Menopause and the perimenopausal woman – putting NICE guidance into practice

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Spring Symposium 4.3.17
Overview

- The perimenopause
- What contraception is suitable and when to stop
- Basic menopause management, HRT and overview of NICE guideline 2015
- Update on management of HMB in primary care (NICE 2007)
Aims: Perimenopause and Menopause

- To be confident giving contraceptive advice in the perimenopause
- To be confident in giving advice about the menopause
- Understand evidence-based strategies from NICE for menopause management
The Perimenopause
NICE Menopause guideline 2015

- **Perimenopause**: “The time in which a woman has irregular cycles of ovulation and menstruation leading up to menopause and continuing until 12 months after her final period.”

- The perimenopause is also known as the menopausal transition or climacteric.

- Give information about contraception to women who are in the perimenopausal and postmenopausal phase.
Reproductive Aging Workshop Staging System (STRAW): 7 stages of menopausal transition

<table>
<thead>
<tr>
<th>Stage</th>
<th>-5</th>
<th>-4</th>
<th>-3</th>
<th>-2</th>
<th>-1</th>
<th>+1</th>
<th>+2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Terminology</strong></td>
<td><strong>REPRODUCTIVE</strong></td>
<td><strong>MENOPAUSAL TRANSITION</strong></td>
<td><strong>POSTMENOPAUSE</strong></td>
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<tr>
<td><strong>Menarche</strong></td>
<td><strong>Final Menstrual Period</strong></td>
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<tr>
<td><strong>Menstrual cycle</strong></td>
<td>Variable to regular</td>
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<td>Regular</td>
<td>Variable cycle length (≥7-day difference from normal)</td>
<td>≥2 skipped cycles and an interval of amenorrhea ≥60 days</td>
<td>Amenorrhea for 12 months</td>
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<td><strong>Endocrine</strong></td>
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<td><strong>Symptoms</strong></td>
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</table>

What happens in the perimenopause?

- Decreased background fertility but still risk of pregnancy
- May be a time of increasing menstrual dysfunction
- Many women experience intermittent vasomotor symptoms
Contraception
Where to get advice

Contraception in the perimenopause

- No method is contra-indicated by age alone

BUT with age incidental medical conditions may develop that could impact on contraceptive choice.

- In 2008/2009, Office for National Statistics data for women aged 40–49 years who were using at least one method of contraception, the 4 most common methods were:
  - Sterilisation (male or female)
  - The pill
  - Male condoms
  - Intrauterine methods
Combined hormonal contraception (CHC) pills, patch, ring

- Can use until age 50
- Consider low dose 20mcg
- May help with BMD
- May help with menopausal symptoms (tricycling)
- Protects against endometrial, colon and ovarian cancer
- Can help with menstrual pain and bleeding
CHC

- There may be a very small increased risk of ischaemic stroke with CHC use.
- Women with cardiovascular disease, stroke or migraine with aura should be advised against the use of CHC.
- Hypertension may increase the risk of stroke and MI in those using CHC.
- There may be a small additional risk of breast cancer with CHC.
Progestogen Only Methods (POM)

- Includes pills, injection, implant and IUS
- Overall evidence is reassuring for breast ca risk
- May help with dysmenorrhoea
- Irregular bleeding is common
- No increase risk of stroke or MI, and little or no increase in VTE risk
POM – specific considerations

- LNG-IUS can be used for HMB
- DMPA causes a reversible small reduction in BMD – no maximum age as long as risk assessed (review every 2 years)
- Caution when prescribing DMPA to women with cardiovascular risk factors due to the effects of progestogens on lipids
Non-hormonal contraception

- Cu-IUD - Women should be informed that spotting, heavier or prolonged bleeding and pain are common in the first 3–6 months
- Male condoms and female condoms are, respectively, up to 98% and 95% effective
- Diaphragm and caps are, respectively, 92% and 96% effective (with spermicide)
# When to Stop Contraception?

