Some Oral Contraceptive Issues In Pharmacy Practice

by

Chief Yomi Oduwole

Society for Family Health, Orile Iganmu, Lagos.

Of all contra-ceptive methods the general practice pharmacist probably has greatest involvement with the pill. The information demand is higher for the pill than for the barrier methods (condoms, vaginal foaming tablets, diaphragms) apparently due to the unsophis-tication of these methods and relative lack of untoward effects (emanating from their mode of action-barriers). On another hand, the pill is not an invasive family planning method like the injectables, the IUCD, the implant and the surgical methods. The client need not go beyond the pharmacist for supply, administration and information on the pill. In addition the pill is the most popular family plan-ning method in Nigeria. In 1992, 57% of contracepting Nigerian women were on the pill. All other methods together accounted for 43%.

To the general practice pharmacist therefore, every issue on oral contraceptives is important. Considering the time at our disposal however, my talk will focus on the more important issues. I will talk on distribution, drug interaction, contra-indications, side effects, myths and rumors, and non-contraceptive benefits.

Distribution: Although classified as an ethical product, oral contraceptives can be distributed from many outlets, provided sensible rules are followed. These outlets include pharmacies family planning clinics and hospitals. Because oral contraceptives have been classified in the primary health care schedule they are also distributed by community based distributors (CBDs) and patent medicine stores (PMS). The role of CBDs and PMS is limited to supply of refill orders. It is nevertheless substantial since PMS distribute 42% of oral contraceptives used in the private sector.

The general practice pharmacist must ensure adequate conselling of new pill users. Screening must exclude those from whom the pill is contraindicated. These include women who smoke and are over 40 years old with a history of hypertension, women who have had a stroke, heart attack, cancer of the breast or genital tract, liver disease or thrombophlebities and pregnant women. Each new user of the pill is supplied only one cycle. On subsequent visits, up to 3 cycle of the pill can be supplied. The pharmacist needs to counsel clients who though have been on the pill but buying from his pharmacy for the first time. This way any lapses in or lack of a previous counseling are corrected.

The basic steps to follow in counseling clients can be found in the guide to family planning practice in Nigeria.

Drug interaction: As a general rule, the pharmacist must seek information on what other medication the pill user is using. When used concurrently, the pill is affected by or has effect on some medications. Two categories of medications should be considered: (a) Medications that may reduce the efficacy of oral contraceptives. (b) Medications that are affected by oral contraceptive use.

Medications that reduce the efficacy of oral contraceptives include antibiotics, anti-convulsants barbiturates and antifungals. Clients on antibiotics should be advised to use a back-up method in addition to oral contraceptives for up to two weeks after stopping the anti-biotic therapy use for longer than one week. Clients on anti convulsants and anti fungals for one week or less should use a back up method for up to two weeks after stopping the medica-tion. Should treatment with anti convulsant or antifungal is for longer than one week, client should be advised to switch to a non-hormonal method.

Oral contraceptives affect some medications by increasing their efficacy or increase the risk of toxicity. The pill when used concurrently with tricyclic anti- depressants, beta blocking anti-hypertensive agents and some benzo-diazepine tran-quilizers has an enhancing effect. The dose of these medica-tions may need to be reduced. On the other hand, oral contrace-ptives reduce the efficacy

of anti coagulants, anti-diabetic drugs (insulin and the oral hypoglycaemics), the non-selective anti-hypertensive agents (methyldopa, guane-thidine, etc), loraze-pam, and temazepam, when used con-currently. Clients are advised to either switch to low dose pills or switch to progestin-only pills or any other non-estrogen containing method. The toxicity of trolendomycin, phenytoin and theophyline based anti-asthmatics are increased with concomitant use of oral contraceptives. Clients are advised to switch to non-hormonal method.

Contraindications:

Contraindications of the pill are either absolute or relative.

Those who should not take the oral contraceptive are:

i. pregnant women
ii. those with past history of stroke or coronary heart diseases
iii. those with hormone dependent cancers (e.g. breast cancer).
iv. clients with thrombophlebitis
v. clients with liver diseases

Women who can take the pill, but only under the supervision of a physician are:

i. Diabetics
ii. Asthmatics
iii. Those with family histories of varicose veins or other arterial diseases
iv. Epileptic clients
v. Women with undiagnosed vaginal bleeding.

It is important that the pharmacist ensures that his pill-using client does not fall under any of the categories above.

Side effects: Management of side effects of oral contraceptives constitute a major factor in keeping clients on this method. The single most important reason for client default and switch to other methods is side effects. The common side effects of oral contraceptives in descending order of frequency and severity are:

i Amenorrhoea
ii Spotting or bleeding between periods
iii Nausea
iv Headaches
v High blood pressure
vi Unwanted weight gain or weight loss
vii Bloated abdomen
viii Breast tenderness (mastalgia)
ix Depression
x Loss of libido
xi Chloasma ("mast of pregnancy")
xii Acne.

