PSF426 dan PSF427

Pendahuluan Farmasi Klinis

Pertemuan 1

Topik Sesuai RPS:
Memahami Tugas dan Peran Apoteker dalam pelayanan farmasi Klinis di Rumah Sakit dan Komunitas

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Topik Sebelum UTS

Sesi 1

Pendahuluan Farmasi Klinis

Sesi 2

Farmakokinetika Klinis dan aplikasinya

Sesi 3

Farmakokinetika Klinis untuk populasi khusus (Geriatri, Pediatri, Ibu hamil dan menyusui)

Sesi4

Data klinis dan interpretasinya

Sesi 5

Evidence Based Medicine

Sesi 6

Adverse Drugs Reaction

Sesi 7

Self-Medication

Ujian Tengah Semester

Clinical Pharmacy

This mission is exemplified through the practice of medication therapy management (MTM) services.

Meningkatkan outcome terapi dan meminimalkan risiko efek samping dan untuk tujuan keselamatan pasien sehingga kualitas hidup pasien (quality of life) terjamin.

- **UU 17 tahun 2023 tentang Kesehatan**
- **Permenkes 72 tahun 2016 Farmasi RS**
- **Permenkes 73,74 tahun 2016 Farmasi Apotek, Puskesmas**

- **Manajemen Farmasi**
- **Farmasi Klinis**

Pharmaceutical Management

Task of Pharmacist - Management

1. **Sediaan Farmasi**
2. **Alat Kesehatan,**
3. **Bahan Medis Habis Pakai**

a. pemilihan;
b. perencanaan kebutuhan;
c. pengadaan;
d. penerimaan;
e. penyimpanan;
f. pendistribusian;
g. pemusnahan dan penarikan;
h. pengendalian; dan
i. administrasi.

Pengadaan
analisis - pengadaan - penerimaan

Pengelolaan dan administrasi
manajemen penyimpanan - depo ruang - evaluasi - administrasi

Clinical Pharmacy

Clincial Pharmacy

1. Pengkajian dan pelayanan resep
2. Penelusuran riwayat penggunaan obat
3. Rekonsiliasi obat
4. Pelayanan Informasi Obat (PIO)
5. Konseling
6. Visite
7. Pemantauan Terapi Obat (PTO)
8. Monitoring Efek Samping Obat (MESO);
9. Evaluasi Penggunaan Obat (EPO);
10. Dispensing sediaan steril
11. Pemantauan Kadar Obat dalam Darah (PKOD);

Rumah sakit

a. pengkajian dan pelayanan resep;
b. dispensing;
c. Pelayanan Informasi Obat (PIO);
d. konseling;
e. Pelayanan kefarmasian di rumah (*home pharmacy care*);
f. Pemantauan Terapi Obat (PTO); dan
g. Monitoring Efek Samping Obat (MESO).

Apotek

Clincial Pharmacy

Puskesmas

1. Pengkajian dan pelayanan Resep
2. Pelayanan Informasi Obat (PIO)
3. Konseling
4. Visite pasien (khusus puskesmas rawat inap)
5. Monitoring Efek Samping Obat (MESO)
6. Pemantauan Terapi Obat (PTO)
7. Evaluasi Penggunaan Obat

Klinik

Rawat Jalan

1. Pengkajian dan Pelayanan Resep
2. Pelayanan Informasi Obat
3. Konseling
4. Pemantauan Terapi Obat
5. Monitoring Efek Samping Obat (MESO)/Farmakovigilans
6. Evaluasi Penggunaan Obat (EPO)
7. Pelayanan Kefarmasian di rumah *(Home Pharmacy Care)*

Rawat Inap

1. Pengkajian dan Pelayanan Resep
2. Penelusuran Riwayat Penggunaan Obat
3. Rekonsiliasi Obat
4. Pelayanan Informasi Obat
5. Konseling
6. Ronde/Visite pasien
7. Pemantauan Terapi Obat
8. Monitoring Efek Samping Obat (MESO)/Farmakovigilans
9. Evaluasi Penggunaan Obat (EPO)
10. Pelayanan Kefarmasian di rumah *(Home Pharmacy Care)*

Pengkajian Resep

Analisis Administratif

- Nama, umur, jenis kelamin, berat badan dan tinggi badan pasien;
- Nama, nomor izin, alamat, dan paraf dokter;
- Tanggal resep; dan
- Ruangan/unit asal resep.

Analisis Farmasetik

- Nama obat, bentuk, dan kekuatan sediaan;
- Dosis dan jumlah obat;
- Stabilitas; dan
- Aturan dan cara penggunaan.

Analisis Klinis

- Ketepatan indikasi, dosis dan waktu penggunaan obat;
- Duplikasi pengobatan;
- Alergi dan Reaksi Obat yang Tidak Dikehendaki (ROTD);
- Kontraindikasi; dan
- Interaksi obat

Penelusuran Riwayat Obat dan Rekonsiliasi

Aims to list, compare, analyse and give suggestion/ recommendation

Penelusuran Riwayat Obat

Mendapatkan informasi mengenai seluruh obat/sediaan farmasi lain yang pernah dan sedang digunakan, riwayat pengobatan dapat diperoleh dari wawancara atau data rekam medik/pencatatan penggunaan obat pasien.

