



Applying population level evidence with individual patients: An HRT decision aid example

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Barriers to implementing evidence in practice

(2004) Survey of random sample of 107 GPs (unpublished)

- Sources used for decision making are still less evidence-based than they should be
 - Only 23.4% said they used 'evidence-based' resources to solve a clinical problem in practice
 - 50.5% said they would use 'opinion-based' source (eg peers, specialists, personal experience)
 - 27.1% said they would use 'commerce-based' sources (free publications, medical magazines etc)



Barriers to implementing evidence in practice

(2004) Survey of random sample of 107 GPs (unpublished)

- ‘System’ and ‘skills-based’ barriers are becoming less of an issue but the quality and application of evidence remain problematic
 - GPs want evidence summaries in improved format
 - Mechanisms for tailoring evidence to the individual
 - Efficient and effective mechanisms for involving patients in decision-making & eliciting their preferences
-



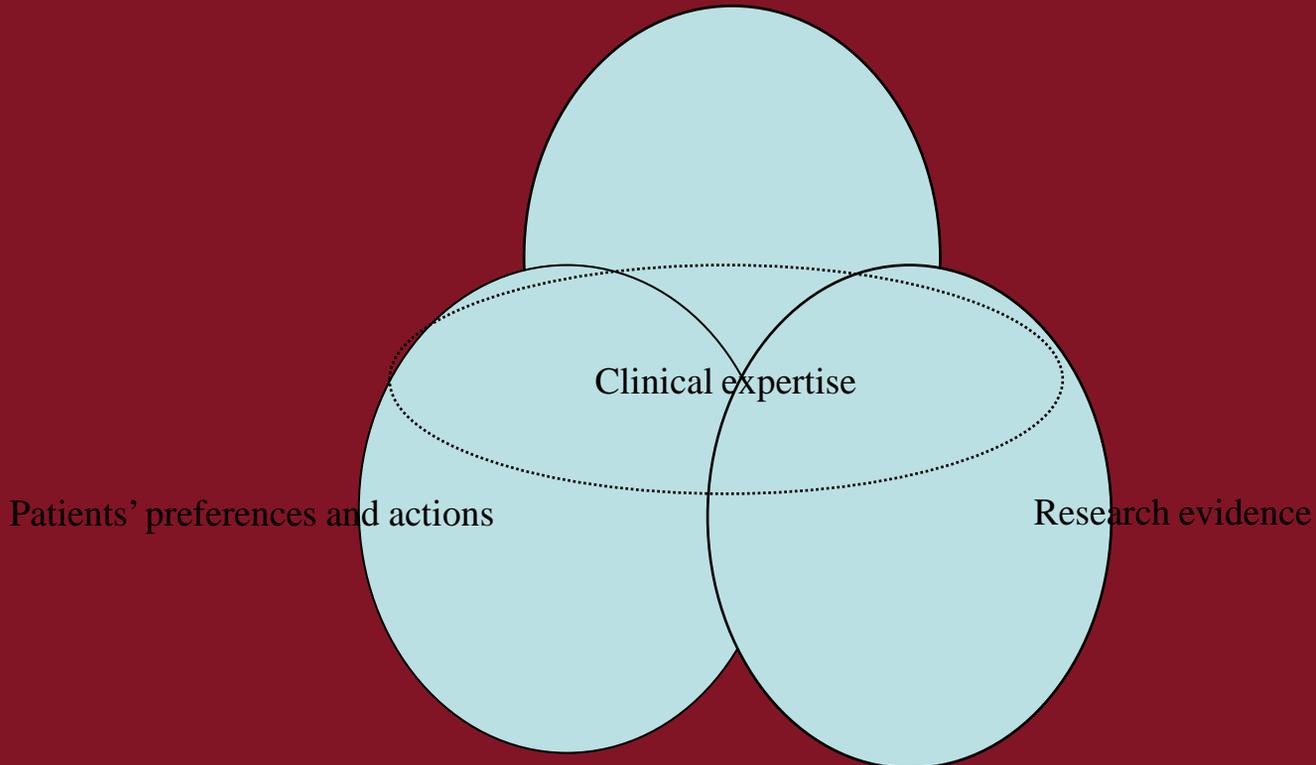
Steps of Evidence-Based Health Care

1. Convert information needs into answerable questions;
2. Track down, with maximum efficiency, the best evidence with which to answer them (clinical examination, diagnostic laboratory, research evidence or other sources)
3. Critically appraise that evidence for its validity and usefulness
4. Apply the results of this appraisal in our clinical practice
5. Evaluate our performance



