NATIONAL UNIVERSITY OF LESOTHO

FACULTY OF HEALTH SCIENCES

Department of Pharmacy

PHA 5305: ADVANCED TOPICS IN PHARMACY PRACTICE

JANUARY 2024 **TIME: 3 HOURS** **100 MARKS**

Instructions:

- The paper consists of **seven (7) printed pages** including the **cover page**
- Answer **all** the questions
- Begin every question on a **NEW PAGE**
- The page consists of **three questions**

QUESTION ONE **40 MARKS**

a) An open, randomized, parallel-group study was conducted to investigate whether asthmatic patients, considered adequately treated via pressurized metered-dose inhaler (pMDI), could be transferred to a corresponding nominal dose via turbohaler, an inspiratory flow-driven multidose dry powder inhaler. Calculate the incremental cost effectiveness ratio (ICER); show all calculations and formulae used.

Technology	Cost (M 1 million)	Incremental cost (M 1 million)	Effectiveness (QALY)	Incremental effectiveness (QALY)	ICER M1 million/ QALY
New technology	4		1.5		
Comparator	3	-	1.0	-	-

The ICER is regarded as being too large, what judgement do you place to the turbohaler regarding cost-effectiveness? **10 marks**

b) NUL Pharmacy department intends to establish a retail pharmacy in campus. Based on the costs, a capital of M 65 000.00 is secured for this project. The project is expected to generate M100 000.00 in profit in the next 3 years. The rate of return based on inflation data is 2%. Calculate and interpret the cost-benefit ratio; show all calculations and formulae used. **10 marks**

c) **Scenario 1**: Supercare PTY (LTD) is a pharmaceutical distribution company seeking to venture into prepackaging of antiretroviral medicines into unit packs for patient dispensing. The company has secured supplier for the medicines in bulk. The company rents 40 tablet counting and packaging machines. Again the company hires 8 pharmacist technicians to oversee 5 machines each.

Scenario 2: Suprahealthcare PTY (LTD) is a pharmaceutical distribution company seeking to venture into prepackaging of antiretroviral medicines into unit packs for patient dispensing. The company has secured supplier for the medicines in bulk. The company rents 20 tablet counting and packaging machines. Again the company hires 20 pharmacist technicians to oversee 1 machine each.

Assumption: the productivity of these two companies is the same in terms of unit packs produced per day.

Additional information: 1 table counting packaging machine rent is M2 000.00 per month and hiring pharmacy technician is M1 500.00 per month.

Choose the appropriate cost analysis method and interpret the results; show all calculations. **10 marks**

d) Patients with chronic renal failure who are on hemodialysis suffer from profound anemia, which is often extremely debilitating. Historically, these patients have been managed by the use of blood transfusions. Now, synthetic erythropoietin is available. It is considered to be highly effective, but at a very high cost. Total costs to manage the 1000 patients for 1 year using blood transfusions is M3,128,000.00 Total costs to manage the 1000 patients for 1 year using erythropoietin is M5,547,100.00 So the alternatives are to either give erythropoietin or to give blood transfusions when the patient's "haemoglobin level is below 8g/dl. Utility data for the two alternatives available from the literature suggest that patients maintained on erythropoietin value their health states at a higher level than those maintained on blood transfusions. In a study, 100 patients stated that for a treatment period of 10 years, their utility value for each year (when valued from 0 to 1) on erythropoietin was 0.80, whereas on blood transfusions it was 0.75.

How many extra QALYs are produced by erythropoietin per year of treatment, for the 1000 patients? Calculate and interpret the incremental cost-utility ratio for erythropoietin; show all calculations. **10 marks**

QUESTION TWO **30 MARKS**

You are a pharmacist working at the national pharmacovigilance unit; intending to undertake the causality of assessment of suspected renal impairment. In order to assess the likelihood that the suspected ADR is actually due to the pharmaceutical product, **discuss** the Bradford-Hill criteria under the following; citing the pharmacovigilance data below;

a) Biological gradient
b) Strength
c) Consistency
d) Temporality
e) Plausibility
f) Coherence

Name of facility	**Age**	**M/F**	**Treatment**	**ADR**	**Treatment**	**Date medicine Started**	**Date of reporting**	**Additional information**	**Laboratory tests**
Maluti	33	NI	1.HCTZ25 mg, 2.Nifedipine 10mg od, 3.TDF/3TC/DTG	Renal failure	TDF was switched to ABC, Patient was given Lactulose to decrease amonium compound	None	8/10/2021	Tested HIV+ 2016 and started HAARTTDF/3TC/EFV. Treated for TB in 2016 that was confirmed X-pert Rif-susceptible and completed in march 2017.Dignosed Hypertension in Dec 2018 and put on HCTZ and Adalat later. Oct 2020 EFV was substituted to DTG due to phasing out of EFV.	**11/4/19** Creat 123, ALT52, AST39. **8/10/20** AST 46, Cholesterol 15.94,Urea 4.7 **01/10/21** ALP 163,AST34,T-protein 63, Albumin 51.5Creatinine 297 Urea 6.4