Rekonsiliasi

Membandingkan instruksi pengobatan dengan obat yang telah didapat pasien. Rekonsiliasi dilakukan untuk mencegah terjadinya kesalahan obat (medication error), seperti obat tidak diberikan, duplikasi, kesalahan dosis atau interaksi obat.

Kesalahan obat (medication error) rentan terjadi pada pemindahan pasien dari satu rumah sakit ke rumah sakit lain, antar-ruang rawat, serta pada pasien yang keluar dari rumah sakit ke layanan kesehatan primer dan sebaliknya.

Pemberian Informasi Obat

Jenis PIO	Sasaran	Tujuan
PIO dalam penyerahan obat kepada pasien	Pasien dan/ Keluarga Obat	Penjelasan 5O Ketepatan dan kepatuhan terhadap terapi
PIO dalam penyerahan obat kepada sejawat tim kesehatan	Teman sejawat kesehatan Dokter, Perawat, Gizi, dkk	Ketepatan pemberian terapi, Ketepatan penyimpanan Laporan terkait ADR Jawaban dari pertanyaan sejawat
PIO dalam konteks penyusunan formulasi	Tim Farmasi Terapi/ Manajemen Medis/ penunjang medis, direktur dkk	Penyusunan formularium, penyusunan tatalaksana terapi, dkk
Penyuluhan masyarakat	??	??

Konseling

Konseling obat adalah suatu aktivitas pemberian nasihat atau saran terkait terapi obat dari apoteker (konselor) kepada pasien dan/atau keluarganya.

Kriteria Pasien Konseling:

- Pasien **kondisi khusus** (pediatri, geriatri, gangguan fungsi ginjal, ibu hamil dan menyusui)
- Pasien dengan **terapi jangka panjang/penyakit kronis**
- Pasien yang menggunakan obat dengan **instruksi khusus**
- Pasien yang menggunakan obat dengan **indeks terapi sempit**
- Pasien yang menggunakan banyak obat **(polifarmasi)**
- Pasien yang mempunyai **riwayat kepatuhan rendah**

Prime Questions:

- Apa yang disampaikan oleh dokter tentang obat Anda?
- Apa yang dijelaskan oleh dokter tentang cara pemakaian obat Anda?
- Apa yang dijelaskan oleh dokter tentang hasil yang diharapkan setelah Anda menerima terapi obat ini?

Visite

- Visite Bersama
- Visite Mandiri

Mengamati kondisi klinis pasien secara langsung, dan mengkaji masalah terkait obat, memantau terapi obat dan reaksi obat yang tidak dikehendaki (ROTD), meningkatkan terapi obat yang rasional, dan menyajikan informasi obat kepada dokter, pasien, dan profesional kesehatan lain.

Pemantauan Terapi Obat (PTO)

Suatu proses yang mencakup kegiatan untuk memastikan terapi obat yang aman, efektif, dan rasional bagi pasien. Tujuan PTO adalah meningkatkan efektivitas terapi dan meminimalkan risiko reaksi obat yang tidak dikehendaki (ROTD).

1. Anak-anak dan lanjut usia, ibu hamil, dan menyusui.
2. Pasien yang menerima lebih dari lima jenis obat.
3. Pasien yang memiliki multidiagnosis.
4. Pasien dengan gangguan fungsi ginjal atau hati.
5. Pasien yang menerima obat dengan indeks terapi sempit.
6. Pasien yang menerima obat yang diketahui sering menyebabkan reaksi obat yang merugikan.

Tools: SOAP & DRPs

Subjective, Objective, Assessment, Planning

FORM PEMANTAUAN TERAPI OBAT

Hari/Tanggal :

A. Identitas Pasien :

Nama Pasien : Medrec :

Umur : MSR :

Berat Badan : Poliklinik dan :

Tinggi Badan : Nor Penyakit :

B. Tanda Vital

TD : Kec. Respirasi (RR) : PO2 :

Suhu : Nadi (HR) :

C. SOAP

Penilaian	Uraian
Subjektif	
Objektif	
Assessment	
Plan	
Keterangan :	

D. Diagnosa Kerja

-
-
-
-
-

E. Pemeriksaan Fisik

F. Hasil Laboratorium

Drugs Related Problems by PCNE

Drugs Related Problems (DRPs) Checklist (PCNE)			
No	Items	Details	Checklist
1	Lack Of Drugs	Terdapat indikasi tidak terobati	
2	Unnecessary Drugs	Terdapat obat tanpa indikasi	
3	Wrong Medicine	Interaksi obat aktual	
		Interaksi obat potensial	
		Kontraindikasi	
		Salah obat (inappropriate)	
		Salah sediaan (inappropriate)	
4	Dosage	Dosis terlalu rendah	
		Dosis terlalu tinggi	
		Durasi terlalu pendek	
		Durasi terlalu panjang	
5	Adverse Events	Reaksi Efek Samping	
		Reaksi Obat yang Tidak Diinginkan	
6	Patients Related Problems	Masalah dalam kepatuhan	
		Kesalahan konsumsi obat	

Monitoring Efek Samping Obat

Pemantauan setiap respons terhadap obat yang tidak dikehendaki, yang terjadi pada dosis lazim yang digunakan pada manusia untuk tujuan profilaksis, diagnosis, dan terapi.

