (08) 9340 1535

Fax: (08) 9340 1096

ADELAIDE

Adelaide Hormone and Menopause Centre

REPROMED Building

180 Fullarton Road

Dulwich SA 5065

Phone: (08) 8333 8170

Fax: (08) 8333 8175

Women's Health Centre

(Tues mornings)

Royal Adelaide Hospital
Cnr North Terrace & Frome
Road

Adelaide SA 5000

Phone: (08) 8222 5587

Fax: (08) 8222 5645

Women's and Children's Hospital

72 King William Road

North Adelaide SA 5006

Phone: (08) 8161 7646

Fax: (08) 8161 7652

Menopause Clinic

(Mon afternoons)

Queen Elizabeth Hospital
Woodville Road

Woodville SA 5011

Phone: (08) 8222 7040

Fax: (08) 8222 7986

Menopause Clinic

(Thurs afternoons)

East Adelaide
Medical Centre

50 Hutt Street

Adelaide SA 5000

Phone: (08) 8210 9422

Fax: (08) 8210 9433

HOBART

Women's Midlife Service

(Mon to Thurs)

Repatriation Centre

90 Davy Street

Hobart TAS 7000

Phone: (03) 6222 7242

Fax: (03) 6222 7252

DARWIN AND ALICE SPRINGS

Family Planning Welfare Association of the NT Inc.

Unit 2, The Clock Tower
Dick Ward Drive, Trower Rd

Coconut Grove

Darwin NT 0820

Phone: (08) 8948 0144

Fax: (08) 8948 0626

Family Planning Association

82 Todd Street

Alice Springs NT 0870

Phone: (08) 8953 0288

Fax: (08) 8952 6859

E:mail fpas@ozemail.com.au

GLOSSARY

Climacteric:	See <i>peri-menopause</i> .
Combined HRT:	Use of oestrogen plus progestogen. This can be 'cyclical' (also called 'sequential'), with oestrogen every day and progestogen added for 10-14 days each month; or 'continuous', with oestrogen and progestogen every day.
Control group:	A control group in a study provides a standard for comparison. For example, participants in a study may be divided into two groups, an 'experimental group' and a 'control group'. The experimental group is given the experimental treatment (eg HRT), while the control group may be given either the standard treatment for the illness or a placebo (a dummy drug). At the end of the study, the results for the two groups are compared.
Coronary heart disease:	A condition in which there is narrowing or blockage of blood vessels supplying heart muscles. This can cause angina and, if severe, can lead to heart attack.
Endometrium:	The inner lining of the uterus.
Estrogen:	The American spelling of oestrogen.
Heart attack:	Damage to muscle of the heart as a result of blockage of blood vessels. It causes severe chest pain and sometimes leads to death.
Hormones:	Chemicals produced by the body that have specific effects, eg testosterone increases sex drive.
Hysterectomy:	Surgical removal of the uterus.
Libido:	Sex drive or sexual desire.
Menopause:	The time in a woman's life when menstrual periods stop.

Observational study:	A study where groups of patients who are already receiving certain therapies (eg HRT) are followed to learn about the safety and effectiveness of one therapy compared with another. Because there is no randomisation procedure (ie using a coin-toss type method to decide who will get which therapy), other things may have influenced the choice of therapy, so the study may not cover a cross-section of the community. This means the results are not as reliable as those of a randomised controlled trial.
Oestrogen:	A hormone produced by the ovaries, which helps to maintain the structures of a woman's reproductive system and plays an important role in the health of the bones.
Osteoporosis:	A condition in which bones become thinner and weaker, and more prone to breaking.
Ovaries:	Two small organs forming part of a woman's reproductive system, which produce hormones and store and release eggs.
Peer reviewed journal:	A publication where the articles are accepted for publication only on the basis of review by a panel of people who have expertise in the subject matter <i>and</i> are independent (both technically and in terms of funding) of the work being reviewed.
Peri-menopause:	(also known as the <i>climacteric</i>) The time immediately before, during and after menopause, when menstrual cycles are changing and some women are experiencing symptoms associated with menopause.
Pharmaceutical Benefits Scheme (PBS):	The scheme under which the Commonwealth Government subsidises about 80 percent of prescription medicines available at pharmacies.
Phytoestrogens:	Substances that are found in some plants and share some of the actions of oestrogen.
Post-menopause:	After menopause—dating from the last menstrual period (which can only be defined in retrospect).
Pre-menopause:	Before menopause.
Progesterin:	The US term for 'progestogen'.

