### Lecture 8

**COMBINED HORMONAL CONTRACEPTIVES (CHC):**
- Introduced in the 1960s
  - Thickens cervical mucus, alters endometrial lining
- Since that time
  - Dose of estrogen & progestosterone
  - New progestins with fewer side effects
- Popular because of:
  - Ease of administration, fairly low incidence side effects
  - Modest pregnancy rate (9% with typical use)
  - Standard 28-day regimen or extended/continuous use
  - Poor compliance limits effectiveness → 42% of unplanned pregnancies
- One electronic device study, in 1st cycle of use, 30% of women missed ≥ 3 pills

### ABSOLUTE CONTRAINDICATION FOR COCs:
- Established pregnancy
- Lactation at < 6 weeks post-partum, postpartum < 3 weeks (not breastfeeding)
- Smoker > 35 years of age (≥ 15 cigarettes/day)
- Migraine with aura at any age
- Major surgery with prolonged immobilization; current or past hx of DVT/PE
- Hypertension (SBP ≥ 160 mmHg or DBP ≥ 100 mmHg)
- Complicated heart disease (ischemic, atrial fibrillation, valvular conditions)
- Breast cancer, liver tumor or severe cirrhosis
- Diabetes with microvascular complications

### CHOICE OF ORAL CONTRACEPTIVE:

<table>
<thead>
<tr>
<th>Monophasic OCs</th>
<th>30-35 µg &gt; estrogen SEs than 20 µg</th>
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<tbody>
<tr>
<td>Multiphasic OCs</td>
<td>20 µg &gt; bleeding pattern disruptions than 30-35 µg</td>
</tr>
<tr>
<td>Progestin-only OC (minipills)</td>
<td>If estrogen contraindicated or if breastfeeding Must take same time each day</td>
</tr>
</tbody>
</table>

**Initial choice**
1. Monophasic 20-25 µg EE + low androgen progestin
2. Adjust dose/product based on side effects

### CYCLE CONTROL:
- Critical factor whether new COC user continues contraception:
  - Spotting Light bleeding, does not require pad
  - Breakthrough bleeding (BTB) Requires sanitary pad
  - Amenorrhea Absence of pad
- Contributing factors to BTB
  - Decreased BTB
  - Increased BTB (and spotting)
    - OC with ↑ estrogen and ↑ progestin potency
    - Missed doses
    - Smoking
    - Chlamydia (check if past good control)

### DISCONTINUATION OF COCs:
- Most women who D/C do so in first 2 months
- Reason for discontinuation:
  - Side effects (46%)
  - No longer desire contraception (23%)
  - Too difficult, expensive, or unsafe (14%)
  - Another unspecified reason (17%)
- Of those who D/C, 42% do NOT consult MD or Rxist!

### MECHANISM OF ACTION:
- **Within brain**
  - Inhibits ovulation by suppressing LH surge at mid-cycle
  - LH is required for follicular maturation & rupture
- **Within reproductive genital tract**
  - Thickens cervical & endometrial mucus forming a mechanical barrier
  - Creates a hypoplastoc (underdeveloped) endometrium that isn’t receptive to implantation

### NON-CONTRACEPTIVE HEALTH BENEFITS:
- ↑ cycle regulation, ↓ premenstrual symptoms, ↓ menstrual flow, ↓ dysmenorrhea, ↓ perimenopausal symptoms
- ↓ acne, ↓ hirsutism, ↓ bone mineral density
- ↓ endometrial & ovarian cancer, ↓ fibroids
- ↓ pelvic inflammatory disease

### SIDE EFFECTS:
- **COMMON SIDE EFFECTS** in first 3 months:
  - Nausea (39%), mood swings (14%), breast tenderness (11%)
  - Compliance enhanced by counselling
  - Reassure pt that early SEs typically resolve in a few cycles
  - Weight gain (14%) – may concern patient
  - Take weight when start and at follow-up
  - Changes in bleeding patterns – breakthrough bleeding (32%)
  - Often due to taking pills irregularly