- **Mendeteksi adanya kejadian reaksi obat yang tidak dikehendaki (ESO);**
- **Mengidentifikasi obat-obat dan pasien yang mempunyai risiko tinggi mengalami ESO;**
- **Mengevaluasi laporan ESO dengan algoritme Naranjo;**
- **Mendiskusikan dan mendokumentasikan ESO di Komite/Tim/Panitia Farmasi dan Terapi;**
- **Melaporkan ke Pusat Monitoring Efek Samping Obat Nasional melaui website e-MESO BPOM.**

FORMULIR PELAPORAN EFEK SAMPING OBAT (ESO) | Kode Sumber Data :

PENDERITA

Nama (Singkatan) : | Umur : | Suku : | Berat Badan : | Pekerjaan :

Kelamin (Beri Tanda √) :
- Pria
- Wanita
- Hamil
- Tidak hamil
- Tidak tahu

Penyakit Utama :

Kesudahan Penyakit Utama (Beri Tanda √) :
- Sembuh
- Sembuh dengan gejala sisa
- Belum sembuh
- Meninggal
- Tidak Tahu

Penyakit / Kondisi Lain yang Menyertai (Beri Tanda √) :
- Gangguan Ginjal
- Gangguan Hati
- Alergi
- Kondisi medis lainnya
- Faktor lokasi, pertanian, sosial
- Lain-lain :

EFEK SAMPING OBAT

Reaksi / Manifestasi ESO yang Terjadi / Kelainan Lain :

Masalah pada Mutu/ Kualitas Produk Obat :

Saat/Tanggal Mulai Terjadi :

Kesudahan ESO (Beri Tanda √) :
Tanggal :
- Sembuh
- Sembuh dengan gejala sisa
- Belum sembuh
- Meninggal
- Tidak tahu

Riwayat ESO yang Pernah Dialami :

OBAT

Nama (Nama Dagang/Nama Generik/Indonesi/ Farmasi)	Bentuk Sediaan	Obat (Ya/Tidak) (Beri Tanda √)	No. Batch	Obat yang Dihentikan (Beri Tanda √)	Penberian				Indikasi Penggunaan
					Cara	Dosis/ Waktu	Tgl. Mulai	Tgl. Akhir	
1.									
2.									
3.									
4.									
5.									
6.									
7.									
8.									
9.									
10.									

Keterangan Tambahan (misalnya : kemungkinan timbulnya Efek Samping Obat, reaksi setelah obat dihentikan, pengobatan yang diberikan untuk mengatasi ESO):

Data Laboratorium (bila ada) :

Tgl. Pemeriksaan :

..... /tgl ..... /20..

Tanda Tangan Pelapor

(.....)

Evaluasi Penggunaan Obat

Evaluasi penggunaan obat yang terstruktur dan berkesinambungan secara kualitatif dan kuantitatif

ATC/DDD Index 2024

A searchable version of the complete ATC index with DDDs is available below. The search options enable you to find ATC codes and DDDs for substance name and/or ATC levels. In your search result you may choose to show or hide the text from the Guidelines for ATC classification and DDD assignment linked to the ATC level. The text in the Guidelines will give information related to the background for the ATC and DDD assignment.

Search query

ATC code | or | name | Search

containing query

ATC code

- All ATC levels are searchable.
- A search will result in showing the exact substance/level and all ATC levels above (up to 1st ATC level).

A ALIMENTARY TRACT AND METABOLISM
B BLOOD AND BLOOD FORMING ORGANS
C CARDIOVASCULAR SYSTEM
D DERMATOLOGICALS
G GENITO URINARY SYSTEM AND SEX HORMONES
H SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS
J ANTIINFECTIVES FOR SYSTEMIC USE
L ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS
M MUSCULO-SKELETAL SYSTEM
N NERVOUS SYSTEM
P ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS
R RESPIRATORY SYSTEM
S SENSORY ORGANS
V VARIOUS

Dispensing

- Steril
- Terapi Parenteral Nutrisi (TPN)
- Sitotoksik

Teknik aseptik untuk menjamin sterilitas dan stabilitas produk dan melindungi petugas dari pajanan zat berbahaya serta menghindari terjadinya kesalahan pemberian obat.

Pemantauan Kadar Obat dalam Darah

Personalized Dosing

≤ 2 ml trough blood sample collection

Therapeutic drug monitoring

Dose adjustment probabilities discussion

Interpretation of results

Sample analysis and results communication

Home Pharmacy Care

Melakukan pelayanan kefarmasian yang bersifat kunjungan rumah, khususnya untuk kelompok lansia dan pasien dengan pengobatan penyakit kronis lainnya.

Ultimate Goals?

