Hormonal contraception and menopause management: a 2021 update

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Declaration of Interest

In my role as Medical Director of Family Planning NSW I have attended advisory committees for Bayer, Organon and Besins but have not received personal remuneration for these services

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Hormonal contraception and menopause management

- Hormonal contraceptive choices
  - 19.5mg levonorgestrel IUD
  - 4 mg drospirenone progestogen-only pill
- Case Studies:
  - Women living with HIV
  - Trans and gender diverse
  - Perimenopause
- Menopause Management
  - Menopausal Hormone Therapy
  - Topical vaginal estrogen
  - Non-hormonal approaches

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What's in the 2021 hormonal contraceptive toolkit?

Progestogen-only
OR
Estrogen + Progestogen

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Contraceptive choice:

effectiveness

risks and side-effects

medical eligibility
drug interactions

personal preference

discretion (reproductive coercion)

non-contraceptive benefits

reversibility
future fertility plans

provider bias

religious beliefs

access and costs

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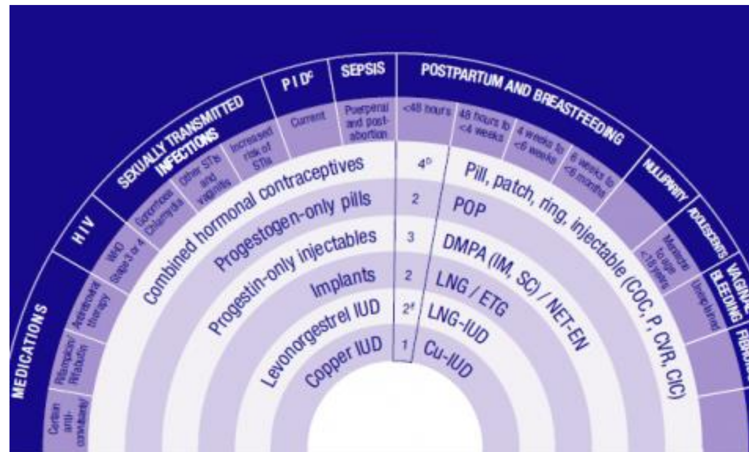
Medical Eligibility Criteria for the safe use of contraception

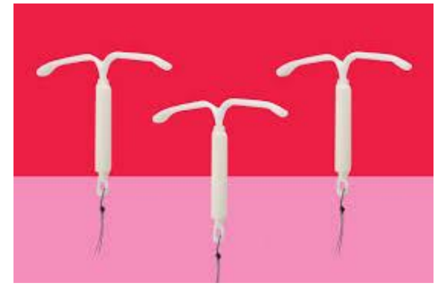
www.fsrh.org/ukmec/

Condition CHC	UKMEC
Hypertension	
a) Adequately controlled hypertension	3
b) Consistently elevated blood pressure levels (properly taken measurements)	
(i) Systolic >140–159 mmHg or diastolic >90–99 mmHg	3
(ii) Systolic ≥160 mmHg or diastolic ≥100 mmHg	4
c) Vascular disease	4
History of high blood pressure during pregnancy (where current blood pressure is measurable and normal)	2

UKMEC	Definition of category
Category 1	A condition for which there is no restriction for the use of the method.
Category 2	A condition where the advantages of using the method generally outweigh the theoretical or proven risks.
Category 3	A condition where the theoretical or proven risks usually outweigh the advantages of using the method. The provision of a method requires expert clinical judgement and/or referral to a specialist contraceptive provider, since use of the method is not usually recommended unless other more appropriate methods are not available or not acceptable.
Category 4	A condition which represents an unacceptable health risk if the method is used.



