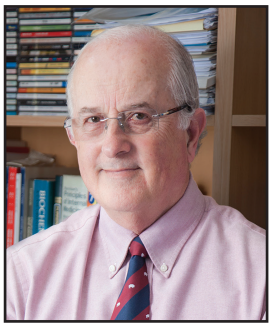
New menopause guidelines

IMPLICATIONS FOR SOUTH AFRICAN CLINICIANS

Introduction



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"Menopause impacts negatively on a woman's quality of life and her economic contribution to our society" – Professor Alan Alperstein

The UK National Institute for Health and Care Excellence (NICE)'s new guidelines for women undergoing menopause[1] provide some useful clinical tools for South African clinicians, according to Professor Alan Alperstein, of UCT and Kingsbury Hospital, Cape Town.

These guidelines, like the South African guidelines,[2] focus on an individualised approach to menopause treatment. The South African guidelines, last published in 2014, are also patient orientated with the recommendation that therapy choices be a joint decision between the healthcare provider and an informed patient, based on her current clinical status and evidence-based medicine.

When considering the health costs of treating menopausal symptoms, the reduced productivity of women undergoing menopause needs to be taken into account.[3] "This is particularly true in our society today, where women are key to the productiveness of many sectors of our economy," Professor Alperstein noted.

Clinicians need to spend time assessing the extent of symptoms in individual patients, informing them of the benefits and risks of therapy. The NICE guidelines again emphasise that for most women, hormone therapy (HT) is a very effective treatment for vasomotor symptoms, such as hot flushing, and also reduces the risk of osteoporotic fractures.

A Diagnosis of perimenopause and menopause

The diagnosis of the advent of the menopause is based on clinical evaluation of symptoms, with the following key clinical insights:

1. Diagnose perimenopause in otherwise healthy women aged over 45 years, based on vasomotor symptoms and irregular periods, but without laboratory tests.
2. Diagnose menopause in women over the age of 45 years who have not had a period for at least 12 months and are not using hormonal contraception, but without laboratory tests.
3. Diagnose menopause in women without a uterus over the age of 45 years based on symptoms and without laboratory tests.
4. Take into account that it can be difficult to diagnose menopause in women who are taking hormonal treatments, for example for the treatment of heavy periods!
5. Use a follicle stimulating hormone (FSH) test in women younger than 45 years with menopausal symptoms and in younger women under 40 years in whom menopause is suspected.

Professor Alperstein points out that this emphasis on limiting FSH tests in the NICE guidelines is with a view to achieving savings in the health sector. "In my view this is not an issue, if FSH tests are used properly. I use FSH tests to help prove to doubting patients that they are indeed menopausal and to introduce to younger symptomatic patients the concept that ovarian function is declining." It is important to note that the FSH test is not essential to the diagnosis of the menopause in women older than 45 years with symptoms.

In the younger symptomatic woman, two FSH tests should be done, 4-6 weeks apart, to make the diagnosis of premature ovarian insufficiency (POI), which will be dealt with separately in section D.

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MSD Be well

B Managing menopausal symptoms

The new NICE guidelines recommend HT for menopausal symptoms after discussing the short-term (up to five years) and longer-term benefits and risks. A combination of estrogen and progestogen is recommended for women with a uterus while for women who have had a hysterectomy, estrogen alone is recommended. Tibolone is recommended for women with a uterus as well as women who have had a hysterectomy. Tibolone offers similar clinical benefits and risks to other estrogen and progestogen formulations.

The exception to this treatment approach is in women with POI.

C Long-term benefits and risks of HT

"When prescribing HT, it is vital to relate the risk of use to the situation of the individual patient in front of you. The new NICE guidelines provide useful tables for the clinician to simplify in discussion with patients," Professor Alperstein said.

Risk of cardiovascular disease

The NICE guidelines point out that the presence of cardiovascular risk factors is not a contraindication to HT as long as these risks are being addressed; neither does HT increase cardiovascular disease risk when started in women aged under 60 years. Table 1 provides data summarising the *absolute* rates of coronary heart disease (CHD) for different types of HT, while Table 2 addresses the stroke rate per 1 000 women users of HT over a 7.5 year period.

Risk of breast cancer

The principle should be noted from the outset that the baseline risk of breast cancer for women around menopausal age varies according to underlying risk factors. HT with estrogen alone is associated with little or no change in risk while estrogen plus progestogen can be associated with an increase in the risk of breast cancer (Table 3).