- [x]
- [x]
- [x]
- [x]

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Today's Recaps

PSF426

Aplikasi Farmakokinetika Klinis

Pertemuan 2

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Ujian Tengah Semester

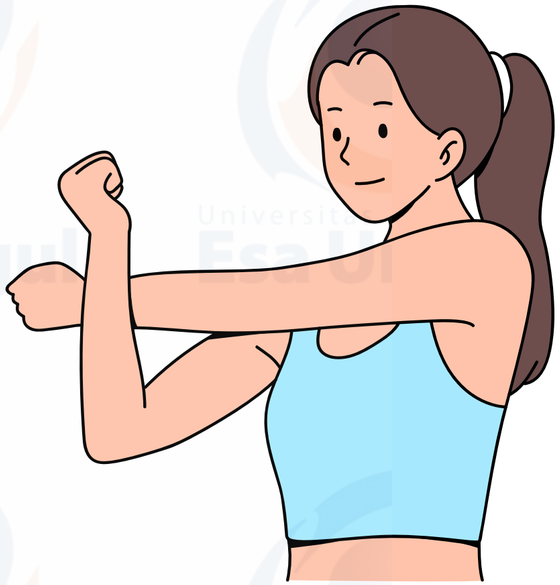
Clinical Pharmacy

Increase the effectivity, Reducing the ADRs

Using Pharmacokinetics to optimize the treatment.

- **Therapy Drugs Monitoring** → **Narrow therapeutic index, cytotoxic**
- **Individualization of Drugs Dosage Regimens** → **Renal Disease, Hepatic Disease Cancer/ autoimmune**
- **Converting Drugs Form** → **Inpatients to Outpatients**

How is pharmacokinetics implementation on daily



EXCERCISE:
SULPHONYLUREAS
BISOPROLOL

1. **Frequency**
    a. **what parameters affect to that items**
2. **Toxicity and adjustment dose**
    a. **Renal parameters**
    b. **hepatic parameters**

Narrow Therapeutic Index

Keep it on Range

- Select drug.
- Design dosage regimen.
- Evaluate patient response.
- Determine need for measuring serum drug concentrations.
- Perform pharmacokinetic evaluation of drug concentrations.
- Readjust dosage regimen, if necessary.
- Monitor serum drug concentrations.
- Recommend special requirements.

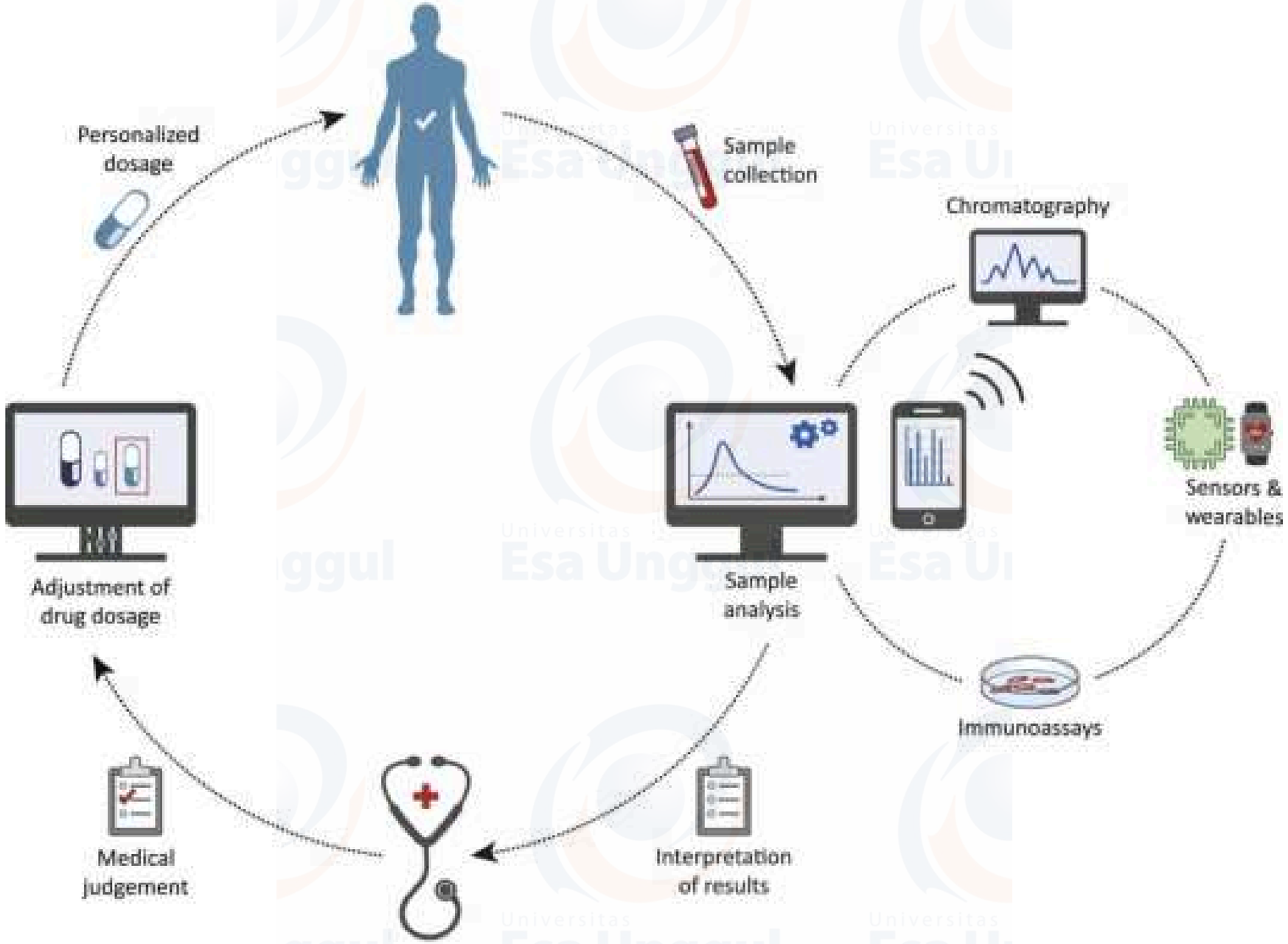
TABLE 22-2 Factors Producing Variability in Drug Response