Hormonal IUDs: 52mg levonorgestrel IUD (Mirena)



- **99.8% effective; 5-years (extended use 45 + years); PBS listed**

- No drug interactions; No BMD impact
- Licensed for heavy menstrual bleeding
- Reduces menstrual pain/ endometriosis pain
- Licensed for endometrial protection as part of menopausal hormone therapy (MHT)

Risks of:

- insertion-related complications
- hormonal side-effects

Kyleena: lower hormone dose and a smaller frame

- **PBS listed 19.5mg LNG IUD**
- 99.7% effective; 5-years
- Frame size (mm) 28 W x 30 H (Mirena 32 W x 32 H)
- Insertion tube diameter: 3.8 mm (Mirena 4.4mm)

- Possibly more bleeding/spotting days and lower rates of amenorrhoea (19% vs 24% at 3 years)
- Similar risks and side effects to Mirena

  - **NOT licensed for management of HMB or endometrial protection as part of MHT; NO extended use from 45 years**

Nelson A. et al, Obstet Gynecol 2013; Gemzell-Danielsson K. et al, Fertil Ster 2012

Does size matter?

Kyleena vs **Mirena**

- Insertion ***easy*** in 94% vs 86% ($p < 0.001$)
- Pain ***mild or none*** in 72% vs 58% ($p<0.001$)

- Pain ratings with Kyleena insertion - 19% none; 45% mild; 27% moderate; 8% severe

June 2021

"Insertion and removal of IUDs can be painful and not being prepared can make it all worse"

ABC

Offer analgesic options……

Nelson A. et al, Obstet Gynecol 2013; Gemzell-Danielsson K. et al, Fertil Ster 2012

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Menstrual cups and IUDs: care needed

Van Eijk AM. et al. Menstrual cup use, leakage, acceptability, safety, and availability: a systematic review and meta-analysis. The Lancet Public Health; Aug 2019.

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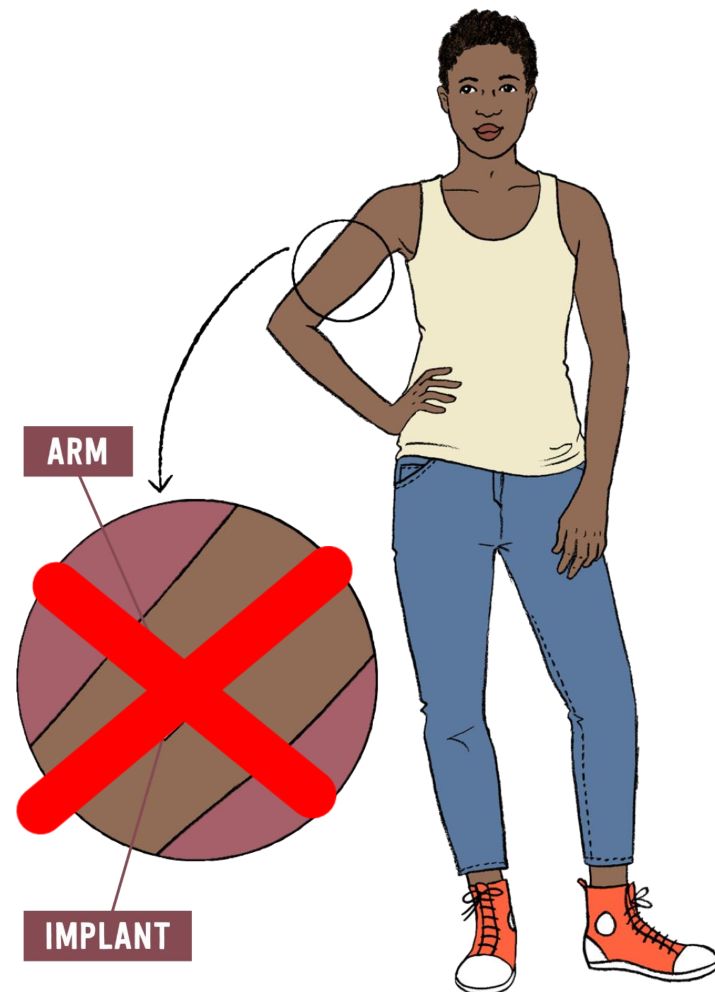
Contraceptive implants

- PBS listed etonogestrel implant (Implanon NXT)
- 99.95% effective; lasts 3-years
- No impact on BMD

- Drug-drug interactions
- Hormonal side-effects including unscheduled bleeding



Guidance for management of troublesome vaginal bleeding with progestogen-only long-acting reversible contraception (LARC)

Initial consultation

- **Provide accurate information about expected bleeding patterns, emphasising that troublesome bleeding is likely to improve with time:**

Implant: 1/5 amenorrhoea, 3/5 infrequent, irregular bleeding, 1/5 frequent or prolonged bleeding; approximately 1/2 with frequent or prolonged bleeding will improve after three months.