The investigation steps and management of each side effect is stated on the addendum to this paper. With proper management of the side effects of the pill, clients are kept satisfied on the pill.

Myths and Rumors: False rumors about family planning are common in some places. They can scare some women out of asking for the pill. They can scare some pill users into stopping. Rumors start from misunderstanding, incomplete or mistaken new stories and common but mistaken beliefs about the body and how family planning methods work. The pharmacist help keep rumors from starting and stop false rumors by:

i. Encouraging clients to ask questions
ii. Use correct words during counseling
iii. Ask the client what she has heaad about the pill. Always take her answers seriously.
iv Gently correct mistaken ideas.

Some common rumors about the pill are:

- "A woman does not need to use the pill after she becomes a grandmother"
- "A woman is still protected after she stops taking the pill because she has been using the pill for a long time"
- "The pill makes you weak"
- "The pill causes deformed babies"
- "The pill makes a woman sterile"
- "The pill collects in the stomach"
- "The pill will make the heart weak"
- "The pill causes cancer"

The consumer pamphlet on oral contraceptives distributed by the Society for Family Health gives standard answers to these rumors.

Nor-contraceptive benefits: In addition to it's contraceptive effect, the pill is beneficial to the consumer in the following ways.

i. **Ectopic pregnancies** - Oral contraceptives help to prevent ectopic pregnancies
ii. **Pelvic inflammatory diseases** - Women on the pill face about half the risk of developing pelvic inflam-matory diseases that non-users face. Pelvic inflammatory diseases are in-fections often starting in the cervix and ascend-ing to the upper reproductive tract. They are a major cause of fallopian tube blockade leading to permanent infertility.
iii. **Menstrual benefits** - Oral contraceptives menstrual bene-fits include less iron deficiency anaemia due to lighter menstrual blee-ding, less dysmenorrhoea. About 90% of women affected by dysmenorrhoea experience significant relief from symptoms when they use oral contraceptives.
iv. **Protection from cancer** - The pill protects users two types of cancers:
- Endometrial cancer
- Ovarian cancer

As little as one year's use of the pill reduces the risk of endomentrial cancer by 50%. This protection lasts long after the women stop using the pill.

Women who use oral contraceptives for ten years or more reduce their risk of ovarian cancer by 80%. Use even for only 3-6 months reduce the risk by 40%.

v. **Others** - The pill protects users against benign breast disease and ovarian cysts.

From the issues discussed above, the pill is indeed the centre of family planning practice in general practice pharmacy.

Management of Side Effects of the Pill

Women on pills may complain of multiple concerns, which may or may not be due to pill use. The following side effects are discussed in des-cending order of frequency and severity

1. Amenorrhea
2. Spotting or bleeding between periods
3. Nausea
4. Headaches
5. High blood pres-sure
6. Unwanted weight gain or weight loss
7. Bloated abdomen
8. Breast tenderness (mastalgia)
9. Depression
10. Loss of libido (sex drive)
11. Chloasma ("mask of pregnancy")
12. Acne

Side Effects	Investigation Steps	Management
Amenorrhea which Concerns the Client	A. Ask how she has been taking her pills.	A. Missed pills or pills taken late raise risk of pregnancy. Clients on 21-day pill packets may forget to leave a pill-freeweek for menses.
	B. Rule out pregnancy by menstrual history exam. See Appendix 2: "Diagnosis of Pregnancy."	B. If client is pregnant, refer her according to her preference. If she intends to continue the pregnancy, stop the pill. If not pregnant, go to item C.
	C. Is she using a low-estrogen pill (35 micrograms or less of estrogen)?	C. If the client is taking the pill correctly, reassure. Explain absent menses may be due to lack of build-up of uterine lining: when no lining is present to be shed, there will be no menstrual blood. If, despite reassurance, a lock of menses is unacceptable to the client, try switching to a pill with a more potent progestin (e.g., levonorgestrel, norgestrel). If this is not possible, switch to a pill with more estrogen for cycles. If available, a 50 mcg estrogen pill may be used. (Clients on higher dose estrogen pills should be strongly discouraged from smoking).
	D. Has she already been on 50 mcgestrogen for a least 3 months?	D. If the client is taking the pill correctly, reassure. If the client is unsatisfied, and pregnancy has been carefully ruled out, amenorrhea may still be due to insufficient hormonal stimulation of the lining of the uterus. Switch to a pill with a progestin which given more endometrial support (such as levonorgestrel or norgestrel). If amenorrhea persists, refer as appropriate.
	E. Has she recently discontinued the pill.	E. Rule out pregnancy. If the client is not pregnant, explain that there may be a delay in the return of her menses after stopping the pill. If her periods were irregular before beginning the pill, they will be irregular when the pill are stopped and may take some months to return. Help the client make an informed choice of another contraceptive method.