Patent Factors	Drug Factors
Age	Bioavailability and biopharmaceutics
Weight	Pharmacokinetics (including absorption, distribution, and elimination)
Pathophysiology	Drug interactions
Nutritional status	Receptor sensitivity
Genetic variability Gender	Rapid or slow metabolism

TABLE 22-1 Therapeutic Range for Commonly Monitored Drugs

Amikacin	20–30 μg/mL
Carbamazepine	4–12 μg/mL
Digoxin	1–2 ng/mL
Gentamicin	5–10 μg/mL
Lidocaine	1–5 μg/mL
Lithium	0.6–1.2 mEq/L
Phenytoin	10–20 μg/mL
Procainamide	4–10 μg/mL
Quinidine	1–4 μg/mL
Theophylline	10–20 μg/mL
Tobramycin	5–10 μg/mL
Valproic acid	50–100 μg/mL
Vancomycin	20–40 μg/mL

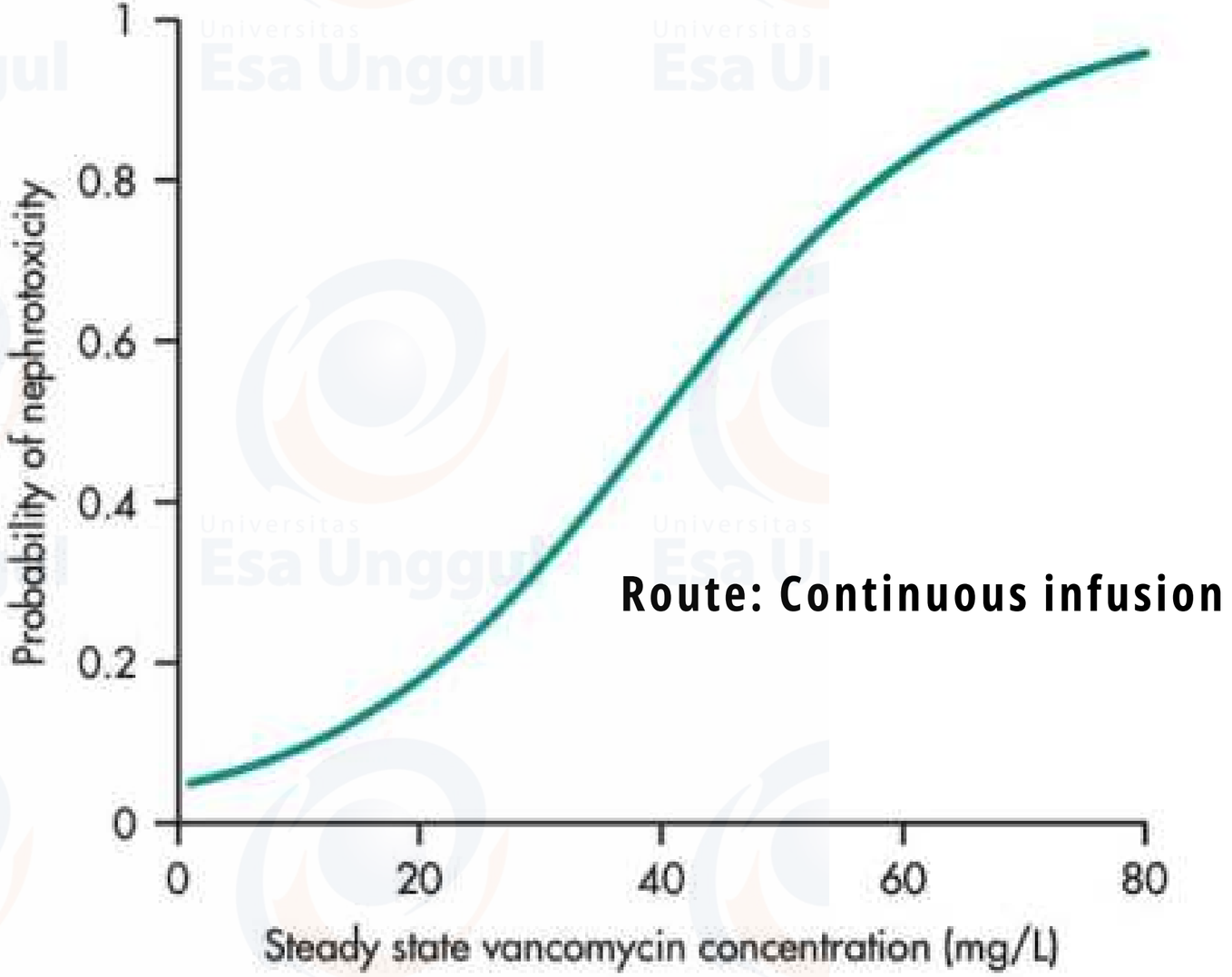
Therapeutic drug monitoring



Trends in Biotechnology

Example

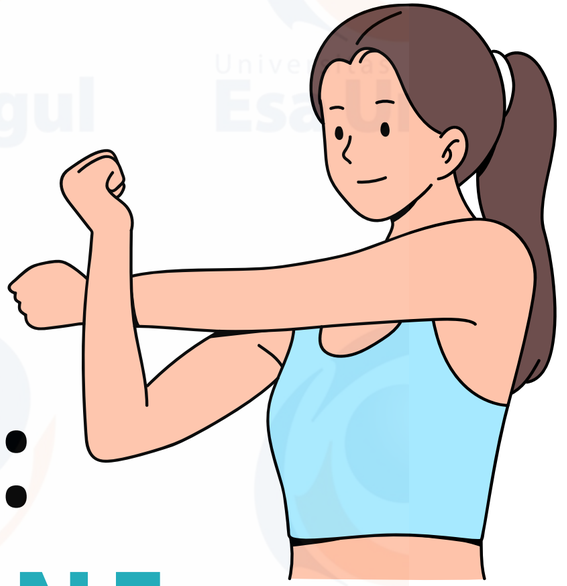
Vancomycin



Route: Continuous infusion

EXCERCISE:

VANCOMYCINE
METHOTREXATE



VANCOMYCINE

1. **The best form for vancomycine**
2. **Toxicity and adjustment dose**
    a. **Renal parameters**
    b. **hepatic parameters**
3. **Peak value - therapeutic range (minimize the toxicity - nephrotoxicity)**

METHOTREXATE

1. Toxicity and adjustment dose
    a. Renal parameters
    b. hepatic parameters
2. The best time to give the leucovorin ca/ ca folinate rescue in accordance to toxicity of MTX

HEPATIC/RENAL DISEASE DOSE - ADJUSTMENT

Clinical Parameters

Renal Disease:

- **Creatinine Clearance**
- **GFR**

Hepatic Disease

- **Child Pugh Score**

- The Cockroft-Gault formula

$$GFR = [(140 - age) \times weight]/[(72 \times SCr) \times 0.85 \text{ (if female)}]$$

Parameter	Assign 1 point	Assign 2 points	Assign 3 points
Ascitis	Absent	Slight	Moderate
Bilirubin (mg/dL)	< 2	2-3	>3
Albumin (g/dL)	>3.5	2.8-3.5	<2.8
Prothrombin time (second over control) or INR	<4 <1.7	4-6 1.7-2.3	>6 >2.3
Encephalopathy	None	Grade 1-2 (Mild to moderate)	Grade 3-4 (Severe)

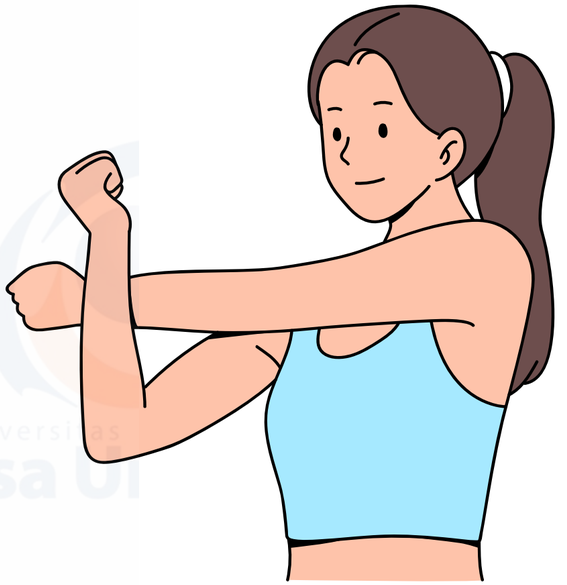
Clinical Parameters

GFR Category	GFR (mL/min/1.73 m²)	Description
G1	≥90	Normal or High
G2	60-89	Mildly decreased
G3a	45-59	Mildly to moderately decreased
G3b	30-44	Moderately to severely decreased
G4	15-29	Severely decreased
G5	<15	Kidney failure

The severity of cirrhosis:

- Child-Pugh A: 5 to 6 points
- Child-Pugh B: 7 to 9 points
- Child-Pugh C: 10 to 15 points

EXCERCISE:
LEVOFLOXACIN
DEFERASIROX



LEVOFLOXACIN

1. **What is toxicity major on that drugs?**
2. **Toxicity and adjustment dose**
    a. **Renal parameters**
    b. **hepatic parameters**

DEFERASIROX

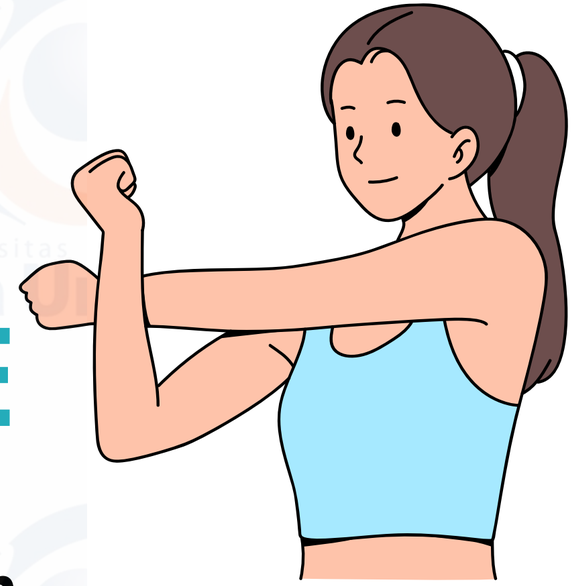
1. **What is toxicity major on that drugs?**
2. **Toxicity and adjustment dose**
    a. **Renal parameters**
    b. **hepatic parameters**

WHAT WE NEED TO KNOW WHEN CHANGING THE FORMS

PHARMACEUTICS & PHARMACOKINETICS Parameters

1. **S** (fraction of active compound on salt)
2. **BA** (BIOAVAIBILITY - percentage)

EXCERCISE:
AMINOPHYLLINE



An adult male asthmatic patient (age 55 years, 78 kg) has been maintained on an intravenous infusion of aminophylline at a rate of 34 mg/h. The steady-state theophylline drug concentration was 12 µg/mL and total body clearance was calculated as 3.0 L/h. Calculate an appropriate oral dosage regimen of theophylline for this patient.

where S is the salt form of the drug and D0/t is the dosing rate.

Answer

Aminophylline is a soluble salt of theophylline and contains 85% theophylline ($S = 0.85$). Theophylline is 100% bioavailable ($F = 1$) after an oral dose.

where S is the salt form of the drug and D0/t is the dosing rate.

$$\text{Theophylline dose rate} = \frac{SFD_0}{\tau}$$

$$= \frac{(0.85)(1)(34)}{1} = 28.9\text{mg/h}$$

Answer

The theophylline dose rate of 28.9 mg/h must be converted to a reasonable schedule for the patient with a consideration of the various commercially available theophylline drug products. Therefore, the total daily dose is 28.9 mg/h × 24 h or 693.6 mg/d. Possible theophylline dosage schedules might be 700 mg/d, 350 mg every 12 hours, or 175 mg every 6 hours. Each of these dosage regimens would achieve the same C_{av}^{∞} but different C_{max}^{∞} and C_{min}^{∞}, which should be calculated. The dose of 350 mg every 12 hours could be given in sustained-release form to avoid any excessive high drug concentration in the body.

Additional topics: Drugs Interaction!

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Today's Recaps

PSF426

Aplikasi Farmakokinetika Klinis - Populasi Khusus

Pertemuan 3

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Adverse Drugs Reaction

Sesi 7

Self-Medication

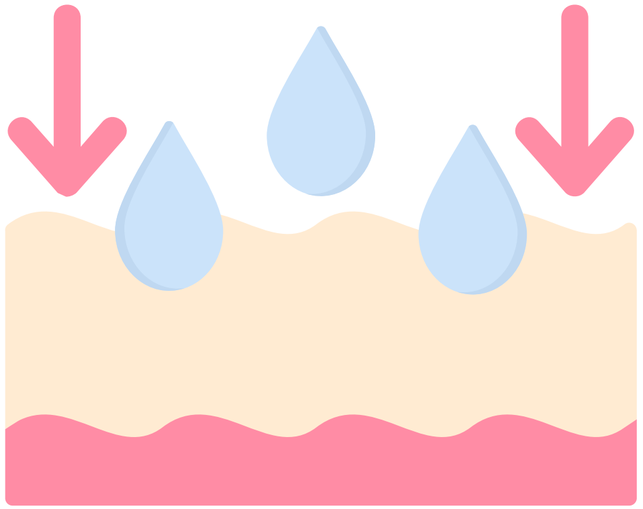
Ujian Tengah Semester

Specific populations

Populations that have important differences in pharmacokinetic

- **Geriatric** → Functional deficits of multiorgan systems
- **Pediatric** → Not miniature adults, nor belong to a homogeneous population as their anatomical development and physiological functions
- **Obesity** → Since the actual fat content in body tissues is difficult to measure in a clinical setting