Hormonal IUD: frequent spotting/bleeding common in first 3-5 months; either

Management of troubl

1. **Exclude other causes**

Pregnancy, sexually transmitted infe
inducing medications (implant only)

2. **If no suspicion of another caus**

Reassure this is 'normal' and not ha

3. **Advise medication manageme**

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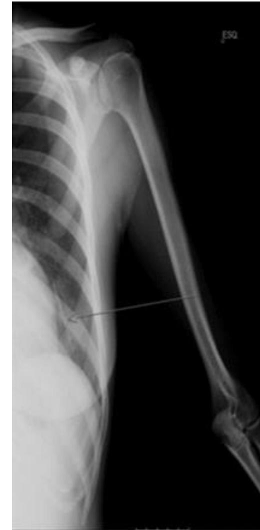
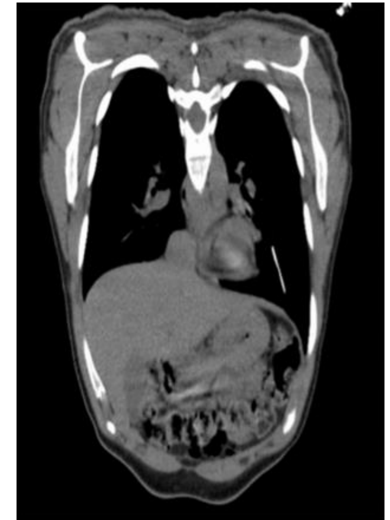
2020 change in placement guidance

- Place over the triceps 8-10cm from medical epicondyle
- **AVOID the sulcus**

- Rare reports of implants reaching the lung via the pulmonary artery
- Absolute risk very low (1.3 per million)





https://www.gov.uk/drug-safety-update/nexplanon-etonogestrel-contraceptive-implants-reports-of-device-in-vasculature-and-lung

Depot medroxyprogesterone

- IM injection every 12 weeks
- Efficacy:
  - 99.8% (perfect use) 96% (typical use)
- Increasing rates of amenorrhoea
- No drug interactions
- Discreet and private
  - -ve impact on BMD
  - not 1st line under 18 or 45 years +

➢ **Subcutaneous self-injectable (Sayana Press) available in many countries……**

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Combined hormonal contraceptives

- Efficacy: 99.5% perfect use; 93% typical use
- Benefits for heavy menstrual bleeding and acne
- May improve perimenopausal vasomotor symptoms
- Overall +ve effect on bone density
- Reduced ovarian, endometrial cancer risks
- **Extended/continuous cycling without hormone-free breaks**

BUT

- Can't be used if CIs to estrogen
- Increased risk of VTE, ischaemic stroke and MI
- Drug interactions
- Diarrhoea and vomiting reduce COC efficacy

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Combined oral contraceptives: available options

- PBS and non-PBS listed options
- Until 2010 all COCs contained ethinyl estradiol (EE)
  - COCs with ≤30µg EE + LNG 1st line
  - 20mcg EE COCs: safety benefits but more breakthrough bleeding
  - **No place for 50mcg EE COCs**
  - COCs with estradiol (Zoely; Qlaira) may be safer than EE pills but evidence pending
- Other progestogens can be used for non contraceptive benefits

……understand licensing of cyproterone pills

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Vaginal rings: increasing interest!