<table>
<thead>
<tr>
<th>Contraceptive Method</th>
<th>Advice on Stopping Contraception</th>
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<tbody>
<tr>
<td></td>
<td><strong>Age &lt;50 years</strong></td>
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<tr>
<td>Non-hormonal</td>
<td>Stop contraception after 2 years of amenorrhoea</td>
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<tr>
<td>CHC</td>
<td>Can be continued up to age 50 years&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>DMPA</td>
<td>Can be continued up to age 50 years&lt;sup&gt;a&lt;/sup&gt;</td>
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<tr>
<td></td>
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<td></td>
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<tr>
<td>Implant, POP, LNG-IUS</td>
<td>Can be continued to age 50 years or longer&lt;sup&gt;a&lt;/sup&gt;</td>
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</table>
CAN I GET BIRTH CONTROL PILLS HERE?

SURE, BUT DO YOU HAVE A PRESCRIPTION FROM YOUR CONGRESSMAN?
Menopause: diagnosis and management

NICE guideline
Published: 12 November 2015
nice.org.uk/guidance/ng23
Definition of Menopause

“The cessation of the menstrual cycle”

- It is caused by ovarian failure, and is usually a gradual process
- The average age in the UK is 51
- 1/100 women will have premature ovarian insufficiency with a menopause < age 40
Diagnosis – NICE 2015

Diagnose the following without laboratory tests in otherwise healthy women aged over 45 years with menopausal symptoms:

- **perimenopause** based on vasomotor symptoms and irregular periods

- **menopause** in women who have not had a period for at least 12 months and are not using hormonal contraception

- **menopause** based on symptoms in women without a uterus.
When to use FSH- NICE 2015

Consider using a FSH test to diagnose menopause only:

- in women aged 40 to 45 years with menopausal symptoms, including a change in their menstrual cycle

- in women aged under 40 years in whom menopause is suspected

FSRH guidelines - serial FSH 6 weeks apart may be useful in women using implant, IUS or POP for contraception to diagnose menopause
Symptoms

- Symptoms are due to oestrogen depletion and include:
  - Irregular periods (peri-menopause)
  - Hot flushes and night sweats
  - Mood changes, headaches
  - Memory and concentration loss
  - Vaginal dryness, a lack of interest in sex
  - Joint and muscle stiffness.
Symptoms

- 8 out of 10 women will experience some symptoms typically lasting 4 years
- Symptoms may last up to 12 years in 10% of women
- Quality of life may be severely affected.
- Consider long term effects of menopause eg. cardiovascular health and bones (osteoporosis)
Assessment

- Assess her symptoms and their severity.
- Assess her risk of cardiovascular disease (CVD)
- Assess her risk of osteoporosis
- Discuss the woman's expectations
- Investigations and examinations are not routinely indicated

consider if VTE, breast ca, gynae path…
Treatment for menopausal symptoms NICE 2015

Women should be given information on all available treatment options

- Hormonal, for example hormone replacement therapy (HRT)
- Non-hormonal, for example clonidine
- Non-pharmaceutical, for example cognitive behavioural therapy (CBT).
Treatment for short term symptoms

NICE 2015

- Vasomotor and symptoms of low mood may benefit from HRT
  - oestrogen and progestogen to women with a uterus
  - oestrogen alone to women without a uterus.

- Uncertainties about isoflavanes and black cohosh for vasomotor symptoms

- HRT and CBT for low mood

- Testosterone for low sexual desire

- Vaginal oestrogens for urogenital atrophy

- St Johns wort may help where oestrogen is Contra- indicated
Advice and Management
NICE 2015

- Women should be given information about the menopause, symptoms and all treatment options with risks.
- If HRT is commenced it should be reviewed at 3 months and then at least annually.
- Women should be referred if there are contra-indications to HRT or uncertainties as to which treatments will be of benefit.
- Consider lifestyle changes and interventions with general health benefits.
- Keep up to date with National Screening Programmes.
Starting HRT

- Oestrogen relieves symptoms
- HRT will be Oestrogen only (no uterus) or with a progestogen (uterus present)
- Can be continuous (post menopausal) or sequential (perimenopausal) with withdrawal bleed
- Unscheduled bleeding is common side effect in the first 3 months for women with a uterus
- Choose preparations to suit women’s individual needs balance with risks (oral, transdermal, Oe gel, IUS)
Long Term Risks of HRT - VTE

- the risk of venous thromboembolism (VTE) is increased by oral HRT compared with baseline population risk

- the risk of VTE associated with HRT is greater for oral than transdermal preparations

- the risk associated with transdermal HRT given at standard therapeutic doses is no greater than baseline population risk.

