Table 1: Benefits & Risks

Benefits:
- Simple and highly effective
- Reduces need for sterilization & abortion
- Significantly improves menstrual symptoms & regularity
  - Reduces dysmenorrhea and mittelschmerz
  - Reduces menstrual blood loss (up to 50%)
  - Reduces risk of anemia
  - Reduces PMS
  - Alleviates menorrhagia/hot flashes in perimenopausal women
- Decreases incidence of disease
  - Bacterial pelvic inflammatory disease (60%)
  - Ectopic pregnancy
  - Endometriosis
  - Endometrial cancer (>50%)
  - Varicose veins (10-40%)
  - Ovarian cysts (>60%)
  - Acne and hirsutism
  - Fibrocystic breast disease (50-75%)
  - Osteoporosis
  - Rheumatoid arthritis (50%)

Risks:
- Venous thromboembolism – ↑ 3-4x with low dose OCs and possibly further ↑ 1.7x with new progestins
  - Activation of Protein C so ↑ risk of thrombus)
- Arterial thrombosis (myocardial infarction and stroke) – related to estrogen dose ≥ 50 ug, age ≥ 35, smoking, hypertension, and other risk factors for CVD (↑ ~2-3x); otherwise no ↑ risk over baseline in young non-smoking woman.
- Breast cancer – ↑ 1.3x; women who started OCs at early age for long duration at greatest risk; persists for <10yrs after discontinuation (also related to nulliparity/delay in childbearing).
- Cervical cancer – ↑ 1.5x with long term use (>5yr); also related to early sexual activity & multiple partners
- Gall bladder disease – ↑ 1.5x during 1st 5yrs of OC use
- Does not protect against sexually transmitted diseases (STDs)
- May exacerbate and/or precipitate: hypertension, diabetes, gallbladder and liver disease, SLE, migraine headaches, depression, GERD, vaginal yeast infections
- Failure esp. if missed doses with 20ug estrogen formulations

Table adapted from RxFiles newsletter – Hormonal Contraception – Jan 00

Table 2: Contraindications and Precautions

Contraindications:
- Active thromboembolic disease
- Undiagnosed vaginal bleeding
- Acute or chronic obstructive liver disease
- Known or suspected breast cancer
- Known or suspected pregnancy

Precautions:
- Hypertension – may use OCs if hypertension controlled
- CVD, hyperlipidemia – OCs with new progestins preferred because of more favorable lipid profile
- Diabetes – low dose OCs unlikely to affect glucose control but estrogen may complicate vascular disease
- Epilepsy – some anticonvulsants ↓ OCs efficacy due to ↑ metabolism; may require use of OCs with >35ug EE
- Hepatitis, cirrhosis – avoid OCs if active disease; may use if liver enzymes have returned to normal
- Gallbladder disease – may be exacerbated by OCs
- Migraine – avoid OCs if classic, complex, age ≥ 35 (↑ stroke)
- Inflammatory bowel disease – active diarrhea may reduce absorption and efficacy of OCs and require backup method
- Systemic lupus erythematosus – avoid OCs as estrogen can complicate vascular disease
- Smoking women over age 35 – if light smoker (<15cigs/day) or on nicotine patch, can use 20ug EE product but ↑ risk.

Table 3: Starting Hormonal Contraceptives

Starting Combined OCs:
- Most effective if started Day 1 of menstrual period
- Can be started any day up to Day 6
- To avoid weekend period, start on 1st Sunday after period begins
- If started after Day 5 use backup method for first 7-10 days as ovulation may not be suppressed
- Starting Progestin-only Pill (POP): irregular bleeding common
- Start on Day 1 of menstrual period and daily thereafter
- Use backup method for first month
- Take pills at the same time each day to ↓ BTB & pregnancy

Starting Depo-Provera:
- Should be injected during 1st 5 days of menstrual cycle to rule out pregnancy
- Repeat injection q12 weeks – effective for up to 14 wks
- Return of fertility delayed 4-31 (median 10) months after last inj

Starting Norplant:
- [Note: Norplant no longer made in Canada]
- Insert within the first 7 days of menstrual cycle to rule out pregnancy
- Must be removed and replaced after 5 yrs

Table 4: ACHES - OCs Early Danger Signs

SIGN
- Abdominal pain (severe)
- Chest pain (severe)
- Headache (severe)
- Eye problems

PROBLEM
- Gallbladder disease, pancreaticitis, hepatic adenoma, thrombosis
- Pulmonary embolus or acute MI
- Stroke, hypertension, migraine
- Stroke, hypertension, vascular insufficiency