- **SERIOUS SIDE EFFECTS**: pts should seek medical attention immediately
  - A = abdominal pain
  - C = chest or arm pain, SOB, coughing up blood
  - H = headaches: severe, not relieved by acetaminophen/ibuprofen
  - E = eye problems, blurred vision, flashing lights
  - S = swelling, redness, or pain in legs

### ADVERSE EFFECTS OF COCs:
- Generally subside after 4th cycle
- If estrogen-related effects, switch to lower dose
- If progestin-related effects, switch to alternate product
- If androgen-related effects (ex/ acne, hirsutism), switch to COC with less androgenicity
- If headaches, switching product may help
  - Extended COC regimen may reduce menstrual headaches
  - Vaginal dryness may improve with using ↑ EE COC, ring or POP
  - Chlorasma (darkening facial skin) is rare but may not disappear

### LONG TERM SAFETY OF COCs:

<table>
<thead>
<tr>
<th>VTE</th>
<th>Any EE has a higher risk than no EE</th>
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<tr>
<td></td>
<td>↑ risk: smoking, BMI &gt; 35, asthma, ill health, age</td>
</tr>
<tr>
<td>CV risk</td>
<td>Newer COCs with EE &lt; 50 µg = ↓ risk stroke &amp; MI</td>
</tr>
<tr>
<td></td>
<td>Smoking + COCs at &gt; 35 yrs of age = ↑↑ risk MI</td>
</tr>
<tr>
<td></td>
<td>Severe HTN &amp; atypical migraines = ↑ stroke</td>
</tr>
</tbody>
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### EPILEPSY AND CONTRACEPTION:
- Enzyme-inducing drugs: ↑ liver metabolism of COC = ↓ effectiveness
- Lamotrigine: non-enzyme inducing but CAN reduce hormone levels
- Non-enzyme inducing drugs: unlikely to impact drug effectiveness

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**FEATURES OF AN IDEAL CONTRACEPTIVE:**
- 100% effective & forgettable
- 100% convenient and acceptable
- 100% reversible
- Beneficial non-contraceptive SEs
- 100% safe
- Inexpensive & easy to distribute
- Independent of medical profession
- Used by/obviously visible to women

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- ↑ risk: smoking, BMI > 35, asthma, ill health, age
- Newer COCs with EE < 50 µg = ↓ risk stroke & MI
- Smoking + COCs at > 35 yrs of age = ↑↑ risk MI
- Severe HTN & atypical migraines = ↑ stroke

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**EPILEPSY AND CONTRACEPTION:**
- Enzyme-inducing drugs: ↑ liver metabolism of COC = ↓ effectiveness
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- Non-enzyme inducing drugs: unlikely to impact drug effectiveness
CONTRACEPTION FOR ADOLESCENTS:
1. MD evaluation: wt, ht, BP, pulse, pregnancy test, gonorrhea + chlamydia tests
2. Quick Start approach: start contraception regardless of time in cycle on day of visit
   - LARC should be considered as first-choice agent
   - Stress importance of condoms (in first cycle as backup) and with every new partner for STI prevention
3. Follow-up and side effect monitoring are important
   - Give info on what if miss dose
4. Encourage pt to contact pharmacists or MD before discontinuing contraception

EXTENDED OR CONTINUOUS OCs:
- Original OCs imitated average 28-day cycle
  - Withdrawal bleeding induced by ↓ hormone levels
  - Most critical time for accurate OC dosing is before or after hormone-free interval (HFI), or will risk ovulation
- Extended/continuous dosing may increase effectiveness
  - Extended use: 84 days OCs, 7 days inert pills
  - Continuous use: continuous OCs until 7 days breakthrough bleeding, then 3 days off, restart