- **Consider transdermal for women at high risk of VTE**
Long Term Risks of HRT – Cardiovascular Disease

- HRT does not increase cardiovascular disease risk when started in women aged under 60 years.
- Does not affect the risk of dying from cardiovascular disease.
- The baseline risk of coronary heart disease and stroke for women around menopausal age varies from one woman to another according to the presence of cardiovascular risk factors.
- HRT with oestrogen alone is associated with no, or reduced, risk of coronary heart disease.
- HRT with oestrogen and progestogen is associated with little or no increase in the risk of coronary heart disease.
- Taking oral (but not transdermal) oestrogen is associated with a small increase in the risk of stroke.
<table>
<thead>
<tr>
<th></th>
<th>Current HRT users</th>
<th>Treatment duration &lt;5 years</th>
<th>Treatment duration 5–10 years</th>
<th>&gt;5 years since stopping treatment</th>
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<tbody>
<tr>
<td><strong>Women on oestrogen alone</strong></td>
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<td>RCT estimate²</td>
<td>6 fewer (-10 to 1)</td>
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<td>No available data</td>
<td>6 fewer (-9 to -2)</td>
</tr>
<tr>
<td>Observational estimate³</td>
<td>6 fewer (-9 to -3)</td>
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<td>No available data</td>
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<tr>
<td><strong>Women on oestrogen + progestogen</strong></td>
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<tr>
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<td>No available data</td>
<td>4 more (-1 to 11)</td>
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<tr>
<td>Observational estimate³</td>
<td>No available data</td>
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</table>
Table 2 Absolute rates of stroke for different types of HRT compared with no HRT (or placebo), different durations of HRT use and time since stopping HRT for menopausal women

<table>
<thead>
<tr>
<th></th>
<th>Difference in stroke incidence per 1000 menopausal women over 7.5 years (95% confidence interval) (baseline population risk in the UK over 7.5 years: 11.3 per 1000)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Current HRT users</td>
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<tr>
<td>Women on oestrogen alone</td>
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<td>Observational estimate$^3$</td>
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<tr>
<td>Women on oestrogen + progestogen</td>
<td>RCT estimate$^2$</td>
</tr>
<tr>
<td></td>
<td>Observational estimate$^3$</td>
</tr>
</tbody>
</table>
Long Term Risks of HRT – Breast Cancer

- the baseline risk of breast cancer for women around menopausal age varies from one woman to another according to the presence of underlying risk factors
- HRT with oestrogen alone is associated with little or no change in the risk of breast cancer
- HRT with oestrogen and progestogen can be associated with an increase in the risk of breast cancer
- any increase in the risk of breast cancer is related to treatment duration and reduces after stopping HRT.
<table>
<thead>
<tr>
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<tr>
<td>RCT estimate&lt;sup&gt;2&lt;/sup&gt;</td>
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<td>No available data</td>
<td>No available data</td>
<td>5 fewer (-11 to 2)</td>
</tr>
<tr>
<td>Observational estimate&lt;sup&gt;3&lt;/sup&gt;</td>
<td>6 more (1 to 12)&lt;sup&gt;4&lt;/sup&gt;</td>
<td>4 more (1 to 9)</td>
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<td>5 fewer (-9 to -1)</td>
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<tr>
<td><strong>Women on oestrogen + progestogen</strong></td>
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<td>Observational estimate&lt;sup&gt;3&lt;/sup&gt;</td>
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<td>12 more (6 to 19)</td>
<td>21 more (9 to 37)</td>
<td>9 fewer (-16 to 13)&lt;sup&gt;5&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Table 3 Absolute rates of breast cancer for different types of HRT compared with no HRT (or placebo), different durations of HRT use and time since stopping HRT for menopausal women.