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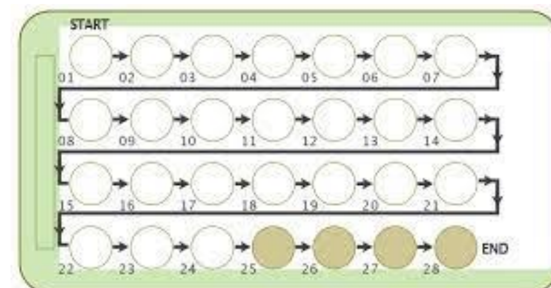
Progestogen-only pills

- Traditional POPs: LNG (30mcg); NET (350mcg)
- PBS listed
  - thicken cervical mucus
    - narrow 3-hour missed pill window
- **A new drospirenone 4mg 24/4 POP (Slinda) available from August 2021**
  - inhibits ovulation
    - 24-hour missed pill window
  - > 99% efficacy
  - good safety profile; no increased VTE risk
  - 4-day hormone-free break designed to reduce unscheduled bleeding; 45% amenorrhoeic by cycle 9



Palacios S et al. Acta Obstet Gynecol Scand. 2019; 98(12)

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Emergency Contraception

Emergency contraceptive pills inhibit or prevent ovulation

- LNG ECPs – licenced up to 72 h
- Ulipristal acetate (EllaOne) – licensed up to 120 h
- Drug-drug interactions (double dose LNG ECP)

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Abigail, 32 years, is living with HIV

- New relationship 2 months; partner HIV - ve
- On Triumeq (Abacavir 600mg + Lamivudine 300mg + Dolutegravir 50mg)
- Undetectable viral load
- Using condoms; interested in a longer acting method
- Medically well; nil other medications
- Never smoker; normotensive; BMI 24 Kg/m^2

What advice can we give Abigail?

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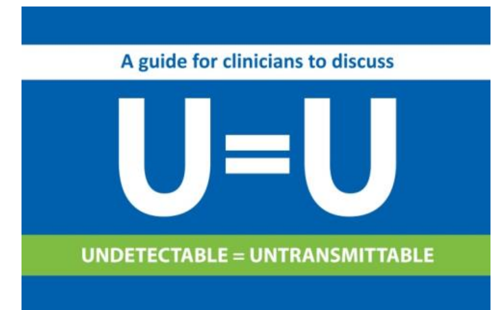
Contraception for women living with HIV

WLHIV require information about all methods

- Same considerations as for all individuals
- Preconception care and pregnancy planning important



- Effect on disease progression (CD4 count, mortality)
- Effect on bone density
- Other chronic medical conditions
- Effect on horizontal transmission
  - partner status?
  - on suppressive therapy?
- Drug interactions

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Pharmacology of ART and hormonal contraception

HIV DRUG INTERACTIONS

UNIVERSITY OF LIVERPOOL

- **No drug-drug interactions with 1st line ART prescribed in Australia and hormonal contraceptives**
- Consider drug-drug interactions with efavirenz, nevirapine or a boosted protease inhibitor
  - Interactions with CHCs, POPs, implants and ECPs
  - Choices include DMPA, LNG IUDs (evidence lacking for Kyleena), copper IUDs

Abigail is medically eligible for all longer acting contraceptives…..

Hormonal contraceptive choices and HIV: depot medroxyprogesterone injectable

- No interactions with any ART
- Induces hypoestrogenic state:
    - bone density loss (impact on fracture risk less clear)
        - vaginal atrophy

HIV incidence among women using intramuscular DMPA, a copper IUD, or a levonorgestrel implant for contraception: a randomised, multicentre, open-label trial. The Lancet Vol 394 July 27, 2019

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Hormonal contraceptive options and HIV: LNG IUDs

- No increased risk of post-insertion infection or perforation
- Safe to insert in WLHIV (MEC 3 if CD4 count < 200)
- HIV diagnosed during use: IUD can stay in place

- No evidence of effect on disease progression/increased viral shedding or transmission
- No impact on bone density
- No interactions with any ART

Abigail chooses a 52mg LNG IUD

Hannaford P, et al Copper intrauterine device use and HIV acquisition in women: a systematic review. BMJ SRH 2020 (46)

Charlie, 29, requests contraceptive advice

- Identifies as male; assigned female at birth
- Ex-smoker, never drinks alcohol
- Testosterone therapy for 4 years
- Bilateral mastectomy 3 years ago
- Multiple sexual partners including cisgender men

What advice can we give Charlie?