Table 1: Absolute rates of CHD for different types of HT compared with no HT (or placebo)*

Difference in CHD incidence per 1000 women over 7.5 years		
Women on estrogen only	**Current users**	**>5 years since stopping**
RCT Observational data	6 fewer 6 fewer	6 fewer –
Women on estrogen and progestogen	**Current users**	**>5 years since stopping**
RCT Observational data	5 more –	4 more –

– There are no available data in this category
RCT – randomised clinical trial
*Simplified from NICE guidelines
Observational – is based on cohort studies with several thousand women

Table 2: Difference in stroke incidence per 1000 women on HT over 7.5 years

Women on estrogen only	Current users	>5 years since stopping
RCT Observational data	0 3 more	1 more –
Women on estrogen and progestogen	**Current users**	**>5 years since stopping**
RCT Observational data	6 more 4 more	4 more –

– There are no available data in this category

Table 3: Absolute rates of breast cancer for different forms of HT compared with no HT, different durations of HT use and time since stopping

Difference in breast cancer incidence per 1000 women over 7.5 years				
Women on estrogen only	**Current users**	**Treatment <5 years**	**Treatment 5-10 years**	**>5 years since stopping**
RCT Observational data	4 fewer 6 more	– 4 more	– 5 more	5 fewer 5 fewer
Women on estrogen and progestogen	**Current users**	**Treatment <5 years**	**Treatment 5-10 years**	**>5 years since stopping**
RCT Observational data	5 more 17 more	– 12 more	– 21 more	8 more 9 fewer

– There are no available data in this category

Benefits in osteoporosis

The baseline population risk of fragility fractures in South Africa is not known; nonetheless HT is effective in decreasing the incidence of fractures in patients at both high and low risk of fractures as they age. In some patients, a degree of fracture prevention persists after cessation of HT, but in many patients bone-sparing medication will be needed.

D Managing POI

"This is an often misdiagnosed condition and, when identified, it is poorly treated," Professor Alperstein noted.

In the NICE guidelines, the management of POI emphasises the importance of starting hormonal treatment either with HT or a combined hormonal contraceptive and continuing treatment until at least the age of natural menopause.

The principles of treatment that apply to women undergoing a natural menopause in their 50s are not applicable to young women with POI.

POI needs sympathetic and supportive handling. It is far more reasonable to place these younger women on a combined oral contraceptive (COC) than conventional HT. One then transitions these women onto HT from COC at the appropriate age.

SOUTH AFRICAN RESEARCH ON WOMEN'S EXPERIENCE OF MENOPAUSE – NEED FOR CLINICAL EDUCATION AT DIAGNOSIS

There is still a lack of published information on South African women's attitudes to and experience of menopause and its treatment. If you have data that you wish to share with deNovo Medica readers, please contact info@denovomedica.com

The World Health Organisation estimates that 76% of post-menopausal women will be living in developing countries by 2030.

A study undertaken 10 years ago in private practice in women of middle-to-high socioeconomic status[4] in the Western Cape found that these women were well informed about the menopause and treatment with HT. A significant number of patients surveyed had been on HT for

more than 10 years. Their most important reason for initiation of HT was vasomotor symptoms (70%) and 10% were aware of the skeletal protection of HT.

In contrast, in the same time period, a study of rural Xhosa women[5] showed that they experienced the menopause at a comparable age to their urban Caucasian counterparts. Despite a high incidence of vasomotor symptoms, they were not aware of the potential benefits of HT. These research initiatives were largely stimulated by the publication of the WHI study (2002), when clinicians needed to re-evaluate their stance on hormonal therapy.

Subsequently, there has been a paucity of data on African women's experience of the menopause. The Study of Women's Health across the Nation (SWAN) study[6] in the USA showed that African-American and Hispanic women had particularly persistent vasomotor systems lasting an average of 10 years compared to the median duration of 6.5 years in their white counterparts.

A recent evaluation of techniques[7] to stage the menopausal transition in sub-Saharan African women provides pointers to a different current experience of women resident in Soweto (Source study: Birth to Twenty Plus Cohort).

The median age of final menstrual period (FMP) was 49 years, somewhat younger than in western women. Defining features of the menopause was vasomotor symptoms, sexual problems in early menopause and irritability in late menopause. Obesity was strongly related with more severe vasomotor symptoms. HIV was judged to have no effect on menopause symptoms.

Of great importance was the fact that 50% of the cohort did not understand the meaning of the term 'menopause', but were able to give reasonably precise information about changes in bleeding patterns. Primary care practitioners need to ask about vasomotor symptoms, irritability and other factors (such as sleeping patterns) that can affect women in this age group in order to assess whether the menopausal transition is affecting the patient's quality of life.

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