1. Baseline population risk in the UK over 7.5 years: 22.48 per 1000.
2. RCT: Randomized Controlled Trial.
3. Observational: Observational Study.
4. Estimate range: 1 to 12.
5. Estimate range: 14 to 20.
Other benefits of HRT - Osteoporosis

- The risk of fragility fracture is decreased while taking HRT.
- The benefit is maintained during treatment but decreases once treatment stops.
- The benefit may continue for longer in women who take HRT for longer.
The Mirena® IUS for endometrial protection

- The Mirena® IUS is licensed for protection from endometrial hyperplasia during oestrogen replacement therapy, for up to 4 years (SmPC)
- FSRH – can be used for up to 5 years (out of license)
- Mirena® provides targeted delivery of levonorgestrel directly to the endometrium
- With Mirena® in situ, menopausal women have the freedom to choose the type, route of administration and dose of oestrogen most appropriate to their needs, preferences or lifestyles
Key points

- All methods of contraception can be used in the peri-menopause

- Individualise and adapt treatment to a women’s changing symptoms and review risks

- Evidence based recommendations from NICE around HRT prescribing and use

- Useful tables in BNF (risks) and MIMS (treatments)

- Less commissioning of specialist services means most advice and prescribing will be from primary care
Case 1

- Vera age 49 suffers with migraines and is taking the POP (amenorrhoea), she is having severe vasomotor symptoms.

- would you discuss HRT?

- does she need contraception?

- what would you suggest?
Case 1 - Vera

- Discuss all management options for vasomotor symptoms
- Consider using FSH to establish menopause
- Migraines do not contraindicate HRT
- Will need a combined preparation
- POP cannot be used as progestogen arm but could be continued if contraception required
Case 2

- Daphne age 51 has a mirena fitted at age 45 (amenorrhoea), would like it removed as she thinks she is going through the change (night sweats and vaginal dryness)

- Do you remove it?

- what are the options for her symptoms?
Case 2 - Daphne

- Best to do FSH prior to removal – will need to stay in 1 year after FSH confirms menopausal
- Do nothing, what does Daphne want
- Local treatment for vaginal dryness
- Short trial of systemic HRT, mirena will need changing if using as progestogen arm.
Questions?

THE GOOD NEWS
IS NO MORE
PERIODS.
Overview - HMB

- Definition and impact of problem
- Causes
- Diagnosis and management
- Contraception and HMB
- Other treatment options
Aim of session

- Be clear as to what HMB means and the impact on women’s lives
- Be confident in understanding treatment options and where contraception may have a dual purpose
- Be confident in giving evidence based advice and when to refer on
Definition HMB:
NICE HMB guidance(CG44) 2007

“Excessive menstrual blood loss which interferes with a woman’s physical, social, emotional and/or material quality of life. It can occur alone or in combination with other symptoms.”

Replaced physical definitions for MBL used in research settings
How common is HMB?

- Studies show that between 4% and 51.6% of women experience HMB$^1$
- 1:20 women between ages 30-49 consult their GP annually with HMB$^2$
- HMB accounts for 12% of all gynaecological referrals from primary care$^3$
- 30,000 women undergo surgical treatment each year for HMB$^4$

1. NICE Guidance HMB CG44, 2007
Why is HMB important?

- Negative impact on QOL
- Negative effect on social life and relationships
- Time of work, school reduced productivity
Causes

50% will be Dysfunctional Uterine Bleeding with no cause found

- Hypothyroidism
- Coagulopathy
- Diabetes
- Obesity

Local
- Polyps 10%
- Carcinoma 1%
- Fibroids 30%
- Adenomyosis

Systemic

Treatment related
- IUD
- Anti-coagulants
## Endometrial Cancer

**Symptoms suggestive of pathology**
- Pelvic pain
- Pressure symptoms
- Post coital bleeding
- Intermenstrual bleeding

**Risk factors for endometrial cancer**
- High BMI
- Unopposed oestrogen
- Drugs: eg. Tamoxifen
- Genetic factors
- Smoking
- Age
History and Examination