Progesterone:	A hormone produced by the ovaries, which helps to prepare the lining of the uterus each month in case a pregnancy occurs.
Progestogen:	A synthetic form of the hormone progesterone.
Randomised controlled trial:	A research study in which participants are allocated at random to receive one of two or more alternative forms of care (eg HRT or no HRT), so the results for the different groups can be compared. Participants have an equal chance of being allocated to each of these groups.
Literature review:	An assessment of all relevant literature related to a particular topic.
Testosterone:	This is the main male hormone (or androgen), but is also produced naturally in smaller quantities in women, influencing hair growth and promoting sex drive.
Therapeutic Goods Administration (TGA):	A unit of the Australian Government Department of Health and Ageing. The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances.
Thrombosis:	The formation of a blood clot.
Tibolone:	A tablet that mimics the effects of oestrogen, progestogen and testosterone. Tibolone is metabolised differently in different parts of the body, and this means that it has different effects on the various organs. For example, it is thought to have less effect than HRT on breast tissue.
Troches:	Lozenges containing so-called ‘natural hormones’, that are placed in the cheek to dissolve.
Unopposed oestrogen:	HRT with oestrogen alone (no progestogen). This is normally prescribed only for women who have had a hysterectomy.
Uterus:	(also called the ‘womb’) Part of a woman’s reproductive system. The uterus holds and nourishes the developing baby if pregnancy occurs.

APPENDIX I: WORKING PARTY MEMBERSHIP

Dr Edith Weisberg (Chair)	Director of Research, FPA Health, Ashfield, NSW
Ms Fiona Stoker (Co-chair)	Member, Health Advisory Committee, NHMRC; Principal Nurse Adviser, Department of Health & Human Services, Hobart, TAS
Ms Sally Crossing	Chair, Breast Cancer Action Group NSW; Chair, Cancer Voices NSW
Prof Annette Dobson	Professor of Biostatistics, School of Population Health, Faculty of Health Sciences, University of Queensland, QLD
Prof Ian Fraser	Professor in Reproductive Medicine, Department of Obstetrics and Gynaecology Queen Elizabeth II Research Institute for Mothers and Infants, The The University of Sydney, NSW
Dr Anne Krickler	Research Director, Cancer, Genes, Environment & Behaviour Program, School of Public Health, University of Sydney, NSW
Dr Julia Shelley	Principal Research Fellow, Australian Research Centre in Sex, Health & Society, La Trobe University, Melbourne, VIC
Prof Martin Tattersall	Professor of Cancer Medicine, Department of Medicine, The University of Sydney, NSW
Dr Linda Welberry	General Practitioner, Ainslie, ACT; Medical Director, Sexual Health & Family Planning, ACT (until April 2004)
Dr Helen Zorbas	Member, Health Advisory Committee, NHMRC; Director, National Breast Cancer Centre, Camperdown, NSW

SECRETARIAT

Phil Callan Health Advisory Section, NHMRC

Lorraine O'Connor Health Advisory Section, NHMRC

LITERATURE REVIEWERS

Health Technology Sydney, NSW
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TECHNICAL WRITER

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APPENDIX 2: PROCESS REPORT

In September 2002, the National Health and Medical Research Council (NHMRC) established the Working Party on *Hormone Replacement Therapy to review Hormone Replacement Therapy for Peri- and Post-Menopausal Women: A booklet for Health Professionals* and *Menopause and Hormone Replacement Therapy: A booklet for Women* which were published in 1996.

As a major part of the process of revising the publications, the NHMRC commissioned a comprehensive literature review and a draft report to present the evidence relating to both the benefits and risks associated with the therapies commonly used at or after the menopause. The report arising from the literature review was used to develop an information booklet for both women and General Practitioners. A decision aid providing a step-wise approach to the determination of appropriate HRT use by women was also developed.

Two rounds of public consultation were conducted. The first stage consultation was conducted in December 2002 to assess the currency of the 1996 publications, 13 submissions were received.

The second stage public consultation on the draft publications was undertaken during October and November 2004, calling for comments on the three draft replacement documents were advertised in the *Commonwealth Notices Gazette* and all major metropolitan newspapers. Invitations to make a submission were also forwarded to key stakeholders and those with a known interest in hormone replacement therapy. The NHMRC Working Party on Hormone Replacement Therapy met on 17 December 2004 to consider the 21 submissions received.

All submissions received during both rounds of consultation were taken into consideration in finalising the documents. All comments were addressed by the Working Party before consideration by the NHMRC Health Advisory Committee and endorsement by the NHMRC at its 156th session in March 2005.

Submissions were received from the following individuals and organisations.

December 2002

Professor Alastair H MacLennan	Adelaide University
Associate Professor John Eden	University of NSW
Australian Menopause Society	Buderim QLD
Dr Di Palmer	Royal Women's Hospital, Melbourne
Dr Eleanor Long	Royal Australian & New Zealand College of Obstetricians & Gynaecologists
T J Nash	Wyeth Australia and New Zealand
Ms Kirsten Braun	Women's Health Queensland Wide Inc
Dr Troels Wolthers	Eli Lilly Australia Pty Ltd
Berry Engel Jones	Coffs Harbour Women's Health Centre
Ms Sally Crossing	Breast Cancer Action Group NSW
Chris Ferlazzo	Women's Health Victoria
Bernadette Roberts	Women's Health Statewide
Andrew Weekes	Servier Laboratories (Australia) Pty Ltd