Berea	25	F	1. TDF/3TC/DTG 2. JandJ Vaccine	Headache and generalised body pain	None	None	24/8/21	None	None
Leribe	31	M	1.TDF/3TC/DTG 2.INH300mg, 3. Furosemide20 mg, 4. Captopril25mg	Worsening of coughing after ART initiation(Paradoxical iris)	INH was stopped ATT was initiated	15/08/21	27/8/21	A 31year old diagnosed with Cardiomyopathy and was initiated on HAART TDF/3TC/DTG on 18/8/21. Presumptive TB case gene-X-pert not done when requested. Chest X-Ray showed bilateral lung infiltration. Coughing became worse after ART and that of ART patient came to hospital the gene X-pert came out positive and patient had to start ATT.	13/3/21X-Ray infiltration and enlarged heart, RPR Neg WBC 3.11.22/8/21 X-pert +, Urine PH 5, Protein Urea 3+, Rif-susceptible
Ntshekhe	33	NI	1.HCTZ 25mg 2.Nifedipine 10mg od 3.TDF/3TC/DTG	Renal failure	TDF was switched to ABC, Patient was given Lactulose to decrease amonium compount	1.26/9/18 2.11/4/2019 3.10/2020	8/10/2021	Patient tested +ve 2016 and started HAAR TDF/3TC/EFV. Treated TB in 2016 that was confirmed X-pert Rif-susceptible and completed march 2017. Diagnosed hypertension 19/12/18. October 2020 EFV was switched to DTG due to phasing out of DTG	**11/4/19**Crea123 Cr 73.9,ALT 52,AST 39 **8/10/20**AST 46 Cholestrol 15.94, Urea 4. 7/10/21 ALP 163,AST 34,T-protein63,Albumin51.5, Urea 6.4

Mafeteng	39	NI	TDF/3TC/DTG	Vomiting, waist pain, coldness, yellowish sclera	Patient was switched to Kaletra	20/8/2021	25/8/21	None	None

QUESTION THREE **30 MARKS**

You are a pharmacist recently recruited in a hospital with no DUR program. You have made an observation that antibiotics are not properly used in this hospital. **Outline** the steps you would undertake in setting up a DUR program to address the problem observed gradually over a five-year period; using the information below to justify your steps, making some assumptions where necessary. **1 mark per step**

Access	This group includes antibiotics that have activity against a wide range of commonly encountered susceptible pathogens while also showing lower resistance potential than antibiotics in the other groups. Selected Access group antibiotics are recommended as essential first or second choice empiric treatment options for infectious syndromes reviewed by the EML Expert Committee and are listed as individual medicines on the Model Lists of Essential Medicines to improve access and promote appropriate use.
Watch	This group includes antibiotic classes that have higher resistance potential and includes most of the highest priority agents among the Critically Important Antimicrobials for Human Medicine[1] and/or antibiotics that are at relatively high risk of selection of bacterial resistance. These medicines should be prioritized as key targets of stewardship programs and monitoring. Selected Watch group antibiotics are recommended as essential first or second choice empiric treatment options for a limited number of specific infectious syndromes and are listed as individual medicines on the WHO Model Lists of Essential Medicines.
Reserve	This group includes antibiotics and antibiotic classes that should be reserved for treatment of confirmed or suspected infections due to multi-drug-resistant organisms. Reserve group antibiotics should be treated as “last resort” options. Selected Reserve group antibiotics are listed as individual medicines on the WHO Model Lists of Essential Medicines when they have a favourable risk-benefit profile and proven activity against “Critical Priority” or “High Priority” pathogens identified by the WHO Priority Pathogens List[1]. These antibiotics should be accessible, but their use should be tailored to highly specific patients and settings, when all alternatives have failed or are not suitable. These medicines could be protected and prioritized as key targets of national and international stewardship programs involving monitoring and utilization reporting, to preserve their effectiveness.

Antibiotic	Class	ATC code	Category	Form	Unit price (M)	Regimen
Amoxicillin	Penicillins	J01CA04	Access	capsules	0.57	2 QID x 7/7
Amoxicillin/clavulanic-acid	Beta-lactam/beta-lactamase-inhibitor	J01CR02	Access	tablets	4.20	2 TDS x 7/7
Ampicillin	Penicillins	J01CA01	Access	injection	15.93	1 BD x 3/7
Benzathine-benzylpenicillin	Penicillins	J01CE08	Access	injection	9.11	1 BD x 3/7
Benzylpenicillin	Penicillins	J01CE01	Access	injection	44.16	1 BD x 3/7
Chloramphenicol	Amphenicols	J01BA01	Access	capsules	0.93	1 TDS x 7/7
Cloxacillin	Penicillins	J01CF02	Access	capsules	0.63	2 TDS x 7/7
Doxycycline	Tetracyclines	J01AA02	Access	tablets	0.60	1 BD x 7/7
Metronidazole_oral	Imidazoles	P01AB01	Access	tablets	0.34	1 TDS x 7/7
Ceftriaxone	Third-generation-cephalosporins	J01DD04	Watch	injection	14.17	1 BD x 3/7
Ciprofloxacin	Fluoroquinolones	J01MA02	Watch	tablets	0.17	1 BD x 3/7
Vancomycin_IV	Glycopeptides	J01XA01	Watch	injection	50.26	1 OD x 3/7
Colistin_IV	Polymyxins	J01XB01	Reserve	infusion	150.00	1 OD x 3/7
Polymyxin-B_IV	Polymyxins	J01XB02	Reserve	infusion	200.00	1 OD x 3/7
Linezolid	Oxazolidinones	J01XX08	Reserve	tablets	100.00	1 OD x 7/7