BENEFITS OF EXTENDED USE OCs:
- Women who will especially benefit:
  - Seizure disorders, menstrual headaches
  - Dysmenorrhea, menorrhagia, endometriosis
  - Premenstrual dysphoric disorder
- Potential benefits:
  - ↓ headaches, ↓ tiredness, ↓ bloating
  - ↓ menstrual pain, ↓ days of bleeding overall

COMPARED WITH STANDARD 28-DAY CYCLES
- No change in satisfaction, compliance or safety

POTENTIAL RISKS OF EXTENDED USE:
- Potential hyperplasia of uterine lining
  - No known cases of hyperplasia on biopsy
- Potential pregnancy because of amenorrhea
  - Women with good compliance are at low risk
  - If missed pills, use OTC pregnancy test
  - COCs not teratogenic, so not harmful in early pregnancy
- COCs have minimal effect on bone density or ovarian cancer so extended use is low risk

MYTHS ABOUT EXTENDED USE:
- Taking extended or continuous OCs will ...
  - ... affect my future fertility
  - ... cause more side effects
  - ... cause a build-up of menstrual blood
  - ... not provide good birth control
  - ... not be normal or “natural”, women should bleed every 28 days

POST-PARTUM CONTRACEPTIVE CHOICES:

<table>
<thead>
<tr>
<th>Contraceptive Choice</th>
<th>Breastfeeding</th>
<th>Not breastfeeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactational amenorrhea method (LAM)</td>
<td>Immediately ≤ 6 months</td>
<td>No</td>
</tr>
<tr>
<td>Progesterone-only pill</td>
<td>&gt; 3 weeks</td>
<td>&gt; 3 weeks</td>
</tr>
<tr>
<td>Long-acting progestin (LNG-IUD)</td>
<td>&gt; 6 weeks</td>
<td>&gt; 6 weeks</td>
</tr>
<tr>
<td>Copper IUD</td>
<td>&gt; 6 weeks</td>
<td>&gt; 6 weeks</td>
</tr>
<tr>
<td>Combination OC (patch, ring)</td>
<td>&gt; 6 weeks (SOGC)</td>
<td>3 weeks (SOGC)</td>
</tr>
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</table>

* research suggests immediate insertion of IUD (10 mins – 48 hrs) postpartum is associated with a higher continuation rate compared to insertion at 6 wk post-partum

FAMILY PLANNING FOR OBESE WOMEN: obesity dramatically increases the hazards of pregnancy (ex/ diabetes, hypertension, C-section)

<table>
<thead>
<tr>
<th>OCs</th>
<th>BMI &gt; 32.2 higher risk of accidental pregnancy, higher risk of VTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evra patch</td>
<td>Higher failure rate in obesity</td>
</tr>
<tr>
<td>IUDs</td>
<td>Challenging to insert, but highly effective</td>
</tr>
<tr>
<td>Tubal ligation</td>
<td>Effective but risk from anesthesia</td>
</tr>
</tbody>
</table>

HORMONAL VAGINAL RING: Etonogestrel – Ethinyl Estradiol (NuvaRing)

| Dose | 120 µg of etonogestrel + 15 µg EE released daily |
| MOA | ↓ FSH + LH surge, thickens cervical mucus |
| How to use | Self-insertion: in 3 weeks, remove 1 wk (backup wk 1) |
| AEs | Nausea, vaginitis |

PROGESTIN-ONLY PILL (POP) “MINI PILL”:

| Dose | POP (Micronor) = 0.35 mg norethindrone |
| MOA | Alters cervical mucus, inhibits sperm motility and penetration |
| Indication | Estrogen-free – often used by women who: |
| AEs | Menstrual cycle disturbances, spotting, amenorrhea |

ACTIONS:
- Start immediately until < 6 months post partum
- Nursing 4 hours during day, q6 hours at night
- No menstural period
- No cost, no Rxist, immediate start, natural
- Not reliable if irregular cycle