- Menstrual History:
  - Life impact
  - Physical impact
  - Amount of bleeding

- Risk factors and symptoms suggestive of pathology

- Medical history

- Physical examination: speculum and bimanual
Investigations

- A full blood count is recommended for all women with heavy menstrual bleeding

- Additional laboratory tests may be indicated in the following situations:
  - Clinical findings suggestive of thyroid disease
  - A history of menstrual bleeding since menarche or a personal or family history of abnormal bleeding
A number of risk indicators for endometrial cancer have been identified. Including IMB, PCB, pelvic pressure and pain.

Presence of one or more of these symptoms should prompt further investigation:
- USS scan +/-
- Endometrial biopsy
NICE care pathway for HMB

1. Adapted from NICE Heavy Menstrual Bleeding Clinical Guideline 44; 2007
Where does contraception fit?
Pharmaceutical Treatment

- “Pharmaceutical treatment should be considered where no structural or histological abnormality is present, or for fibroids <3 cm in diameter which are causing no distortion of the uterine cavity.

- The healthcare professional should determine whether hormonal contraception is acceptable to the woman before recommending treatment (eg. she may wish to conceive). “

HMB NICE 2007
Where does contraception fit? Pharmaceutical Treatment

If history and investigations indicate that pharmaceutical treatment is appropriate and either hormonal or non-hormonal treatments are acceptable, treatments should be considered in the following order:

- LNG-IUS
- Other primary care medical management:
  - tranexamic acid or NSAIDs or **combined oral contraceptives**
  - norethisterone (15 mg) daily from days 5 to 26 of the menstrual cycle, or **injected long-acting progestogens**
The IUS* for HMB

**PROs**

- Contraceptive
- Prevents endometrial proliferation
- Cost effective if used for 12 months
- Bleeding can be reduced by 95%
- 5 year use

**Cons**

- Side effects: irregular bleeding, breast tenderness, headaches, acne, amenorrhoea
- Risks of procedure – infection, perforation,

First choice pharmaceutical treatment for HMB providing long-term (>12 months) use is anticipated.

*Only Mirena® IUS is licensed for HMB*
Bleeding patterns whilst using Mirena® for HMB

Amenorrhoea
- Proportion of reference periods (%): 1.7, 8.8, 17.6, 30.0

Infrequent B/S
- Proportion of reference periods (%): 21.6, 23.8, 27.1, 22.9

Frequent B/S
- Proportion of reference periods (%): 11.2, 6.3, 4.7, 7.1

Prolonged B/S
- Proportion of reference periods (%): 55.6, 25.0, 16.5, 2.9

B/S = Bleeding/Spotting

Mirena®, Jaydess® & Levosert®
A comparison¹⁻⁵

<table>
<thead>
<tr>
<th></th>
<th>Jaydess</th>
<th>Mirena</th>
<th>Levosert</th>
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<tr>
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<td><strong>Initial release rate</strong></td>
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<td></td>
<td>HMB for 5 years</td>
<td>Endometrial protection during HRT for 4 years</td>
<td>HMB for 3 years</td>
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<td><strong>Price</strong></td>
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<td><strong>Contraception Cost per annum</strong></td>
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<td><strong>HMB Cost per annum</strong></td>
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<tr>
<td><strong>Endometrial protection Cost per annum,</strong></td>
<td>Not licensed for HMB</td>
<td></td>
<td>Not licensed for endometrial protection</td>
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</table>

⁴. Mithra promotional material 2014.
⁵. MIMS online. [www.mims.co.uk](http://www.mims.co.uk) Accessed 11.05.15.
Hormonal treatment – Combined oral contraceptives

**PROS**
- Provides contraception
- Can improve dysmenorrhoea
- Can regulate cycle
- Reduces bleeding by 43%
- Other benefits of COC: protective for bowel, endometrial and ovarian ca

**CONS**
- Side effects: mood changes, headaches, nausea, fluid retention, breast tenderness, DVT, stroke, MI
- Affects fertility
LNG-IUS vs COC in HMB treatment\(^1\)

