ASHP CLINICAL SKILLS COMPETITION

PHARMACIST'S PATIENT DATA BASE FORM

(additional HIV reference provided when this case was used in 2003)

Demographic and Administrative Information

Name: LV
Address: 1350 Duncan Loop South
Dunedin, FL 34698
Date of Birth: 1-1-1949
Height: 5'9" **Weight:** 73 kg
Gender: Male

Patient ID: 123-45-6789
Room & Bed: 6244-1
Physician: K. Nostrum, MD
Pharmacy: CVS (Keene & Main) Dunedin, FL
Race: Caucasian
Religion: Unitarian

History of Present Illness

LV arrived at the emergency room via automobile and presents with chief complaint of shortness of breath and relatively non-productive cough. This has been preceded by a three-month history of increasing fatigue.

Past Medical History

HIV diagnosed in 1989
HCV diagnosed in 1999
PCP in 1996, 1997 & 1999
Cryptococcal meningitis in 1999
Type 2 Diabetes Mellitus x 10 years
HIV nephropathy x 4 years
Hyperlipidemia x 8 years
Peripheral Neuropathy x 1 year
Depression x 12 years

Family History

Father: deceased, unknown age or reason
Mother: age 75 alive with HTN
Sister: age 48 alive and well
Brother: age 50 alive and well

Hepatitis Panel

11-19-99 total anti-HAV non-reactive
11-19-99 HBsAb non-reactive
11-19-99 HBsAg non-reactive
11-19-99 HCV Ab reactive
1-24-00 HCV genotype - 1a
1-24-00 HCV Viral load 430,000 copies/ml
4-3-03 HCV Viral load 1,960,000 copies/ml

Vitals & Other Tests

	4-3-03 (clinic)	7-7-03 (clinic)	10-5-03 (clinic)	11-13-03 (admission)
BP	130/68	142/80	148/82	110/60
Pulse	80	74	76	90
Temp	36.6°C	36.9°C	36.8°C	38.1°C
Resp	18	20	16	24
PO_2				61
PCO_2				42
pH				7.4
HCO_3				24

Chem	4-3-03 (clinic)	7-7-03 (clinic)	10-5-03 (clinic)	11-13-03 (admission)
NA	140	N/A	N/A	144
K	4.4			4.0
Cl	100			98
CO_2	22			30
BUN	45			49
SCr	1.2			1.5
FBG	115			200
HbA_{1c}	6.8%			7.0%
Calcium	6.9			8.3
Albumin	2.3			2.1
AST	60			70
ALT	45			150
Total bili				1
Direct bili				0.3

Heme	4-3-03 (clinic)	7-7-03 (clinic)	10-5-03 (clinic)	11-13-03 (admission)
WBC	4.9	N/A	N/A	9.3
Hgb	12.3			9.9
Hct	39.9%			29%
Plts	110			116
PMNs	90%			75%
Lymphs	8%			17%
Bands	1%			6%
Eos	1%			1%
Monos	0%			1%
MCV				90
MCH				27
MCHC				32

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HIV Phenotype Results

Report dated 10/5/03
Current regimen: efavirenz, stavudine, didanosine
Previous meds: saquinavir, ritonavir, lamivudine, zidovudine

efavirenz - resistant	saquinavir - resistant
nevirapine - resistant	indinavir - resistant
delaviridine - resistant	ritonavir - resistant
zidovudine - resistant	nelfinavir - resistant
didanosine - resistant	amprenavir - resistant
zalcitabine - sensitive	lopinavir - sensitive
stavudine - resistant	
lamivudine - resistant	
abacavir - sensitive	
tenofovir - sensitive	

Social History

Tobacco: 1.5 ppd x 32 years
ETOH: none since 1999
Illicit Drugs - intranasal cocaine in the 70's and 80's, has stopped using.
Caffeine: espresso in the morning
Occupation: currently on disability, was an automotive mechanic
Status: never married, is in monogamous relationship with male partner of 4 years who is involved and supportive of patient's care
Children: no children
Physical Activity: Has not exercised regularly due in part to the recent increase in fatigue, but also the increase in numbness and tingling in the his lower extremities. Prior, LV had walked 2 miles on the beach every morning.
Diet: Eats vegetarian diet cooking at home most nights.

HIV Panel	4-3-03 (clinic)	7-7-03 (clinic)	10-5-03 (clinic)	11-13-03 (admission)
CD4 abs	213	165	50	N/A
Viral load (copies/ml)	<50	6500	100,000	

Fasting Lipids	4-3-03 (clinic)	7-7-03 (clinic)	10-5-03 (clinic)	11-13-03 (admission)
Trig	400	560	580	N/A
HDL-C	30	32	38	
LDL-C	125	130	115	

Urinalysis	4-3-03 (clinic)	7-7-03 (clinic)	10-5-03 (clinic)	11-13-03 (admission)
Glucose	(-)			(-)
Ketones	(-)			(-)
SG				1.001
Bacteria				neg
WBC				neg
RBC				neg
Protein	1+			1+
Leuk Est				neg
Nitrite				neg

X-ray

Plain film front and lateral chest x-ray showing interstitial infiltrates with "ground glass" appearance. Costal margins present. No other abnormalities noted.

Procedures

Blood cultures 2 sets from 2 sites pending.
Induced sputum sample sent, gram stain negative for bacteria, silver stain positive for *Pneumocystis carinii* (aka *P.jeroveci*)

Physical Exam (11-13-03)

Gen: mildly cachectic white male appearing to be stated age in mild respiratory distress
VS: BP 110/60, P 90, RR 24, T 38.1°C, Ht 5'11", Wt 73 kg
HEENT: PERRLA, EOMI, R & L fundus exam without retinopathy, sclera slightly icteric, mucus membranes moist, no oral lesions, dentition intact, no oral thrus
Skin: dry skin, no rashes
Neck: No JVD appreciated, no carotid bruits, no thyromegaly
Heart: RRR, no S_3, S_4 no murmur
Lungs: mild diffuse bilateral rales
Abdomen: soft, symmetrical, nontender, nondistended, + BS, liver palpable 3 fingers breadths below the costal margin, spleen not palpable, no ascites
GU: intact and WNL
Extremities: warm to the touch, pedal and brachial pulses present bilaterally

Plan: Admit patient and consult ID Service. Patient placed on 4L oxygen via NC

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Allergies/Intolerance's

Erythromycin—GI upset
Sulfisoxazole—throat swelling

Prescription Coverage

Insurance: none
Copay: N/A
Cost per month: $400
Annual Income: $20,000

Current Drug Therapy

Drug Name/Dose/Strength/Route	*Prescribed Schedule*	*Duration Start-Stop Dates*	*Compliance/Dosing Issue*
1. efavirenz 600 mg po	hs	4/02 - present	
2. stavudine 20 mg po	bid	4/02 - present	
3. didanosine 200 mg tab po	bid	4/02 - present	
4. azithromycin 1200 mg po	q Sunday	1/00 - present	
5. dapsone 100 mg po	daily	1/00 - present	
6. fluconazole 100 mg po	daily	3/99 - present	
7. atorvastatin 20 mg po	qhs	1/02 - present	
8. glipizide 10 mg po	daily	1997? - present	
9. desipramine 25 mg po	hs	1998 - present	
10. lisinopril 10 mg po	daily	1998 - present	
11. metformin 500 mg po	bid	1999? - present	
12. sertraline 50 mg po	daily	4/02 - present	
13. saquinavir (Fortovase) 400 mg po	bid	1/01 to 4/02	
14. ritonavir 400 mg po	bid	1/01 to 4/02	
15. lamivudine 150 mg po	bid	1/01 to 4/02	
16. zidovudine 300 mg po	bid	1989-1990(?), 1/01 to 4/02	

Medication History

Upon diagnosis of HIV in 1989, LV received zidovudine as monotherapy for approximately one year. He was grossly non-compliant and ultimately was not followed by the HIV clinic for much of the 90's in part due to self-destructive behavior. In 1997 LV began visiting his family doctor in part to get off cocaine but also to right his life. After being diagnosed with HCV he again agreed to be followed by the HIV clinic. LV has been compliant with his medications (missing 1-2 doses per month) as verified by pill counts and pharmacy refill records. He is enthusiastic about his care and helpful to the clinicians who follow his care. Patient has failed trimethoprim/sulfa desensitization twice.

Patient_____Pharmacist_____
Location/Room_____Date_____

ASHP CLINICAL SKILLS COMPETITION
PHARMACIST'S CARE PLAN

Clinical Significance	Health Care Need*	Pharmacotherapeutic Goals	Recommendations for Therapy	Monitoring Parameter(s)	Desired Endpoint(s)	Monitoring Frequency
Most Clinically Significant Problem	Probable *P. carinii* pneumonia (now known as *P. jeroveci*, but still properly referred to as PCP)	▪ resolution of acute *P. carinii* infection ▪ prevent further worsening of pulmonary functioning ▪ prevent secondary infection with nosocomial organisms due to immunocompromised state ▪ prevent intubation	▪ Clindamycin 600 mg IV q8h (or 300–450 mg po q6h) + primaquine 15 mg (base) per day for 21 days of therapy OR ▪ pentamadine 300 mg IV daily for 21 days + ▪ prednisone (or equiv) 40 mg bid x 5 days then taper	▪ CBC ▪ temperature ▪ blood gases ▪ CXR ▪ chemistries ▪ resolution of vital abnormalities ▪ stool for c. diff (clindamycin) ▪ adverse effects (intolerance, allergy) to medications (serum glucose if placed on pentamidine)	▪ Maintain WBC <10, although this is confounded by HIV/AIDS ▪ Temperature <100.4 F ▪ Eventually eliminate the need for supplemental oxygen ▪ Resolution of abnormal CXR ▪ Return patient to better general health ▪ Prevent recurrence (see HIV recs)	Q shift: ▪ vitals ▪ oxygen sat Daily: ▪ CBC, Chemistries ▪ tolerance to medications ▪ physical exam Periodically (prn) ▪ blood cx ▪ sputum cx ▪ urine cx ▪ stool for c diff if diarrhea develops

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ASHP CLINICAL SKILLS COMPETITION
PHARMACIST'S CARE PLAN

Clinical Significance	Health Care Need*	Pharmacotherapeutic Goals	Recommendations for Therapy	Monitoring Parameter(s)	Desired Endpoint(s)	Monitoring Frequency
Major Clinical Significance	Uncontrolled HIV (including HIV nephropathy)	▪ suppress replication of HIV ▪ reduce viral load to undetectable levels within 3–6 months ▪ increase CD4 count (ideally above 200 and beyond) ▪ decrease incidence of OI ▪ minimize impact of HIV on other organ systems (kidney, CNS)	▪ d/c ARV current regimen ▪ indinavir 400 mg po + ritonavir 400 mg po bid (or 800/100 or 800/200) on empty stomach + ▪ tenofovir 300 mg po qd w/food if possible + ▪ abacavir 300 mg po bid See Appendix A below for discussion of other possible selections (or if student answered emtricitabine, azatanavir or enfuviritide) Continue azithro & fluconazole for OI prophylaxis. Switch to pentamidine 300 mg via neb. every 4 wks for PCP	▪ CD4 count, viral load ▪ Scr/renal fxn ▪ renal dosing adjustments as necessary (CICr = 58) ▪ adverse effects (NVD, skin discoloration, dyslipidemia, lipodystrophy, paresthesias), abdominal sx (pancreatitis) ▪ compliance	▪ CD4 > 200, ideally above 350 ▪ Viral load undetectable ▪ Maintain baseline renal function (Scr 1.5) ▪ Prevent further OI (PCP, crypto etc.) ▪ Minimize noncompliance (pt doesn't miss any doses) – pill count or refill history	Every three months (HIV clinic appoints): ▪ CD4 ▪ viral load ▪ chemistries ▪ LFT's
Major Clinical Significance	Anemia	▪ return hgb/hct to normal levels ▪ patient returns to normal activity level ▪ regain strength ▪ reduce potential injury from hypoperfusion	▪ transfusion acutely if patient were to continue dropping hgb/hct acutely	▪ h/h ▪ retic count ▪ TIBC ▪ ferritin ▪ total iron stores ▪ patient interview for signs of occult bleed (GI)	▪ hemoglobin 14–18 g/dl ▪ hematocrit 42–52% ▪ patient has less fatigue and is able to return to ADL	▪ h/h daily while an inpatient ▪ h/h with clinic visits as outpatient ▪ other tests once

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ASHP CLINICAL SKILLS COMPETITION
PHARMACIST'S CARE PLAN

Clinical Significance	Health Care Need*	Pharmacotherapeutic Goals	Recommendations for Therapy	Monitoring Parameter(s)	Desired Endpoint(s)	Monitoring Frequency
Major Clinical Significance	HCV/hepatic dysfunction	▪ suppress HCV to undetectable levels ▪ halt progress of liver dysfunction ▪ improve response to HIV therapy by reducing effects of co-infection	▪ interferon alfa 2b + ribavirin (due to low platelet count assuming hgb resolves) see Appendix B for other options Patient is probably a Child-Pugh class B (although we are not given INR)	▪ HCV viral load ▪ LFT's ▪ CBC ▪ chemistries ▪ physical exam ▪ thyroid function tests ▪ psychological exam ▪ monitor for Lctic acidosis due to ribavirin + NRTI combo: ▪ malaise, myalgias, increasing somnolence respiratory distress, or abdominal symptoms	▪ 1 log reduction in HCV viral load in after 6 months of therapy ▪ consistent normalization of LFT's ▪ platelet count >150 and <450 ▪ hemoglobin 14–18 g/dl ▪ hematocrit 42–52% ▪ normal electrolyte panel ▪ HbgA1C = ~7 ▪ FBG = ~100 ▪ Unbound T4 = 0.8–2.7 ng/dL ▪ TSH = 4–12 mcg/dL ▪ No visual spotting or decrease in acuity ▪ No worsening of depression ▪ No suicidal ideations	▪ appointments weekly until patient stabilized (monthly afterwards) ▪ HCV viral load after 6 months (maybe 3 months) ▪ LFT's, chemistries monthly ▪ CBC with each appt ▪ TSH, T4 annually ▪ Visual exam annually ▪ Psych visits initially, annually and PRN

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Clinical Significance	Health Care Need*	Pharmacotherapeutic Goals	Recommendations for Therapy	Monitoring Parameter(s)	Desired Endpoint(s)	Monitoring Frequency
Major Clinical Significance	Dyslipidemia	▪ Reduce LDL, trig & tot cholesterol while maximizing HDL ▪ prevent thromboembolic complications	▪ d/c atorvastatin due to drug interactions ▪ pravastatin 80 mg po qhs (n.b., this is a dose increase) rosuvastatin 40 mg also appropriate, but is newly approved patient should be titrated up on statin before other meds added	▪ Lipid panel, ALT (but pt will likely get LFT panel due to HIV meds and HCV) & CPK ▪ Ask patient about muscle aches, pains	▪ LDL < 100 (patient is diabetic {CHD risk equivalent}), a smoker and age >45 ▪ HDL >40 ▪ Trig <200 ▪ CK 40–200 IU/L	▪ Lipid panel, LFT's & CPK with HIV clinic appts.
Major Clinical Significance	Contraindication to metformin due to SCr = 1.5	▪ Prevent Lactic Acidosis	▪ D/c metformin ▪ Can increase glipizide to 7.5 mg po bid or start another agent Of note, his FBG is 200 but HgbA1c is normal. Acute rise in FBG could be associated with infection or due to a IV started in ER. Would not aggressively address diabetes at this time.	▪ malaise, myalgias, increasing somnolence, respiratory distress, or abdominal symptoms ▪ maintain diabetic control	▪ Prevent Lactic Acidosis ▪ HgbA1c ▪ FBG	▪ With clinic appts.
Major Clinical Significance	Peripheral Neuropathy that interferes with ADL	▪ regain functionality (ADL's, exercise) ▪ decrease or eliminate pain, numbness, discomfort	▪ get HIV under control ▪ increase dose of desipramine to 50 mg po qhs	▪ pain and functionality assessment (as component of PE and pt interview) ▪ monitor for QTc prolongation especially in combo w/clinda, fluconazole & pentamidine	▪ decrease pain, numbness and discomfort ▪ regain functionality (able to walk on the beach again) ▪ improve overall patient disposition restoring ability to perform ADL ▪ prevent arrhythmia	▪ With clinic appointments ▪ EKG annually

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ASHP CLINICAL SKILLS COMPETITION
PHARMACIST'S CARE PLAN

Clinical Significance	Health Care Need*	Pharmacotherapeutic Goals	Recommendations for Therapy	Monitoring Parameter(s)	Desired Endpoint(s)	Monitoring Frequency
Minor Clinical Significance	Depression	▪ regain interest in ADL's and recreation	▪ assess patient for depression (is it worse or is his lack of motivation due to anemia, worsening HIV or other issues) ▪ increase sertraline to 100 mg po daily (keeping in mind liver dysfunction) ▪ consider generic fluoxetine	▪ routine follow up/ psych consult to appropriately gauge depression	▪ regain interest in ADL's and recreation ▪ No worsening of depression ▪ No suicidal ideations	▪ with clinic appointments and acutely as necessary
Minor Clinical Significance	"safer sex" (meaning no sexual relation can be 100% safe) with partner	▪ prevent transmission of HIV to partner ▪ prevent acquisition of more resistant strain from person who may be infected	▪ recommend and provide condoms if possible ▪ education regarding transmission of blood borne pathogens and other STD's	▪ patient interview ▪ HIV testing of partner	▪ prevent transmission to uninfected partner(s)	▪ With clinic appointments
Minor Clinical Significance	Smoking	▪ prevent CHD and complications ▪ prevent lung cancer, COPD and pulm infections	▪ stop smoking ▪ smoking cessation program ▪ nicotine patch: example *week 1–6 21 mg patch/d* *week 7–8 14 mg patch/d* *week 8–9 7 mg patch/d* ▪ or nicotine polarcrilex gum: example *week 1–6 1 piece (4 mg) every 1–2 hours* *week 7–9 1 piece every 2–4 hours* *week 10–12 one piece every 4–8 hours; maximum of 24 pieces per day*	▪ patient interview ▪ physical assessment	▪ prevent CHD and complications ▪ prevent lung cancer, COPD and pulm infections ▪ maintain pulmonary function	▪ With clinic appointments

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ASHP CLINICAL SKILLS COMPETITION
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Clinical Significance	Health Care Need*	Pharmacotherapeutic Goals	Recommendations for Therapy	Monitoring Parameter(s)	Desired Endpoint(s)	Monitoring Frequency
Minor Clinical Significance	Need for vaccinations	▪ prevent Pneumococcal pneumonia and influenza virus infection ▪ avoid hospital admission and illness potentially detrimental to this immunocompromised patient ▪ prevent HAV & HBV infection	▪ Pneumococcal vaccine now and again within 5 years (may choose to wait until CD4 rebounds) ▪ influenza vaccine if time is September to March and again every fall ▪ give hepatitis A vaccine X one (and possible in 6 months in HIV pop.) ▪ give hepatitis B vaccine series (3 injections over 6 months) – may opt for Twinrix vaccine	▪ monitor patient for respiratory illness ▪ adverse reaction from injection ▪ check that patient has received other vaccines (meningococcus, hemophilus) ▪ has patient had varicella (does he need VZVIG? – assess exposure) ▪ anti-HAV ▪ HBsAb	▪ prevent Pneumococcal pneumonia and influenza virus infection ▪ avoid hospital admission and illness potentially detrimental to this patient ▪ prevent HAV & HBV infection	▪ annually for influenza vaccine ▪ every 5 years for pneumococcal vaccine ▪ check that patient has responded to HAV & HBV vaccine in 1 year

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Appendix A: Rationale for Antiretroviral Selections

Using the patient's data and the DTAW, you will be able to develop an effective care plan for your patient. Clearly define the health care needs. Health care needs include treatment of all acute and chronic medical problems, resolution of all actual or potential drug-related problems, and identification of any other health care services from which your patient may benefit.

PI's

- Saquinavir (Fortovase) – patient has developed clinical and phenotypic resistance to saquinavir. This negates the utility of saquinavir in this patient.
- Indinavir (Crixivan) – probably the best PI at this time, drug is sensitive and has relatively easy dosing when boosted with ritonavir. Nephrolithiasis, dyslipidemia (as with all PI's) and worsening hepatic dysfunction are all of concern and should be monitored. Given the patient's complex situation, indinavir is likely the best PI at this point.
- Ritonavir (Retrovir) – although sensitive, should only be used in combination with another PI to boost levels of the primary drug. In this case should be given with indinavir, 100 or 200 mg twice daily of ritonavir are acceptable.
- Nelfinavir (Viracept) - patient has developed phenotypic resistance to nelfinavir. This negates the utility of nelfinavir in this patient.
- Amprenavir (Agenerase) – patient has developed phenotypic resistance to amprenavir. This negates the utility of amprenavir in this patient.
- Lopinavir/ritonavir (Kaletra) – drug is sensitive, but consider risk of worsening dyslipidemia compounded by the risk of elevating LFT's and death due to liver failure (specifically in patients with HBV or HCV). Student should not receive full credit for this choice.
- Azatanavir (Reyataz) – This newly approved PI was not included on the phenotypic analysis, as the student would not have access to drug information given available references. Azatanavir would be a reasonable choice at 300 mg once daily (pt is likely Child-Pugh class B). Reasons not to choose would be unknown resistance pattern, risk of hyperbilirubinemia and dyslipidemia, and worsening diabetes common to other PI's.

NRTI's

- didanosine (ddi, Videx) – patient has developed clinical and phenotypic resistance to didanosine. This negates the utility of didanosine in this patient.
- tenofovir (Viread) – drug is sensitive, frequency of dosing makes it good for compliance. Biggest issue is risk of renal failure, given the patient's underlying dysfunction. Patient should be monitored closely. Drug is contraindicated in a ClCr <60 ml/min. He is right on the border, but ultimately given his limited choices - this is a good NRTI for this patient.
- stavudine (d4t, Zerit) - patient has developed clinical and phenotypic resistance to stavudine. This negates the utility of stavudine in this patient.
- lamivudine (3tc, Epivir) – patient has developed clinical and phenotypic resistance to lamivudine. This negates the utility of lamivudine in this patient.
- zidovudine (AZT, retrovir) - patient has developed clinical and phenotypic resistance to zidovudine. This negates the utility of zidovudine in this patient.
- abacavir (Ziagen) - drug is sensitive, biggest risk is lactic acidosis and hypersensitivity, patient can receive this NRTI with monitoring.
- zalcitabine (ddc, Hivid) - although drug is sensitive, oppressive peripheral neuropathy eliminates this agent. Student should not receive credit for this answer.
- emtricitabine (Emtriva) - This newly approved NRTI was not included on the phenotypic analysis, as the student would not have access to drug information given available references. It would be a reasonable choice as emtricitabine is therapeutically similar to zalcitabine without the toxicities. Dosing is reduced in renal dysfunction.

Appendix B: Rationale for Management of HCV

Patient should be started on Interferon alfa 2b + ribavirin for best possible response. This decision is made assuming his anemia can be properly resolved.

Peginterferon alfa 2a + ribavirin is an option; however, the pegylated interferon products carry a greater risk of thrombocytopenia with an equal risk of anemia due to the ribavirin.

Peginterferon monotherapy is the last option if the anemia cannot be resolved. This would have the lowest possibility of therapeutic response however.