NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Hormone therapy for endometriosis symptoms: patient decision aid user guide for healthcare professionals

Implementing the NICE guideline on endometriosis (NG73)

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This is a user guide for healthcare professionals. It accompanies the decision aid for women with endometriosis symptoms to help them make informed decisions about hormone treatment with hormonal contraceptives to try to improve their symptoms. The decision aid and user guide are based on the NICE guideline on endometriosis published September 2017.

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The decision aid and user guide are not NICE guidance.

National Institute for Health and Care Excellence
Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT
www.nice.org.uk

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Background to patient decision aids

Patient decision aids (PDAs) are tools designed to help people take part in making decisions about healthcare options. They provide information on the options and help people to clarify and communicate how they feel about the different features of the options. PDAs do not advise people to choose one option over another, nor are they meant to replace discussions with their healthcare professional. Instead, they prepare people to make informed, values-based decisions with their practitioner (IPDAS collaboration 2012).

Complex decisions have multiple options with features that people value differently. Sometimes the scientific evidence about options is limited. Therefore the best choice depends on the personal importance the person places on the benefits, harms and scientific uncertainties (IPDAS collaboration 2012). The values and perceptions of individual people, and their attitudes to risk, may be different from those of their healthcare professional (Thornton 2003). Using PDAs in a consultation may help to improve a person's knowledge of the options and outcomes and give them more realistic expectations (Stacey et al. 2017).

Licence status of contraceptives for endometriosis

Hormone treatment with oral contraceptives or long-acting reversible contraception hormone treatment for women with suspected, confirmed or recurrent endometriosis is recommended as an option in the NICE guideline (see the guideline for full details of recommendations). At the time of publication (September 2017), none of these medicines had UK marketing authorisations for this indication. The General Medical Council (GMC), in its Prescribing guidance: prescribing unlicensed medicines, states that although doctors should usually prescribe licensed medicines for their licensed indications, they may prescribe unlicensed medicines when it is necessary to do so to meet the specific needs of the patient. The GMC states that doctors must give patients sufficient information about the medicines they propose to prescribe to allow them to make an informed decision: this can be facilitated by using the PDA. It also states that when prescribing an unlicensed medicine is supported by authoritative clinical guidance (such as a NICE guideline), it may be sufficient to describe in general terms why the medicine is not licensed for the proposed use or patient population.

Using the patient decision aid

As for all its guidelines, NICE expects healthcare professionals to take a woman's individual needs, preferences and values fully into account when implementing its guideline on endometriosis. Relevant recommendations on good practice in shared decision-making are given in the NICE guidelines on patient experience in adult NHS services and medicines optimisation.

Healthcare professionals should explain the PDA to the woman, tailoring the information to reflect her clinical circumstances as necessary. It is, of course, essential to understand the woman's preferences and priorities, especially in regard to fertility. Healthcare professionals should make it clear that, although they may have a view on the choice they would make if they were in the woman's situation, they accept that she may view the balance of risks, benefits and consequences of treatment in a different way and come to a different decision.

It is important to avoid framing information in a way that might lead to an unbalanced picture of either benefits or harms. For example, healthcare professionals should:

- tell the woman about the possible benefits from hormone treatment on the woman's endometriosis symptoms, but also that it is not possible to say for certain the extent to which she is likely to benefit
- tell the woman that (for example):
  - each year, on average 5 to 12 women in every 10,000 who take the combined pill will get a blood clot, but **also** that 9,988 to 9,995 will not **and that**
  - each year, on average 2 women in 10,000 who do not take the combined pill will get a blood clot and 9,998 will not.

Healthcare professionals should also explain that it is impossible to know what will happen to an individual woman or say whether or not she will benefit from the treatment or experience harm. They should also take account of individual factors that might affect the woman's risk (such as additional risk factors for venous thromboembolism).

Sources of data

The PDA was developed with input from an expert steering group that included clinical experts and patient representatives. The hormonal contraceptive options presented in the PDA were selected by the expert group as reflecting those most commonly used in clinical practice.

The primary source of information was the evidence reviewed in the NICE guideline, supplemented where necessary by reference sources such as manufacturers' summaries of product characteristics (SPCs).

The only randomised controlled trial of hormonal contraceptive compared with placebo identified in the NICE guideline was the study by Harada et al. (2008). This compared the combined oral contraceptive pill (ethinylestradiol 35 micrograms plus norethisterone 1 mg), taken conventionally for 4 menstrual cycles, with placebo in 100 women with confirmed endometriosis. Mean dysmenorrhea and non-menstrual pain scores were reduced in the active treatment group compared with the placebo group, but the study did not report on the numbers of women obtaining clinically significant benefits in each group. A network meta-analysis conducted for the NICE guideline found no statistically significant differences among the combined oral contraceptive pill, oral progestogens, intramuscular progestogens and intrauterine progestogens with regard to improvement in pain scores. The PDA reflects this and the expert group members' clinical experience.

Data on the risk of breast cancer and thromboembolism were taken from manufacturers' SPCs and the British National Formulary (BNF). The expert group agreed that levonorgestrel is the progestogen-only pill most often used in clinical practice for endometriosis symptoms, so this was used as a reference for this type of contraceptive.

The risk of breast cancer with the combined pill is shown as the number of women affected per 10,000 at age 45 who took the combined pill for 5 years in their early 30s. This is an additional 10 women with breast cancer; that is, 110 women in 10,000 compared with 100 women per 10,000 never-users. This scenario and numbers were chosen as indicative and to be consistent with the information in the manufacturers' patient information leaflets (package inserts) for combined pills. It is recognised that women with endometriosis may well start taking the combined pill at a younger age and continue taking it until they are older than their mid-30s. The actual risk for an individual woman depends on her baseline risk of breast cancer (which increases with age but is low in women under 40 years of age), the length of time she takes the combined pill and especially the age at which she stops taking it. The manufacturers' SPCs include data derived from the large meta-analysis of individual patient data published by the Collaborative Group on Hormonal Factors in Breast Cancer (1996). This found that the relative risk of having breast cancer diagnosed in current users of the combined pill was 1.24 (95% confidence interval [CI] 1.15 to 1.33); 1 to 4 years after stopping it was 1.16 (95% CI 1.08

to 1.23); 5 to 9 years after stopping it was 1.07 (95% CI 1.02 to 1.13) and 10 or more years after stopping use it was 1.01 (95% CI 0.96 to 1.05, not statistically significant). The cancers diagnosed in women who had used the combined pill were less advanced clinically than those diagnosed in women who had never used it. Healthcare professionals can give an estimate of the risk of breast cancer for the individual woman taking into account her particular clinical circumstances.

Data on contraceptive efficacy was taken from NICE Clinical Knowledge Summaries (accessed July 2017).

Information on effects of contraceptives on menstrual bleeding was taken from manufacturers' SPCs. The Family Planning Association website (accessed July 2017) was used to provide a summary of common side effects of contraceptives.

Expert steering group

Rachel Brown, GP, Bristol

Dominic Byrne, Consultant Gynaecologist, Royal Cornwall Hospitals NHS Trust

Cathy Dean, Endometriosis Clinical Nurse Specialist, The Portland Hospital, London

Lynda Harrison, Patient Representative

Jeremy Hawe, Consultant Gynaecologist, Countess of Chester Hospital NHS Foundation Trust

Lyndsey Hogg, Patient Representative

Wendy-Rae Mitchell, Endometriosis Clinical Nurse Specialist, Royal Surrey County Hospital NHS Foundation Trust

Catherine Nestor, Endometriosis UK

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