A framework for clinical decision-making:

Clinical state and circumstances





Decision aids

Decision aids are designed to enable people to:

- Understand the probable outcomes of options by providing information relevant to the decision
- Consider the personal value they place on benefits versus harms by helping clarify preferences
- Move through the steps in decision-making and;
- Participate in deciding about their healthcare



Sydney Decision Support Framework for developing Evidence-Based Decision Aids (SDSF)

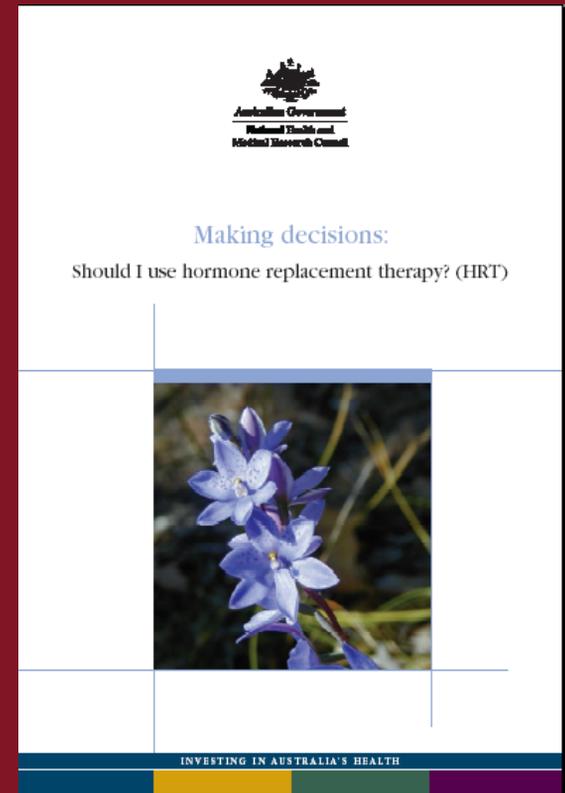
1. Define the parameters of the decision
 2. Search for best available evidence for outcomes of intervention and alternative(s)
 3. Appraise the evidence
 4. Apply the evidence
 5. Evaluate the decision aid
-



Making decisions: Should I use hormone replacement therapy? (HRT)

Step 1: Define the parameters of the decision

- Who are the users? (P)
- What is the treatment/test under consideration? (I)
- What are the alternative(s)? (C)
- What are the issues relevant to the patient and for making an informed decision? (O)
- What is the most appropriate timeframe for the effect (T)?





Making decisions about HRT

This decision aid is specially designed for women:

- who are approximately 50 years old and
- who are considering hormone replacement therapy (tablets or patches containing oestrogen and progesterone) and
- who have troublesome hot flushes.

This decision aid is designed to be used with a health worker who is aware of your health and personal situation — it should not replace professional health advice. It is part of a package of information provided by the National Health and Medical Research Council (NHMRC), which includes a summary of the research on HRT and a booklet with information about the menopause and treatment options. Other documents in the package include *Hormone Replacement Therapy: Exploring the Options for Women* and *Hormone Replacement Therapy: A Summary of the Evidence for General Practitioners and other Health Professionals* and are available on the NHMRC website www.nhmrc.gov.au/

This decision aid is less useful for you if:

- your hot flushes are mild
- you have had a hysterectomy (oestrogen-only HRT is usually prescribed and is not covered in detail here)
- you have had breast cancer (you should seek special advice from your doctor)
- you have had your menopause at a very young age.



Making decisions: Should I use hormone replacement therapy? (HRT)

Step 2: Search for best available Evidence for outcomes of intervention and alternative(s)

- Women's Health Initiative (WHI) randomised controlled trial (n=16,000)
- Cochrane reviews
- Cohort studies for natural history of menopause
- 35 references

Appendix B: Scientific references

If you would like to read some of the original research, go to your favourite search engine (eg www.google.com.au) and type in 'PubMed'. This will take you to the US National Library of Medicine, which hosts a free version of the medical database 'Medline'. Type in the surname of the first author AND a keyword from the title and you should be able to find the article of interest. (NB: Not all journal articles are available in their complete form free of charge).