Table 5: Side Effects & Their Management

- Breakthrough bleeding (BTB) - most common in 1st 3 months if persists beyond 3-6mon check for other causes (eg. chlamydia). Change to OC with ↑ estrogen/progestin depending on when BTB occurs in the cycle; may also be related to poor compliance, smoking, DIs
- Breast tenderness – if persists beyond 1st 3 months rule out pathologic causes; change to OC with ↓ estrogen/progestin
- Weight gain – may ↑ appetite in 1st month but overall weight gain is minimal with low dose OCs & within normal limits for age-related gain; may be cyclical due to Na & H2O retention
- Nausea – often subsides within 3 months; take at hs with food or change to lower estrogen content
- Headache – tension headaches unaffected but hormone related or vascular migraines may ↑ ↓; if precipitated or exacerbated by OCs should avoid their use
- Acne – sometimes worsens initially but usually improves in the long term; change to ↓ androgenic OC or use topical therapy
- Chloasma – irreversible and idiosyncratic; exacerbated by sunlight so use sunscreen and reduce exposure; ↓ estrogen dose

References:
### New Ways and Means...

**Contraception: what’s new; Pharmacy Practice May 2003**

#### Extended Dosing of OC’s:
- **Bi-cycling or Tri-cycling** refers to taking 2-3 consecutive packages of active pills (i.e. 42-63 days) followed by a week off for menstruation (menses is no different than with traditional dosing)
- **method appears safe & effective**
- **Advantages:** ↓ in menses and associated symptoms
- **A monophasic product must be used since the bi- and tri-phases can cause spotting.** • Currently **SEASONALE** (84 day pill pack) is approved in the USA Sep/03

#### New Products:
- **MIRCETTE**
  - 28 day pill pack with 21 active tabs followed by 2 placebo tabs; then 5 tabs of estradiol 10ug (↑ risk of missing first active pills of 21day cycle with ultra low dose products)
  - **EVRA TRANS-DERMAL PATCH** 1st releases 20ug estradiol + 150ug norelgestromin daily; 1 patch weekly x3 weeks; off for one week; can be used consecutively for 9 weeks, 1 week off. Cost ~$400/year
- **NUVARING**
  - releases estradiol 15ug + etonogestrel 120ug daily; insert vaginally for 3 weeks, then remove for 1 week
- **MIRENA Intrauterine System** is a T-shaped IUD with a levonorgestrel reservoir that releases 20ug daily and last up to 5yrs. Decreases menstrual periods (frequency & duration); 20% of users amenorrhic within 1st year. Fertility returns immediately after removal. ($350/yr)
- **IMPLANON** = **NORPLANT** DC’s reformulated into single rod system that releases 60ug etonogestrol daily. Effective for up to 3yrs.

### Product Selection guided by Signs & Symptoms of...

#### Estrogen Deficiency
- early bleeding & spotting: days 1-9
- continuous bleeding or spotting: ↓ decrease in flow
- absence of withdrawal bleeding
- pelvic relaxation symptoms
- atrophic vaginitis
- vaginal secretions
- nervousness

#### Progestin Deficiency
- late bleeding and spotting days 10-21
- delayed withdrawal bleeding

#### Estrogen Excess / Progestin Deficiency
- PMS
- bloating, edema
- headache (cyclic)
- dizziness
- irritability
- nausea, vomiting
- visual changes (cyclic)
- weight gain (cyclic)
- leg cramps
- dysmenorrhea
- hypermenorrhea, menorrhagia
- ↑ breast size or cyst changes
- mucorrhea
- cervical erythrosis
- uterine enlargement or fibroid growth
- thromboembolism
- hypertension
- vascular headaches
- chloasma
- depression
- fatigue
- libido decrease
- weight gain
- (non-cyclic)
- ↑ appetite
- symptoms of hypoglycemia
- leg vein dilatation
- hypertension
- hirsutism
- acne
- skin irritation
- edema
- cholestatic jaundice
- All OCS likely beneficial in acne - due to estrogen binding to sex hormone binding globulin (SHBG )
- **Official Acne Indication**
- ALESSE, TRI-CYCLEN & DIANE 35 **(ethinyl estradiol 35ug + cyproterone 2mg; Health Canada Apr/03 warning:** not for contraception only; discontinue within 4 months of resolution of acne; Cost $345 / 12 packs)

#### ACNE
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### Cost
- $otal 1yr cost in Sask. $ non-formulary Sask. ⬅ covered NIHB Note: both 21 & 28 tablet packages avail. for most products (28 packages incl. 7 inert tablets)
- Progestin Only
- Levonorgestrel
- PLAN B 0.75mg tab -indicated for emergency contraception. Norethindrone MICROGON 0.35mg tab -indicated in 9 with contraindication or intolerance to estrogen, venous thromboembolism history or migraine, post-partum/lactating & in smokers; $213/yr.
- Medroxyprogesterone (MPA) DEPO-PROVERA 150mg/1ml for deep IM Inj 3 months: 1st dose injected in the first 5 days cycle; repeat injections at ~12 week intervals (dose is effective for up to 14 weeks); $150/yr.
- **Diane 35**: officially indicated for women with severe acne, unresponsive to oral antibiotic & other available treatments, with associated symptoms of androgenization, including seborrhea and mild hirsutism.

### References: