TH 4120 Therapeutics II
Exam #2 – Application
April 8, 2004 **Name _____**

Case #1 (10 points)

HPI: Elaine is a 33 year old female who presents to your clinic complaining of BTB and spotting during the first week of her cycle. She has experienced this ever since she started her OCP.

PMH: Asthma

Current Meds:
Albuterol 1-2 puffs prn SOB
Advair diskus 250/50mg one puff bid
MVI po qd
Calcium 500 mg po bid
Demulen 1/35 (started 4 months ago, previously used the sponge)

SH: Denies smoking, alcohol, illicit drugs
Occupation: Works as a 2nd grade teacher; lives with husband and cat
FH: Mom with HTN, type 2 DM, Dad with CAD s/p MI 2001

PE

General: WDWNF NAD
Skin: no rashes, wounds, bruises
HEENT: non remarkable
CV: NSR
Pulm: CTA (b)
GI: soft, NT
GU: Non-contributory
Psychiatric: normal affect

Vitals today: HR 80 BP 120/78 5'7" 122lb
Allergies: PCN

Labs:
Na 140, K 4.2 Cl 95, BUN 11, S.Cr 0.8, BG 100, Ca^{2+} 10
TSH 4 MIU/L
Lipid panel (2/04) TC 150, TG 130, HDL 46, LDL 88

1. Please evaluate Elaine's OCP (including appropriateness, ADRs, contraindications and drug interactions). (4 points)

   Demulen 1/35

   Appropriateness**: The combination OCP is an appropriate hormonal method for a 33 year old non-smoking female.** (1 pt)

   ADRS: **BTB and spotting during first week of cycle (1 pt) which is secondary to an estrogen deficiency.** (1 pt)

   Drug Interactions: **None** (0.5 pt)

   Contraindications: **None** (0.5 pt)

2. Please recommend a new OCP for Elaine including, medication, dose, route, frequency AND justification for your selection. (6 points)

   Nelova 1/35
   Norinyl 1+35
   Necon 1/35
   Ortho-Novum 1/35
   (Could accept Desogen, Ortho-Cept, or Mircette based on justification)
   No credit for 50 ug OCP

   (2 points drug)

   One pill (1 pt) **by mouth daily** (1 pt)

   Justification:
   Elaine was experiencing ADRs from an estrogen deficiency . By increasing estrogenic activity and keeping the progestational activity fairly consistent, this should correct the early BTB/spotting. (2 pt)

FYI:
In class the following instructions were giving for adjusting for ADRs:
Principles for adjusting OCPs based on ADRs

1. Determine the cause of the ADR (estrogen vs progestin; excess vs deficiency)
2. Look at relative composition of current OCP (Appendix B)
3. Try to keep the non-offending component of the OCP the same (or at least within 1 plus mark of the current OCP)
4. Adjust the offending component by 2 pluses if possible (if not, then 1 plus will be fine)

I have included Appendix B for your use if you want to give partial or full credit based on their justification.

Product	Composition				Relative Activities			
	Estrogen	mcg	Progestin	mg	Estrogenic	Progestational	Androgenic	Spotting & BTB[$] (%)
50 mcg Estrogen								
Ovral	E. estradiol	50	norgestrel	0.5	++++	++++	+++	4.5
Necon 1/50/Nelova 1/50M/Norinyl 1+50/Ortho-Novum 1/50***	mestranol	50	norethindrone	1.0	+++	+++	++	10.6
Ovcon 50	E. estradiol	50	norethindrone	1.0	++++	+++	++	11.9
Demulen 1/50, Zovia 1/50E	E. estradiol	50	ethy. diacetate	1.0	++	++++	++	13.9
Sub 50 mcg Estrogen Monophasic								
Lo-Ovral/Low-Ogestrel	E. estradiol	30	norgestrel	0.3	++	++	++	9.6
Desogen/Ortho-Cept	E. estradiol	30	desogestrel	0.15	++	++++	+	9.9
Ovcon 35	E. estradiol	35	norethindrone	0.4	++++	+	+	11.0
Levlen/Nordette/Levora	E. estradiol	30	levonorgestrel	0.15	++	++	++	14.0
Ortho-Cyclen	E. estradiol	35	norgestimate	0.25	+++	+	+	14.3
Brevicon/Modicon/Nelova 0.5/35/Necon 0.5/35	E. estradiol	35	norethindrone	0.5	++++	+	+	14.6
Nelova 1/35E/Norinyl 1+35/Necon 1/35/Ortho-Novum 1/35	E. estradiol	35	norethindrone	1.0	+++	+++	++	14.7
Demulen 1/35, Zovia 1/35E	E. estradiol	35	ethy. diacetate	1.0	+	++++	++	37.4
Yasmin	E. estradiol	30	Drospirenone	3.0				
Loestrin 1.5/30, Loestrin Fe 1.5/30	E. estradiol	30	nor. acetate	1.5	+	+++++	+++	25.2
Loestrin 1/20, Loestrin Fe 1/20	E. estradiol	20	nor. acetate	1.0	+	+++	+++	29.7
Alesse/Levlite	E. Estradiol	20	Levonorgestrel	0.1	+	+	++	26.5
Mircette	E. estradiol	20 (21) 0 (2) 10(5)	Desogestrel	0.15(21)	++	++++	+	19.7
Sub 50 mcg Estrogen Multiphasic								
Ortho Novum 7/7/7	E. estradiol	35(21)	norethindrone	0.5(7) 0.75(7) 1.0(7)	++++	++	++	12.2
Jenest	E. estradiol	35(21)	norethindrone	0.5(7) 1.0(14)	+++	++	++	14.1
Tri-Levlen/TriPhasil/Trivora	E. estradiol	30(6) 40(5) 30(10)	levonorgestrel	0.05(6) 0.075(5) 0.125(10)	++	+	++	15.1
Tri-Norinyl	E. estradiol	35(21)	norethindrone	0.5(7) 1.0(9) 0.5(5)	++++	++	++	14.7
Ortho Tri-Cyclen	E. estradiol	35(21)	norgestimate	0.180(7) 0.215(7) 0.250(7)	+++	+	++	17.5
Estrostep , Estrostep Fe (25 mg ferrous fumarate for 7 inactive days)	E. estradiol	20 (5) 30(7) 35(9)	Norethindrone	1.0(21)	+	+++	+++	26.2
Ortho Novum 10-11/Necon 10/11/Nelova 10/11	E. estradiol	35(21)	norethindrone	0.5(10) 1.0(11)	++++	++	++	19.6
Cylesesa	E. estradiol	25(21)	Desogestrel	0.1(7) 0.125 (7) 0.15 (7)				

Case #2

CC/HPI: MM is a 56-year old man who was referred to Clinical Pharmacy for diabetes management. Patient forgot to bring in his glucometer but states that his morning glucose levels average around 180mg/dl. Patient states that he has been adherent to his drug regimen and does not miss any doses of medications. He states proudly that he hasn't had to change any of his medications or doses for over a year now. Patient states that he can't wait to go to McDonald's and grab a Big Breakfast since he was fasting for his blood work today.

PMH: Type 2 DM (diagnosed in 1997)
Hypertension
Hyperlipidemia
Tobacco abuse

SH: (+) Smoker – 1ppd x 20 years
EtOH: Glass of red wine daily

FH: All immediate family members have Type 2 diabetes.

Meds: Irbesartan 150mg QD
Chlorthalidone 25mg QD
Metformin 1gm BID
Verapamil SR 240mg QD
Simvastatin 5mg qHS

ALL: NKDA

PE:
VS: BP: 138/86 and 134/82on repeated measure HR: 70 RR: 18
Ht 5'5" Wt: 154kg

EXT: Foot exam: Decreased sensation with 5.07 monofilament, Category I

LABS:
Na: 140 K: 4.0 Cl: 110 CO2: 28 BUN: 11 SCr: 1.2 Glu: 120 (Today)

Fasting lipid panel: TC 230 TG 220 HDL 36 (Today)

HgbA1c: 9.0% (Today)

Spot Urine Collection: 30 mcg/mg (1/14/03)
210 mcg/mg (2/14/04)
200 mcg/mg (1/14/04)

1. Please evaluate the following medications from the patient's current regimen. Please include a statement of appropriateness of drug, dose and its efficacy. Utilize appropriate primary literature and/or guidelines to justify your evaluations. (18 points)

Irbesartarn 150mg QD

- **Drug is appropriate for the treatment of microalbuminuria and for the treatment of hypertension in a diabetic per IDNT and IRMA II.** (*2 points, .5pt for appropriateness of HTN, .5pt for appropriateness of MA, and 1 point for the evidence(either trial))*
- **Dose is inappropriate for the treatment of diabetic nephropathy/microalbuminuria.** *(1 point)*
    - **Evidence: IRMA II demonstrated superior efficacy with 300mg of irbesartan for the development of clinical proteinuria** *(2 point, 1 pt study, 1 pt dose)*
- **Efficacy: Drug is efficacious but not currently optimized. (WORDING?) BP is still not at goal and patient has worsening microalbuminuria.** *(1 point)*

Chlorthalidone 25mg QD

- **Drug is appropriate first-line agent for the treatment of hypertension including diabetics per SHEP trial or JNCC7.** (*2 points, 1pt for appropriateness and 1 point for the evidence)*
- **Dose is appropriate.** *(1 point)*
- **Drug is not efficacious as BP not at goal** *(1 point)*

Verapamil SR 240mg QD

- **Drug is appropriate for the treatment of HTN and for the reduction of CV events per INVEST trial.** (*2 points, 1pt for appropriateness(.5pt HTN, .5pt CV EVENTS) and 1 point for the evidence)*
- **Dose is appropriate.** *(1 point)*
- **Drug is not efficacious as BP not at goal.** *(1 point)*

Simvastatin 5mg qHS

- **Drug is appropriate for the prevention of CV events and to reduce both morbidity and mortality per 4S and Heart Protection Study. (Other trials would not be appropriate since they did not study simvastatin)** (*2 points, 1pt for appropriateness and 1 point for the evidence)*
- **Dose is inappropriate because a minimum of 20mg is needed per 4S and ideally 40mg from the Heart Protection Study OR simvastatin 5mg is not adequate dose to achieve an LDL of < 100 in this patient.** (*2 points, 1pt for appropriateness and 1point for the evidence)*
- **Drug appears to be efficacious but may be too early to determine since most of the statin benefits appears after two years. Or may accept: not efficacious b/c not at goal** *(1 point)*

2. Select and recommend new drug therapy and/or modify existing therapy to maximize this patient's drug regimen. Justify the addition of new drug therapy. In your justification, please provide primary literature and/or guidelines. (8 points)

ECASA or ASA 75mg –325 mg QD *(1 point)*

- **Patient is ≥ 40-years of age, smokes, hypertension, obese, hyperlipidemia** *(2 points*)
- **Anti-platelet Trialists Collaboration estimated that 38 ± 12 vascular events per 1,000 diabetic patients would be prevented with aspirin as secondary prevention**

OR

- **Hypertension Optimal Treatment (HOT) trial showed that aspirin reduced cardiovascular events by 15% and myocardial infarction by 36%** *(1 points (.5pt for each trial)*

Increase simvastatin to 20, 40mg or 80mg *(1point)*

Increase irbesartan to 300mg *(1 point)*

Increase metformin 850 mg po TID *(1 pt drug, 1 pt regimen*)
OR add sulfonylurea at starting dose

3. Recommend monitoring parameters for microvascular complications. Include appropriate intervals and rationale. If a parameter is not monitored, justify your reasoning. (4 points)

Nephropathy: *(1 point)*

- **Spot urine collection. No more than once per year**

OR

- **May not choose to monitor since patient is being treated appropriately with irbesartan 300mg QD and that obtaining further work up will not affect this person's therapy.**

Neuropathy: *(2 points)*

- **Daily self foot exams (1 pt)**
- **Podiatrist every 6 months since this person has a Category I risk for ulceration. (1 pt)**

Retinopathy: *(1 point)*

- **Yearly eye exams with ophthalmologist or optometrist with experience in diabetic retinopathy**

Case #3

HPI/CC: A 52-year-old female is seeing her primary care physician for a follow-up visit. Since her last visit 3 months ago, she had broken her wrist – while walking, her dog pulled sharply on the leash to chase a squirrel. The fracture did not require surgical repair.