- ★ 1 Guthrie J, Dennerstein L, Taffe J, Donnelly V. Health care-seeking for menopausal problems. *Climacteric* 2003;6(2):112-117.
- ★ 2 Mishra G, Lee C, Brown W, Dobson A. Menopausal transitions, symptoms and country of birth: the Australian Longitudinal Study on Women's Health. *Australian and New Zealand Journal of Public Health* 2002;26:563-70.
- 3 Australian Drug Evaluation Committee. Advice of Chair of Expert Advisory Group on HRT Hormone Replacement Therapy.
- 4 Australian Bureau of Statistics. National Health Survey. Summary of Results: 2001 ABS Catalogue number 4364.0, 2001.
- ★★ 5 MacLennan A, Lester S, Moore V. Oral oestrogen replacement therapy versus placebo for hot flushes (Cochrane Review). *The Cochrane Library* 2000;1.
- ★★ 6 Greendale G, Reboussin B, Hogan P, Bamabei V, Shumaker S, Johnson S, *et al*. Symptom relief and side effects of postmenopausal hormones: Results from the postmenopausal estrogen/progestin interventions trial. *Obstetrics and Gynaecology* 1998;92:982-8.



Making decisions: Should I use hormone replacement therapy? (HRT)

Step 3: Appraise the evidence

What types of hormones are available for menopausal symptoms?

This booklet focuses on **daily oestrogen and progestogen** and **cyclical oestrogen and progestogen**. These are the most commonly used types of HRT for women who have not had a hysterectomy.⁴ HRT is available in many forms:

- *Daily oestrogen and progestogen* (continuous combined HRT) – this is usually prescribed for women who have had no period for at least 12 months. It may be taken via patches or tablets.
- *Cyclical oestrogen and progestogen* (the synthetic form of *progesterone*) – this involves taking oestrogen daily and adding progestogen for 10–14 days each month (patches or tablets).
- *Tibolone* – this is an artificial tablet form of oestrogen and progestogen.

For more information about other ways to relieve menopausal symptoms see Appendix A (page 29) in this book and the other booklet in this series called *Hormone Replacement Therapy: Exploring the Options for Women*.

Quality of research information

Research studies vary in quality and this affects how confident we can be in their results. The quality of a study depends on the design of the study and how it was carried out.

Throughout this booklet we have used Stars to show how confident we are about each piece of research information presented.

- ★★ Two gold stars indicates information that has been **confirmed** by results from well-designed and conducted research.
- ★ One silver star indicates information that is **suggested but not confirmed** because we are **less** confident in the quality of the research.

What are the benefits of HRT?

HRT can reduce the severity of some menopause symptoms. It may also reduce the risk of some serious illnesses. It is unclear how long this effect lasts after stopping HRT.

Benefits of HRT:

Taking HRT means you have a reduced chance of:

Menopause symptoms

- Hot flushes⁶ ★★
- Night sweats^{7,7} ★★
- Sleep disturbance⁷⁻¹⁰ ★★

Bowel cancer¹¹ ★★

Bone fractures¹¹ ★★

The diagrams on the following pages show how many women are likely to experience the main benefits of HRT compared to women who are not.



Making decisions: Should I use hormone replacement therapy? (HRT)

Step 4: Applying the evidence

- Incorporate the necessary and relevant information for an informed decision
- Estimate the baseline rates for each outcome over the designated timeframe and adjust for key risk factors and the intervention (if appropriate)
- Estimate the rates for each outcome WITH the intervention
- Use appropriate formats to communicate the probabilities of these outcomes, aiming to reduce risk perception bias
- Elicit patient values (ie weighting) for salient behavioural beliefs, normative beliefs and perceived behavioural control



What are the risks of HRT?

Research shows the use of HRT may also have harmful effects for some women. These include some nuisance symptoms and also increased risk of some serious illnesses. It is unclear how long these risks last after stopping HRT.