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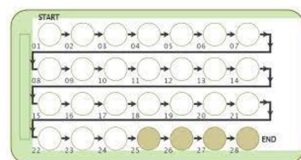
Transgender individuals assigned female at birth: specific considerations

- No restriction on any method on account of current gender identity
- Testosterone therapy can cause amenorrhoea but does not provide adequate contraception
- Pregnancy absolute CI to T therapy

Consider effect of method on:

- menstrual bleeding and desire for amenorrhoea
- counteractive effect of E-containing methods on T therapy



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Soraya, 48, is experiencing heavy periods

- Long term relationship
- Using condoms
- Medically well; BMI 27 Kg/m^2
- Increasingly irregular and heavy periods and mood swings

What do you advise Soraya?

➢ **You organise a transvaginal ultrasound!**

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Perimenopausal contraception: specific considerations

- **Perimenopause:** usually lasts 4-8 years
- **Decline in fertility:** but contraception still needed
- **Age-related** increased risks of cardiovascular disease, obesity, breast, ovarian and endometrial cancers may limit choices
- **Hormonal fluctuations:** irregular/heavy menses, hot flushes & night sweats, mood and sleep disturbance
- **Lower BMD** and higher risk of fractures with accelerated bone mass loss can impact choice

FSRH Clinical Guideline: Contraception for Women Aged over 40 Years (September 2019) - Faculty of Sexual and Reproductive Healthcare

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Perimenopausal choices: combined hormonal contraceptives

- Ensure medical eligibility
- Consider risks and benefits
- Benefits for heavy menstrual bleeding
- May improve vasomotor symptoms
- Offer extended or continuous use
- Overall +ve effect on BMD
  - important choice for premature ovarian insufficiency

- **Advise switching to a P-only or non hormonal method at 50 years of age**
  - **Depo injectables not recommended > 50 years**

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PO methods at the perimenopause

LNG IUDs:

- Mirena and Kyleena both reduce blood loss

Only Mirena:

- Licensed for HMB
- Extended use for contraception if inserted at 45 years +
- Provides endometrial protection as part of MHT (maximum use 5 years)

Soraya chooses a Mirena

POPs and implants:

- BMD neutral
- Can be used alongside MHT but CAN'T be used to protect endometrium

➢ **Stopping contraception at menopause …….**

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Contraception at Age 50 +

Using POP, implant or LNG IUD

Using CHC or DMPA

Using copper IUD or barriers

- Continue to 55 or assess contraceptive needs if amenorrhoeic for 12 m + after 50 with single FSH level:
  - > 30 IU/L - stop after 12 m
  - 30 IU/L or less - continue and repeat in 12 m

- Stop once amenorrhoeic for 12 m after 50

Note a copper IUD inserted age 40+ can be used until menopause

June, 53, presents with hot flushes and night sweats

- Relationship 4 years
- G2P2
- Well controlled HT; BMI 24 Kg/m^2
- Final menstrual period 2 years ago
- Hot flushes and night sweats past year interfering with work and relationship

What do you advise June?