Spotting or Bleeding between Periods (common during first three months after starting the pill)	A. Has the client recently begun the pill?	A. Reassure
	B. Ask if she has missed one or more pills, or if she takes pills at a different time every day.	B. If necessary, re-instruct.
	C. Ask if she has had much vomiting and /or diarrhea.	C. If the client has had vomiting or diarrhea, explain this may have interfered with her body's absorption of the pill. Recommend condoms, spermicides or abstinence until the vomiting and diarrhea resolve.
	D. Ask if the client is taking any new medicines (e.g. rifampicin or medicine for seizures)?	D. Client may require a higher dose pill or a change in her method (See Appendix 9: "Interaction Between Oral contraceptives and Therapeutic Drugs").
	E. Exclude gynecological problems. e.g., tumors, pregnancy, abortion, cervical infection, pelvic inflammatory disease (PID). Ask if she had a normal Pap smear within the last year. Ask if she has spotting after intercourse.	E. Rule out cervical infection, PID or obvious gynecologic cancer by pelvic exam. if available and affordable, do a Pap smear (if more than a year has passed since the last one). Wipe the cervix clean before taking a smear. If gynecologic problems are present, refer as appropriate, or manage according to clinic guidelines.
	F. None of the above?	F. If no gyneco-logical, drug interaction or other problem is detected, the break-through bleeding may be due to inadequate support of the uterine lining. Switch to a more potent progestin (norgestrel, levonorgestrel). If she is already using one of these, switch to a higher estrogen pill (not above 50 mcg estrogen) for several cycles until spotting resolves, then, return to the lower dose pill. If the spotting returns, continue with the 50 mcg pill. (Clients on higher dose estrogen pills should be discouraged from smoking).

Nausea	A. Exclude pregnancy. See Appendix 2: "Diagnosis of Pregnancy".	A. If the client is pregnant, refer her according to her preference. If she intends to continue the pregnancy, discontinue the pill.
	B. Find out if the pill is taken in the morning or on an empty stomach.	B. Advise the client to take the pill with the evening meal.
	C. Rule out other causes of nausea.	C. Evaluate for infection (hepatitis, gastroenteritis) and other causes of nausea.
	D. None of the above?	D. Switch to a lower estrogen pill or a progestin-only method.
Headaches	A. Rule out sinusitis by determining whether she has purulent nasal discharge and tenderness in area of sinuses.	A. Refer for treatment of sinusitis. Continue the pill. Be aware that some antibiotics cause decreased effectiveness of the pill, so recommend use of a backup method while on antibiotics. See Appendix 9: "interactions Between Oral Contraceptives and Therapeutic Drugs."
	B. Ask whether she has ever had high blood pressure (BP).	B. Regardless of history CHECK THE BP. If elevated, see HIGH BLOOD PRESSURE, below.
	C. Try to distinguish between muscle contraction (tension) headaches and migraine (vascular) headaches. **Muscle contraction** headaches are generally in the front of base of the head, they are bilateral. Pain is often pressure-like or dull. Neck muscles are often sore. **Migraine** headaches can vary from mild to severe. Pain is often located in the temporal areas and is throbbing in nature. Nausea or vomiting may be present. Clients may have a warning (aura) that a headache is about to occur. Migraines may occur predictably in response to the same agent (e.g. caffeine) or at time of menstrual cycle. Some clients experience neurologic symptoms: * vision changes (flashing lights,	C. The presence of neurologic symptoms may suggest severe migraine headache. This client is at risk for stroke. Strongly advise her not to smoke cigarettes. If she has had neurologic symptoms, stop the pill. POPs or other estrogen-free methods may be used. Refer as necessary. If the client described headaches without neurologic symptoms, she may continue the pill. Some women report an improvement in their migraines. Have the client keep a record of her headaches.