Risks:

If you take HRT you have an increased chance of:

Breast cancer ¹¹ ★★

Abnormal mammogram during screening ¹² ★★

Stroke ¹¹ ★★

Serious blood clots (thromboembolic disease) ¹¹ ★★

Breast tenderness ⁸ ★★

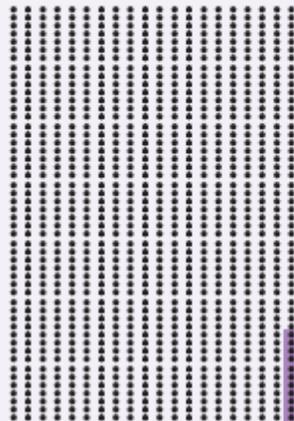
Spotting or the return of periods ¹³ ★★

NB. It is important to note 2 yearly mammographic screening for breast cancer is recommended for all women aged 50-69 years. Most women who have an abnormal mammogram do not have cancer on further testing. In other words, only a small number of those who need follow-up after an abnormal mammogram actually have cancer.

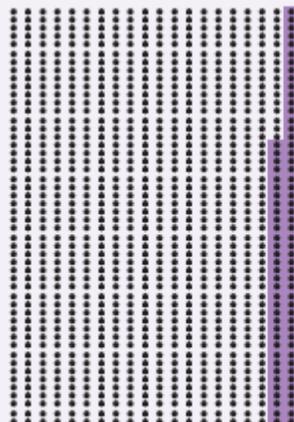
The diagrams over the page show how many women are likely to experience the main risks of HRT compared to women who do not.



Of 1000 women in their 50s who **DO NOT** take HRT, over five years:

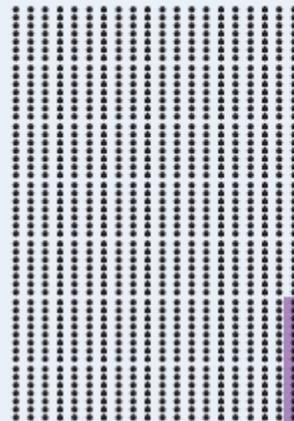


11 women may get breast cancer



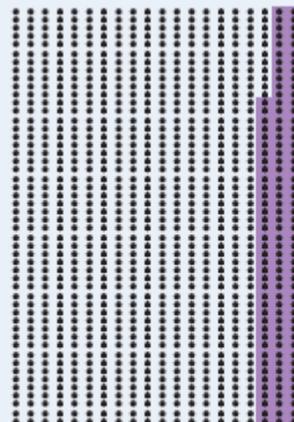
84 women may have an **abnormal mammogram** if screened twice during this period (ie every 2 years)

Of 1000 women in their 50s who **DO** take HRT, over five years¹¹:



15 women may get breast cancer

In other words, 4 extra cases of breast cancer in HRT users



139 women may have an **abnormal mammogram** if screened twice during this period (ie every 2 years)

In other words, 55 extra abnormal mammograms in HRT users

¹¹ This information comes from a ★★ two gold star study in which women took HRT for an average of 4 years and outcomes were measured over 5 years



Summary table of key points

| BENEFITS | RISKS |
|---|---|
| Reduced chance of: | Increased chance of: |
| Menopause symptoms: | Breast cancer |
| ■ Hot flushes | 4 extra cases in 1000 women over 5 years |
| <i>767 women out of 1000 will get relief from hot flushes</i> | Abnormal mammogram |
| ■ Night sweats | 55 extra abnormal mammograms women in 1000 women if screened twice during 5 years (ie every 2 years) |
| ■ Sleep disturbance | Stroke |
| Bowel cancer | 2 extra cases in 1000 women over 5 years |
| 1 fewer case in 1000 women over 5 years | Serious blood clots |
| Hip fractures | 5 extra cases in 1000 women over 5 years |
| Less than 1 fewer hip fractures in 1000 women over 5 years | Breast tenderness |
| | Spotting or the return of periods |

Summary table of key points (continued)

| NO EFFECT ON: | UNCLEAR RESEARCH FINDINGS ABOUT: |
|-----------------------|----------------------------------|
| Uterine cancer | Heart attacks |
| Ovarian cancer | Memory loss and dementia |
| Mental health | Improvements to skin and hair |
| General health | Headache and migraine |
| Weight gain | Urinary symptoms |
| Satisfaction with sex | Nausea and vomiting |
| | Fluid retention |



HRT – Making the decision

What do I do now?