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Menopause: consequences of decline in estrogen

- **Menopause:** final menstrual period (average age 51)
  - Early menopause: < 45 years
    - Premature ovarian insufficiency: < 40 years
      - Post-menopause: 12m after FMP
- **Vasomotor symptoms** can increase
  - mean time for flushes 8 years
  - 20% none; 60% mild; 20% severe; 10% into 60s and 70s
- Vaginal dryness with dyspareunia and UTIs
- Reduced sexual interest
- Joint pains, dry skin, acne, increased facial hair

- **Long term consequences**
  - Weight gain, CV disease, bone loss and osteoporosis

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Menopause: women living with HIV

- All the challenges faced by the general population **PLUS** the consequences of:
  - living longer with HIV & longer exposure to HIV treatments
  - co-morbidities
- Some evidence for younger age at menopause (48 vs 51 years)
  - **menopausal symptoms** may be more intense
  - **greater impact** on bone health and cardiovascular risks
  - **mental health** risks may be exacerbated
  - **greater challenges** in navigating optimal treatments….
- ART may decrease systemic MHT effectiveness; no evidence of effect of MHT on ART (evidence sparse)

Kaida A et al. Prevalence and correlates of early onset menopause among women living with HIV in Canada. Menopause 2019.

Menopause management: therapeutic approaches

- Goal is to relieve symptoms (and reduce osteoporosis risk)
- Systemic menopausal hormone therapy (MHT) is the most effective treatment for vasomotor symptoms (and sleep) and plays a role in management of osteoporosis
- Topical estrogen for genitourinary symptoms
- Non hormonal approaches: CIs to hormones/ personal preference

Menopausal Hormonal Therapy: General Principles

Scary Headlines from 2002

THE KINGSTON WHIG-STANDARD

NATIONAL WORLD

Hormone therapy does more harm than good: Study

By David Derbyshire
LONDON/The Daily Telegraph

HRT: heart attacks, cancer ...

Small Doses
PAUL TAYLOR

Menopausal Hormonal Therapy: General Principles

- **Initiate < 60 years** or within 10 years of menopause and have no CIs
- **Can continue** case by case beyond 60
- **Use lowest dose** to alleviate symptoms
  - Cyclical MHT (continuous E + cyclical P for 10 to14 days/month) within 12m of FMP to provide scheduled bleeding
  - Continuous MHT (continuous E+P) 12m+ FMP
- **E-only post hysterectomy**
- **Topical low-dose vaginal E preferred** when symptoms limited to vaginal dryness and dyspareunia

How to stop MHT….

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Contraindications to MHT

History of:
- TIAs, Stroke, MI
- VTE
- Breast and other hormone-dependent cancers
- High risk of breast cancer

Current:
- Uncontrolled HT
- Significant liver disease
- SLE
- Undiagnosed vaginal bleeding
- Porphyria cutanea tarda

Note migraine is not a contraindication

MHT: estrogens and progestogens

- **Estrogen: oral or transdermal patch or gel**
  - estradiol, conjugated estrogens (low, medium, high dose)

- **Progestogen: oral, transdermal, or Mirena IUD**
  - synthetic progestogens; micronised progesterone

- **Transdermal Estrogen preferred for WLHIV (UK NICE Guidelines)**
  - Combined E+P patch (cyclical or continuous) (Estalis)
  - Transdermal E patch or gel +/- oral P or Mirena IUD
  - Transdermal E alone post hysterectomy

MHT: Tibolone (Livial)

- **Estrogenic, androgenic and progestogenic actions**
- Generally used from 12 m after FMP
- Positively affects mood, QOL, sexual well being
- Useful if concurrent low libido
- Improves bone density; reduced impact on breast density

BreastScreen AUSTRALIA
A joint Australian, State and Territory Government Program

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Evaluating MHT benefits and harms

Benefits outweigh harms in healthy individuals < 60 years

Benefits and risks per 10 000 person years:

E+P:

- 44 fewer fractures; 6 fewer cases colorectal cancer
- 9 and 21 additional stroke and VTE cases respectively
- 9 additional cases breast cancer

E alone:

- 56 fewer fractures
- 11 additional cases each of stroke and VTE
- Breast cancer not significantly increased

Transdermal E confers less risk of VTE and stroke

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June chooses an estradiol + NET continuous patch (Estalis)

AUSTRALASIAN MENOPAUSE SOCIETY
NEW DIRECTIONS IN WOMEN'S HEALTH

Information Sheet

AMS Guide to Equivalent HRT Doses

This Information Sheet has been developed as a guideline only to approximately equivalent doses of the different HRT products available 1st October 2014.

The intention is to help physicians change their patients to higher or lower approximate doses of HRT if needing to tailor therapy, or remain within the same approximate dose if needing to change brands of HRT.
Products which are underlined are Australia only; products in *italics* are NZ only.
Products with an * meaning Private/non PBS script.

Oestrogen and progestogen combination HRT

Cyclical oestrogen & progestogen combinations
use these at peri-menopause or if less than 12 months amenorrhoea

Product	Presentation	Composition
Low Dose		
Femoston	tablet	1mg oestradiol/10mg dydrogesterone
Medium dose		
Trisequens*	tablet	1 and 2mg oestradiol/1mg norethisterone
Femoston	tablet	2mg oestradiol/10mg dydrogesterone
Estalis sequi 50/140	transdermal patch	50mcg 17 β oestradiol/140mcg norethisterone acetate (twice weekly application)
Estalis sequi 50/250 (same oestrogen, more progestogen than Estalis sequi 50/140)	transdermal patch	50mcg 17 β oestradiol/250mcg norethisterone acetate (twice weekly application)

Continuous oestrogen and progestogen combinations

should be used if 12 months since LMP or after 12 months cyclical HRT

Product	Presentation	Composition
Low dose		
Angeliq1/2*	tablet	1mg oestradiol/2mg drospirenone
Femoston-conti	tablet	1mg oestradiol/5mg dydrogesterone
Kliovance*	tablet	1mg oestradiol/0.5mg norethistrone
Livial*, Xyvion* (generally suitable for older women or at least 1 year post-menopause)	tablet	2.5mg tibolone
Medium dose		
Kliogest*	tablet	2mg oestradiol/1mg norethistrone
Premia 2.5 continous*	tablet	0.625mg conjugated equine oestrogens/2.5mg medroxyprogesterone acetate
Premia 5 continous* (same oestrogen, more progestogen than Premia 2.5 continuous)	tablet	0.625mg conjugated equine oestrogens/5mg medroxyprogesterone acetate
Estalis continuous 50/140	transdermal patch	50mcg 17 β oestradiol/140mcg norethisterone acetate (twice weekly application)
Estalis continuous 50/250 (same oestrogen, more progestogen than Estalis continuous 50/140	transdermal patch	50mcg 17 β oestradiol/250mcg norethisterone acetate (twice weekly application)

www.menopause.org.au

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Information Sheet

Oestrogen only therapy

only use these if patient has had a hysterectomy or in combination with a progestogen or Mirena if intact uterus

Product	Presentation	Composition
Low dose		
Estrofem*	tablet	1mg 17 β oestradiol
Progynova	tablet	1mg oestradiol valerate
Premarin*	tablet	0.3mg conjugated equine oestrogen
Climara 25	transdermal patch	25mcg/24hrs 17 β oestradiol (weekly application)
Estradot 25 or 37.5	transdermal patch	25 or 37.5mcg/24hrs 17β oestradiol (twice weekly application)
Estraderm 25 MX	transdermal patch	25mcg/24hrs 17β oestradiol (twice weekly application)
Medium dose		
Estrofem*, Zumenon	tablet	2mg 17β oestradiol
Progynova	tablet	2mg oestradiol valerate
Premarin*	tablet	0.625mg conjugated equine oestrogens
Climara 50	transdermal patch	50mcg/24hours 17β oestradiol (weekly application)
Estradot 50, Estraderm 50 MX	transdermal patch	50mcg/24 hours 17β oestradiol (twice weekly application)
Sandrena	gel	1mg oestradiol (daily application)
High dose		
Climara 75	transdermal patch	75mcg/24hours oestradiol (weekly application)
Estradot 75, Estradot 100	transdermal patch	75 or 100mcg/24 hours (twice weekly application)
Climara 100	transdermal patch	100mcg/24hours oestradiol (weekly application)
Estraderm 100 MX	transdermal patch	100mcg/24hours 17β oestradiol (twice weekly application)
Oestradiol implants - No longer available		
Oestrogen only vaginal therapy		
Product	Presentation	Composition
Ovestin	cream	1mg/g oestriol

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NEW DIRECTIONS IN WOMEN'S HEALTH

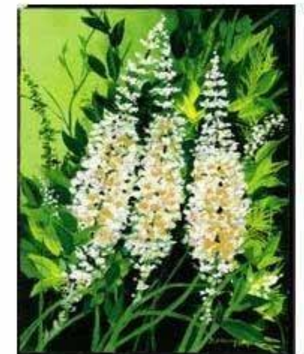
Non hormonal treatments for menopausal symptoms

- **RCTs show benefits for SNRIs or SSRIs**
- Venlafaxine and desvenlafaxine: improve vasomotor symptoms, sleep, mood and QOL
- Escitalopram: most effective SSRI for improving vasomotor symptoms, QOL and sleep with fewest AEs
  - Fluoxetine and paroxetine: may reduce effectiveness of tamoxifen

Gabapentin and Clonidine show benefits for hot flushes

Complementary therapies for hot flushes

- Phytoestrogens: long-term data lacking; potential safety concerns with breast cancer
- Herbal therapies: insufficient evidence
- Lifestyle/behaviour modifications mixed, limited or non-existent
- Placebo controlled trials show benefits for:
  - cognitive behavioural therapy
  - hypnosis
  - weight loss in overweight or obese individuals



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Genitourinary symptoms of menopause

Genital symptoms:

- dryness, burning, and irritation

Sexual symptoms:

- lack of lubrication, discomfort/pain, impaired function

Urinary symptoms:

- urgency, dysuria, recurrent UTI

- topical estradiol (Vagifem Low) or estriol cream (Ovestin)
  - underutilised!
  - no need for added progestogen
  - specialist review with breast cancer

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Bioidentical hormones: a word of warning….

- Compounded troches or creams containing E + P + T and more
- Can cost around $150 a month
- Concerns about dose consistency, purity, safety and efficacy
- Not approved by TGA; not recommended by IMS, AMS,NAMS
- US Endocrine Society Position Statement 2016:

"untested, unregulated and potentially dangerous & should not be prescribed"

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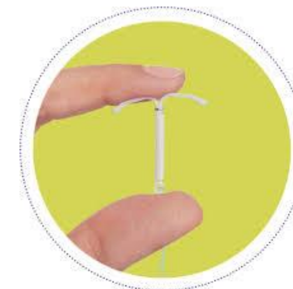
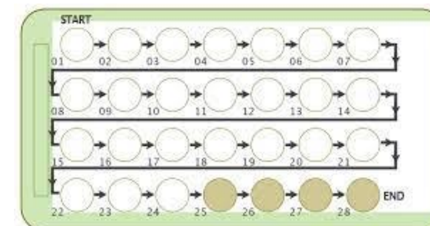
Take home messages





- Multiple factors influence contraceptive choice
  - 19.5mg smaller frame LNG IUD
  - 4mg DRSP 24/4 POP
- Menopausal hormone therapy
  - E-only after hysterectomy
  - E + P if uterus intact
- Transdermal therapy confers safety benefits over oral methods
  - Topical vaginal estrogen for genitourinary symptoms
- Non hormonal methods

family planning nsw
Reproductive & Sexual Health

Thank you

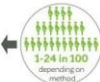
How effective is my contraceptive method?

In 1 year, what are my chances of getting pregnant?

>99% Set and forget

93-99% Works well if used perfectly every time

76-99% Less effective methods



Used perfectly – when the rules are followed perfectly EVERY time
Used typically – real life use where mistakes can sometimes happen (for example: forgetting a pill, condom not used correctly).
If you experience unwanted side-effects with your contraceptive method, it is important to seek medical advice from a health professional.

Without contraception around 80 in 100 women of reproductive age will get pregnant in a year.

eTG complete by Therapeutic Guidelines

Australasian Menopause Society
NEW DIRECTIONS IN WOMEN'S HEALTH