	double vision or loss of vision); * numbness, tingling or weakness in their arms or legs; * speech or memory problems. D. Ask the client if the headaches are worse since she began the pill.	D. If headaches are worse on the pill, switch to a progestin-only or non-hormonal contraceptive method, as appropriate. If headaches are no worse on the pill, explore causes of the headaches. Pills can be continued unless high blood pressure or neurologic symptoms or signs develop, or headaches worsen on the pill.
High Blood Pressure	A. Ask if this is the first time anyone has told her that she has high blood pressure.	A. Allow 15 minutes rest, then repeat BP reading. If systolic is greater than 190 OR diastolic is greater than 110, and client smokes or is over age 40 stop the pill. Otherwise, switch the client to lowest dose pill and ask her to return in one week for BP check.
	B. Re-check blood pressure (BP) on two more visits, one week apart: 1. Assess systolic BP. If over 190 mm on this visit, or over 160 mm on three successive visits, the client has high blood pressure. 2. Assess diastolic BP. If greater than 110 mm on one visit, or greater than 90 mm on three successive visits, the client has high blood pressure.	B. If BP is still elevated, refer for evaluation or manage according to clinic guidelines. Help the client make an informed choice of POPs, NORPLANT, injectables or a reliable non-hormonal method. If none are acceptable, the pill will still be safer than pregnancy.
Significant Unwanted Weight Gain or Weight Loss	A. Interview the client, inquiring about eating habits which might promote weight gain or weight loss.	A. Instruct the client in proper nutrition and exercise.
	B. If the client denies poor eating habits, but complains of increased appetite or weight gain without apparent cause, ask if the weight gain is unacceptable.	B. Explain to the client that all hormonal contraceptives may have slight effect on weight, but the dose of hormones in the pills is very low and should have only a modest effect.
	C. Rule out weight gain due to pregnancy. See Appendix 2: "Diagnosis of Pregnancy".	C. If the client is pregnant, refer her according to her preference. If she intends to continue the pregnancy, stop the pill.

Bloated Abdomen	A. Rule out constipation, pregnancy, tumors. See Appendix 2: "Diagnosis of Pregnancy".	A. If the client is pregnant, refer her according to her preference. If she intends to continue the pregnancy, discontinue the pill.
Breast Tenderness (Mastalgia)	A. Determine whether the woman is pregnant by history and pelvic exam. See Appendix 2: "Diagnosis of Pregnancy".	A. If the client is pregnant, refer her according to her preference. If she intends to continue the pill.
	B. Determine whether the woman has breast lumps or nipple discharge suspicious for cancer. See Appendix 5: "Breast Exam."	B. If the physical exam shows a lump or discharge suspicious for cancer, stop the pill. Help the client make an informed choice of another method. Refer her as appropriate for evaluation.
	C. If she is breast feeding and breasts are tender, examine for breast infection	C. If breasts are not infected, recommend appropriate clothing for support. If breast infection is present, use warm compresses, and advise to continue breast feeding, if appropriate. Refer as appropriate.
	D. Ask whether client notices this only at a certain time of the month.	D. Decrease estrogen in pill or if already on lowest estrogen, try a different progestin.
	A. Ask about causes, e.g., family, financial or social problems.	A. Counsel accordingly and follow-up during her next return visit.
	B. If no other cause is found, ask the client if she thinks depression has worsened while on the pill or is due to this method.	B. If the client feels the depression has worsened on the pill or is due to this method, follow-up on this matter during her next visit. Help her make an informed choice of a non-hormonal method. If the pills have not caused depression to worsen, the pills can be continued.
Loss of Libido (sex drive)	A. Ask if this is due to other causes, e.g. dry vagina, painful intercourse, or marriage problems.	A. Counsel or refer as appropriate.

	B. If no other cause is found, ask if the client sees this as a serious problem	B. If you switch to a pill with a more androgenic progestin (such as levonorgestrel or norgestrel), or switch to a pill with 50 mcg of estrogen. (Clients on higher dose strongly discouraged from smoking).
Chloasma ("mask of pregnancy").	A. Ask about other causes, e.g., use of skin lightening creams containing mercury, recent pregnancy or sunburn.	A. Counsel on stopping creams and avoiding sun. If recently pregnant, advise to wait 3 months and look for improvement.
	B. Look for tinea versicolor or other skin diseases.	B. Treat or refer as appropriate.
	C. If no cause is found and problem is not improving.	C. If no other causes are found and if bothersome facial darkening is associated with the pill, and is perceived by the client to be intolerable, help the client make an informed choice of a non-hormonal method. Advise use of a sun-hat.
Acne	A. Ask how and how often she cleans her face. Rule out inadequate hygiene and use of creams that block pores.	A. Recommend cleaning her face at least daily with water. An astringent, like lemon, may also be helpful. Avoid heavy face creams with lanolin or perfumes.
	B. Ask if she is currently under great stress.	B. Counsel as appropriate.
	C. Ask what type of pill she is taking.	C. Provide a low-androgen pill (by using a progestin such as norethindrone/nore-thisternone or ethynodiol diacetate). If low androgen pills are not available, try an increase in estrogen dose (to a maximum of 50 mcg) or try progestin - only pills (because the dose of progestin is so low). Clients on higher dose estrogen pills should be strongly discouraged from smoking.