To help you decide whether to start HRT, we suggest you follow the steps listed below:

- Step 1 Think about how troublesome your menopausal symptoms are.
- Step 2 Think about your reasons for not taking HRT. Consider your own personal risk factors that may be worsened by HRT.
- Step 3 Weigh up the importance of the benefits and risks of HRT for you.



Step 1: How troublesome are my menopausal symptoms?

HRT is only recommended for the relief of troublesome menopausal symptoms such as hot flushes, night sweats and sleep disturbances. HRT is no longer recommended for preventing heart attacks or osteoporosis. The following are menopausal symptoms that can be relieved by HRT. Tick the box next to the ones that trouble you and are important for you to get relief from. The more boxes you tick the more you are troubled by the symptoms.

Note: If you don't tick any boxes then your symptoms are probably not serious enough to need HRT.

Benefits of taking HRT

Troublesome menopause symptoms*

- Hot flushes
- Night sweats
- Sleep disturbance

* See Appendix A on page 29 for alternatives to HRT.



Step 2: What risk factors do I have that might be worsened by HRT?

When thinking about reasons for not taking HRT you should think about your own personal risk factors. The list below includes factors that increase your risk of breast cancer, stroke and blood clots. Please tick the boxes that are relevant for you. The more boxes you tick, the greater your risk. Taking HRT increases your chance of these occurring.

RISKS OF TAKING HRT

Risk of breast cancer

- Personal history of breast cancer
- Family history of breast cancer
- Previous biopsies showing abnormal breast cells
- Never had children
- First child after 30
- First period at early age

Risk of stroke

- Family history of stroke
- Previous Transient Ischemic Attack (TIA) or stroke
- Atrial fibrillation
- High blood pressure
- Smoker
- Diabetes
- Heart disease

Risk of blood clots

- A previous blood clot
- Family history of blood clots
- Cancer
- Heart disease
- Being inactive for long periods
- Blood disorders that interfere with clotting
- Recent surgery

Step 3: How important to me are the benefits and risks?

Now that you've thought about your personal risk factors for and against HRT, consider which of these is most **important** to you. People often value risks differently so there are no right or wrong answers to this section. Please show how important the benefits and risks of HRT are to you by shading the circles beside the reasons. More shading shows more importance, for example:

Extremely important to you: Not at all important ●●●●○ Extremely important
Not important to you: Not at all important ●○○○○ Extremely important

| BENEFITS OF TAKING HRT | RISKS OF TAKING HRT |
|---|--|
| Relief from menopause symptoms (hot flushes, night sweats, sleep disturbance, irregular periods) Not at all important ○○○○○ Extremely important | Increasing my risk of breast cancer and/or an abnormal mammogram Not at all important ○○○○○ Extremely important |
| Other reasons for taking HRT important to you Not at all important ○○○○○ Extremely important | Increasing my risk of stroke Not at all important ○○○○○ Extremely important |
| | Increasing my risk of blood clots Not at all important ○○○○○ Extremely important |
| | Increasing my risk of nuisance symptoms (breast tenderness, spotting/periods returning) Not at all important ○○○○○ Extremely important |
| | Other reasons for NOT taking HRT important to you Not at all important ○○○○○ Extremely important |

Which way are you leaning in your decision?

Fill in one of the squares below to indicate which way you are leaning in your decision.

| | | | |
|------------|--|-----------------|---------------|
| HRT | | | |
| | | Not sure | No HRT |
| | | 25 | |



Making decisions: Should I use hormone replacement therapy? (HRT)

Step 4: Evaluate the decision aid

- *Developmental (validity)*
 - *Expert review*
 - *Consumer review*
 - *Acceptability questionnaires*
 - *Efficacy*
 - *Extensive qualitative evaluation*
 - *Randomised trials*
-



Sydney Health Decision Group Projects

Existing Decision Aids

| | |
|------------|---------------------------------|
| Vaccines: | MMR |
| Screening: | Mammography 40-49 |
| | Mammography 70-79 |
| | FOBT 50-74 years |
| | HPV testing for cervical atypia |
| Obstetric: | ECV for breech |
| | Analgesia in labour |
| Oncology: | Various |