October – November 2004

Ms Jane Fuller	
Professor Alastair H. MacLennan	Adelaide University
Associate Professor John Eden	University of NSW
Dr Guy Gordon	Organon (Australia) Pty Limited
Dr Di Palmer	Royal Women's Hospital
Professor Henry Burger	Monash Medical Centre
Dr Barry G Wren AM	Consultant Gynaecologist, NSW
Dr Linda Welberry & Dr Rosa O'Kane	Menopause Centre Canberra

Dr James Brodribb	Royal Australian & New Zealand College of Obstetricians & Gynaecologists
Ms Teri Snowdon	Royal Australian College of General Practitioners
Ms Bernadete Roberts	Women's Health Statewide
Ms Kirsten Braun	Women's Health Queensland Wide Inc
Dr Adele Weston	Health Technology Analysts
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Ms Alison Boughey	Breast Cancer Network Australia
Dr Emily Banks	Australian National University
Dr Peter R Mansfield	Healthy Skepticism Inc
Ms Yvonne McCall	Mid-Life and Menopause Support Group
Ms Elenor Clune	National Heart Foundation of Australia
Janet Michelmore AO	The Jean Hailes Foundation
Ms Roberta Higginson	Breast Cancer Action Group Incorporated

Before endorsement by the NHMRC, the draft documents were subject to an independent review against the NHMRC key criteria for assessing public health guidelines, followed by consideration of the Health Advisory Committee.

The NHMRC will ensure that the documents are widely disseminated through well-established channels to ensure that all relevant agencies are advised of the release of the documents.

Working Party Membership

Dr Edith Weisberg (Chair)	Director of Research, FPA Health, Ashfield, NSW
Ms Fiona Stoker (Co-chair)	Member, Health Advisory Committee, NHMRC; Principal Nurse Adviser, Department of Health & Human Services, Hobart, TAS
Ms Sally Crossing	Chair, Breast Cancer Action Group NSW; Chair, Cancer Voices NSW
Prof Annette Dobson	Professor of Biostatistics, School of Population Health, Faculty of Health Sciences, University of Queensland, QLD
Prof Ian Fraser	Professor in Reproductive Medicine, Department of Obstetrics and Gynaecology Queen Elizabeth II Research Institute for Mothers and Infants, The University of Sydney, NSW
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Dr Julia Shelley	Principal Research Fellow, Australian Research Centre in Sex, Health & Society, La Trobe University, Melbourne, VIC
Prof Martin Tattersall	Professor of Cancer Medicine, Department of Medicine, The University of Sydney, NSW
Dr Linda Welberry	General Practitioner, Ainslie, ACT Medical Director, Sexual Health & Family Planning, ACT (until April 2004)
Dr Helen Zorbas	Member, Health Advisory Committee, NHMRC; Director, National Breast Cancer Centre, Camperdown, NSW

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Terms of Reference

The terms of reference of the NHMRC Working Party on Hormone Replacement Therapy are to:

1. Through the NHMRC evidence-based research and consultation process, develop a document and decision tool on hormone replacement therapy for women at and after the menopause;
2. Replace the 1996 documents on hormone replacement therapy with an information document for health professionals and consumers which takes into account the recent research;
3. Recommend an appropriate means of evaluating the effectiveness of the decision tool produced; and
4. Provide advice to the National Health and Medical Research Council through the Health Advisory Committee (HAC) in a timely fashion.

The National Health and Medical Research Council

The National Health and Medical Research Council (NHMRC) was established in 1936 and is now a statutory body within the portfolio of the Australian Government Minister for Health and Ageing, operating under the *National Health and Medical Research Council Act 1992* (NHMRC Act). The NHMRC advises the Australian community and the Australian Government, and State and Territory governments on standards of individual and public health, and supports research to improve those standards.

The NHMRC Act provides four statutory obligations:

- to raise the standard of individual and public health throughout Australia;
- to foster development of consistent health standards between the states and territories;
- to foster medical research and training and public health research and training throughout Australia; and
- to foster consideration of ethical issues relating to health.

The NHMRC also has statutory obligations under the *Prohibition of Human Cloning Act 2002* (PHC Act) and the *Research Involving Human Embryos Act 2002* (RIHE Act).

The activities of the NHMRC translate into four major outputs: health and medical research; health policy and advice; health ethics; and the regulation of research involving donated IVF embryos, including monitoring compliance with the ban on human cloning and certain other activities. A regular publishing program ensures that Council's recommendations are widely available to governments, the community, scientific, industrial and education groups. The Council publishes in the following areas:

- Aged Care
- Blood and Blood Products
- Cancer
- Cardiovascular Health
- Child Health
- Clinical Practice Guidelines – Standards for Developers – Topics
- Communicable Diseases, Vaccinations and Infection Control
- Diabetes
- Drug and Substance Abuse
- Environmental Health
- Ethics in Research–Animal
- Ethics in Research–Human
- Genetics and Gene Technology
- Health Procedures
- Health Promotion
- Human Cloning and Embryo Research
- Indigenous Health
- Injury including Sports Injury
- Men's Health
- Mental Health
- Musculoskeletal
- NHMRC Corporate documents
- NHMRC Session Reports
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