Randomised to LNG-IUS (e.g. Mirena) or 30 mcg COC LNG, monophasic COC over 12 months

Results taken over a 12 month period. Data captured by Alkaline Hematin

\(^1\) Shabaan MM et al. Contraception 2011;83:48-54
Hormonal treatment – Injectable progestogen

**PROS**
- Contraceptive
- Bleeding can stop completely (70% after 1 year use)
- 12 weekly IM/SC injection

**CONS**
- Delay in return to fertility
- Side effects: weight gain; irregular bleeding, amenorrhoea, PMS type symptoms, small reversible loss in BMD
Hormonal treatment – oral progestogen

**PROS**
- Can regulate cycle
- Take day 5 to 26
- Bleeding reduced by up to 83% in the long term

**CONS**
- Not contraceptive
- Side effects: weight gain, bloating, breast tenderness, headaches, acne and depression

?? Not licensed
# Non hormonal treatment – tranexamic acid

## PROS
- No impact on fertility
- Anti-fibrinolytic
- Generally well tolerated
- Cyclical use (day 1-4)
- Bleeding reduced by up to 58%

## CONS
- Not contraceptive
- Does not reduce dysmenorrhoea
- Does not regulate cycle
- Side effects (less common): headaches, diarrhoea, infrequent
## Non hormonal treatment - NSAIDS

<table>
<thead>
<tr>
<th>PROS</th>
<th>CONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Reduces prostaglandin production</td>
<td>- Not contraceptive</td>
</tr>
<tr>
<td>- Improves dysmenorrhoea</td>
<td>- Does not regulate cycle</td>
</tr>
<tr>
<td>- No impact on fertility</td>
<td>- Cannot use with coagulation disorders</td>
</tr>
<tr>
<td>- Cyclical use (until bleeding controlled)</td>
<td>- Effect with fibroids uncertain</td>
</tr>
<tr>
<td>- Bleeding reduced by up to 49%</td>
<td>- Side effects: indigestion, diarrhoea, worsening of asthma, peptic ulcers</td>
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</tbody>
</table>

- NSAIDS: Non Steroidal Anti-Inflammatory Drugs
When to investigate further or refer?\(^1\)

- Age >45
- Endometrial risk factors
- Additional symptoms/signs
- Abnormal ultrasound scanning (USS) findings
- Failure of treatment

\(^1\) NICE Heavy Menstrual Bleeding Clinical Guideline 44; 2007
Key Points

- Individualise treatment to women’s needs
- Beware red flag symptoms
- Can make a real difference to quality of life with relatively simple treatments
- Most cases can be managed in primary care
- Clear stepwise evidence based approach
Case 1

- Miranda age 40 has completed her family, 2 children aged 3 and 6 months old
- Wants to be sterilised/hysterectomy
- Hates her periods
- Feels tired and lethargic

What would you suggest?
Case 1 - Miranda

- Thorough history for any red flags
- FBC and exam
- IUS would be as effective as sterilisation and prevent risks of hysterectomy
- Can give information about endometrial ablation if not keen on hormonal management
Case 1

- Alice 48 year old housewife with HMB
- Has occasional IMB
- using a copper coil for contraception due for change
- BMI 40, type 2 DM borderline BP but otherwise well

what would you recommend?
Case 1 - Alice

- Concerns about risk factors for endometrial ca and IMB
- Needs endometrial sampling
- Likely to need gynae referral
- IUS may be a good solution once pathology excluded
Questions?
Useful Links

- Heavy Menstrual Bleeding, clinical guideline 44, July 2007
  http://www.nice.org.uk/guidance/cg44/evidence/full-guideline-195071293

- Menopause diagnosis and management, NICE guideline 23, November 2015
  http://www.nice.org.uk/guidance/ng23/evidence/full-guideline-559549261

- FSRH guidance. Contraception for Women Aged Over 40 Years, July 2010

- MIMS HRT table
  http://www.mims.co.uk/hormone-replacement-therapy-hrt/womens-health/article/882443