CONTRACEPTION AFTER 40:
- Infertility rates lower than many might expect
  - Age 40 = 17%; age 45 = 55%; age 50 = 95%
  - Among women 40 – 49, 75% of pregnancies unplanned, and abortion rate increasing
- Gestational diabetes, pre-eclampsia, hypertension and birth defects more likely to complicate pregnancy
- Women may safely stop contraception after menopause if:
  - 12 months without a period over age 50
  - 24 months without a period under age 50

ONE KEY QUESTION FOR PRIMARY CARE PROVIDERS TO ASK WOMEN:
“Would you like to become pregnant in the next year?”
- Yes: pre-conception counselling & screenings to ensure in optimal health for a pregnancy
- No: counselling on full range of contraception options to ensure optimal method for their circumstances
- Maybe: clinicians offer these women a combination of both services
4 QUESTIONS TO ENGAGE PATIENTS:
1. How many children, if any, do you hope to have?
2. How long would you like to wait until you become pregnant (again)?
3. What do you plan to do to delay becoming pregnant until then?
4. What can I do to help you achieve your plan?

SHARED DECISION MAKING IN CONTRACEPTIVE COUNSELLING:
- Query to identify preferences
- Ask open-ended questions
- Provide information about SEs, effectiveness, and use of method
- Give context about options
- Ensure access to method placement and removal
- Allow time for questions

"TEACH-BACK" METHOD OF COUNSELLING:

**BENEFITS**
Tell me about some of the benefits of this method.  
How will this method have a positive impact for you?

**SIDE EFFECTS**
Tell me the three most common normal side effects women have when they start this method.  
Tell me what you will use if you experience cramps.

**FOLLOW-UP**
What would be abnormal symptoms with this method?  
Tell me what you will do if you experience spotting that is bothering you.

**TEACH-BACK** METHOD OF COUNSELLING:

HOW PHARMACISTS CAN HELP IMPROVE REPRODUCTIVE HEALTH:
- Increase access to contraception
- Contraception information
- Evaluate consistency of use
- Encourage condom use to prevent STIs
- Advice and counselling
- Pregnancy testing
- Health promotion: folic acid, healthy lifestyles, information about family planning services

RECOMMENDED ACTION AFTER LATE/MISSED COMBINED ORAL CONTRACEPTIVES:

If one hormonal pill is late (< 24 hours)
- Take late or missed pill ASAP
- Continue taking remaining pills at the usual time (even if it means taking 2 pills on the same day)
- No additional contraceptive protection needed
- Emergency contraception not usually needed but can be considered (except UPA) if OC pills were missed earlier in the cycle or in the last week of the previous cycle

If one hormonal pill has been missed (24 to < 48 hours)
- Take the most recent missed pill ASAP (any other missed pills should be discarded)
- Continue taking the remaining pills at the usual time (even if it means taking two pills on the same day)
- Use back-up contraception (ex/ condoms) or avoid sexual intercourse until hormonal pills have been taken for 7 consecutive days
- If pills were missed in the last week of hormonal pills (ex/ days 15 – 21 for 28-day pill packs):
  o Omit hormone-free interval by finishing the hormonal pills in the current pack & starting a new pack the next day
  o Use back-up contraception (ex/ condoms) or avoid sexual intercourse until hormonal pills from a new pack have been taken for 7 consecutive days
- Emergency contraception should be considered (with the exception of UPA) if hormonal pills were missed during the first week and unprotected sexual intercourse occurred in the previous 5 days
- Emergency contraception may also be considered (with the exception of UPA) at other times as appropriate

If two or more consecutive hormonal pills have been missed (> 48 hrs)
- Take the most recent missed pill ASAP (any other missed pills should be discarded)
- Continue taking the remaining pills at the usual time (even if it means taking two pills on the same day)
- Use back-up contraception (ex/ condoms) or avoid sexual intercourse until hormonal pills have been taken for 7 consecutive days
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