PMH: Rheumatoid arthritis (7 years)
Drug-induced diabetes mellitus (2 years)
Menopause (4 years)
Anemia (3 years)
GERD (10 years)

SH: On disability (former secretary) because of arthritis. Exercise limited by pain. Drinks occasional wine (monthly). Smokes ½ pack per day. Denies illicit drugs. Eats balanced diet (meats, fruits, vegetables) that includes 1 cup of milk and 1 cup of yogurt per day.

MED: Methotrexate 10 mg PO weekly (Wednesdays)
Infliximab 300 mg IV Q 8 weeks
Glyburide 10 mg PO QAM
FeSO4 325 mg PO BID
Prednisone 5 mg PO QAM
Ranitidine 150 mg PO QPM PRN (4-5 nights/week)
Dulcolax suppository Q1-2 weeks PRN

ROS: Denies headaches. Wears glasses, vision is slowly deteriorating – especially over last 3 years. Hearing is OK. Denies cough or shortness of breath. Denies fevers. Has occasional heartburn if eats spicy or large quantities of food. Denies difficulty swallowing. Complains of constipation. Denies nocturia. Complains of bilateral hand joint pain and stiffness. Appetite is good. Mood and memory are fairly good. Occasionally gets mild swelling in feet and ankles. Denies abdominal pain, nausea, or jaundice.

PE: Vitals: Ht 5'5", Wt 130#, BP 122/76, HR 78, RR 16

GEN:	Alert, cooperative, good cognition
HEENT:	PERRLA, EOMI
PULM:	Lungs CTA, bilaterally
HEART:	RRR, no S3 or S4, no MGR
ABD:	Soft, no mid-epigastric tenderness, non-distended, no guarding, NABS
EXT:	Joint swelling in MCPs, bilaterally, with + warmth and mild redness. Has + nodules on MCPs and PIPs, has some skin atrophy diffusely
NEURO:	Gait is normal, balance is good

LAB (1 month ago)
BMP: Na 140, K 4.8, Cl 104, CO2 24, BUN 12, Cr 0.9, Glu 128 (fasting).
CBC: WBC 4.9 (67 seg, 20 lymph, 11 mono), H/H 34.3/11.5, Plt 178
ALT 47/AST 33
A1c 7.4
Ca 9.4, PO4 3.7

RAD (last week)
DEXA: L1-L4 T score = -2.3 (Z score = -1.4); FN T score = -1.9 (Z score = -1.1)

1. Please assess this patient's bone health. Include the patient's medical problem and at least 4 risk factors for fracture exhibited by this patient. (7 points)

   Clinical osteoporosis (3 points) **with low BMD (T score -2.3) and fragility fracture. Status: uncontrolled/untreated.**
   Risk factors include female sex (1 point)**, MTX use** (1 point)**, physical inactivity** (1 point)**, cigarette smoking** (1 point)

2. Please select or recommend a pharmacotherapy plan for this patient. Include the drug, dosage, and frequency. (9 points)

   (1 point for drug, 1 point dose, 1 point for frequency)

   Drug**: alendronate 70mg po once weekly**
   Risedronate 35mg po once weekly

   AND

   Calcium carbonate(1 pt) 1200mg (1 pt) po in divided doses (1 pt) (pt >50y.o. with osteoporosis)

   Vitamin D (1 pt) 400-800IU (1 pt) po qd (1 pt)

3. Educate this patient on 4 important non-pharmacologic recommendations to reduce the risk of fracture. (4 points)

   Students need to have four of the following – 1 point for each non-pharmacologic recommendation. Make sure student uses layterms when educating the patient.

   - **Muscle strengthening and balance training (individualized, at home)**
   - **Tai chi exercise**
   - **Use of a cane or walker**
   - **Home hazard assessment (ensuring proper flooring (appropriate use of rugs, etc.); ensuring proper lighting; installation of hand rails; etc.)**
   - **Estrogens**
   - **Ensuring proper vision**
   - **Eliminating medications associated with falls (psychotropics)**
   - **Use of hip pads**