Geriatric



ABSORBTION

GASTROINTESTINAL

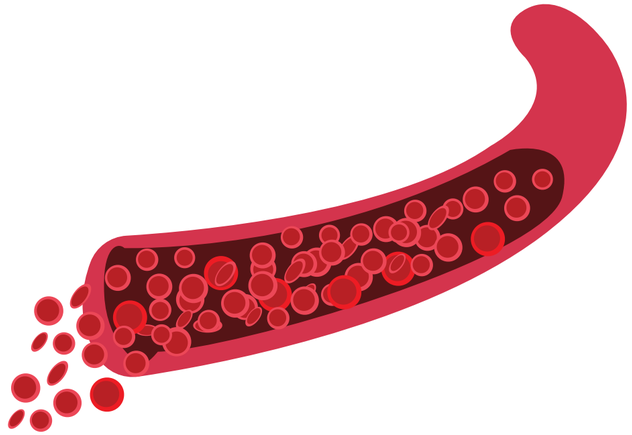
PH, Blood Flow, Motility

TRANSDERMAL

Skin Hidration, Lipid structure

SUBKUTAN DAN INTRAMUSKULAR

Blood flow



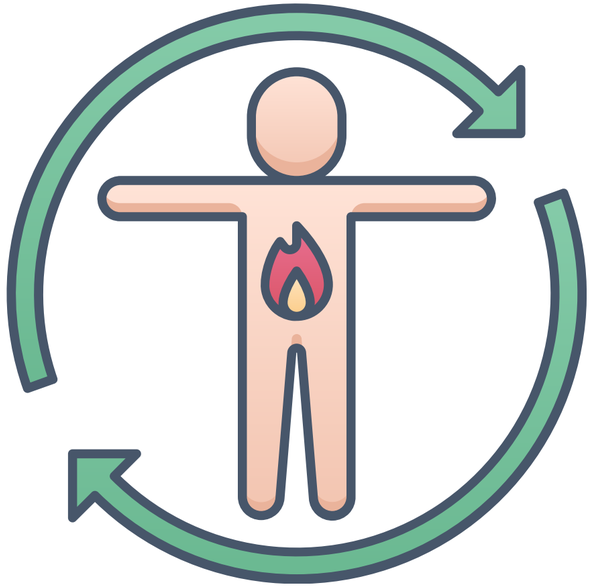
DISTRIBUTION

BODY COMPOSITION

Muscle mass, water, lipid.
co/ benzodiazepin (lipofilik),
digoksin (hidrofilik)

PROTEIN PLASM

Albumin
co/ warfarin (NTI)



METABOLISM
EXCRETION

HEPATIC FUNCTION

size, blood flow, function (enzymes)

RENAL FUNCTION

GFR, Renal Blood Flow

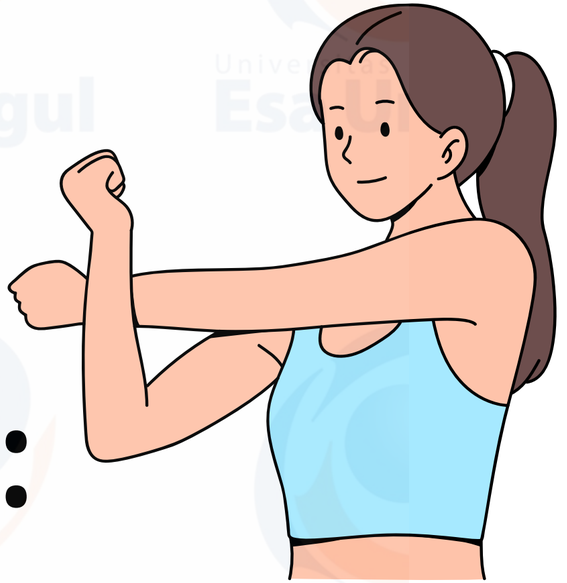
ADJUSTMENT DOSE ON GERIATRICS

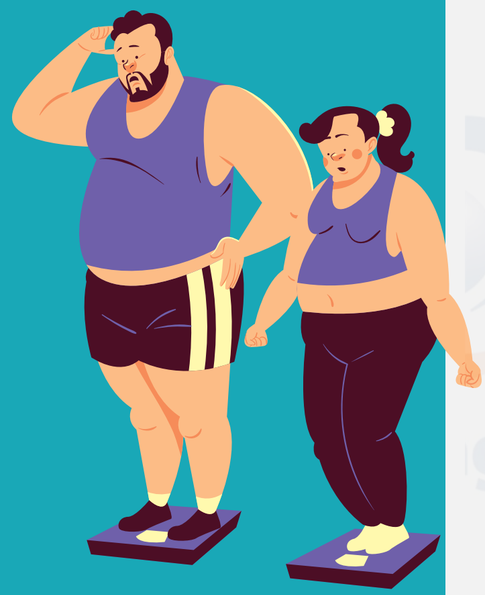
1. **Start Low, go Slow!**
2. **Renal and Hepatic Assessment**
3. **Instrument** Screening Tool of Older Persons' Prescriptions (STOPP)
   Screening Tool to Alert to Right Treatment (START)

Case

1. **Digoksin**: Pada lansia, volume distribusi obat ini berkurang karena penurunan massa otot dan air tubuh total. Oleh karena itu, dosis digoksin perlu dikurangi untuk mencegah toksisitas.
2. **Warfarin**: Karena penurunan metabolisme hati, lansia lebih rentan terhadap akumulasi warfarin, yang meningkatkan risiko perdarahan. Pemantauan rutin kadar INR (International Normalized Ratio) sangat penting, dan dosis warfarin sering kali perlu dikurangi.
3. **Metformin**: Karena metformin terutama diekskresikan melalui ginjal, dan lansia cenderung mengalami penurunan fungsi ginjal, dosis metformin harus disesuaikan untuk menghindari risiko asidosis laktat.

EXCERCISE:
Gentamycin





Obesity

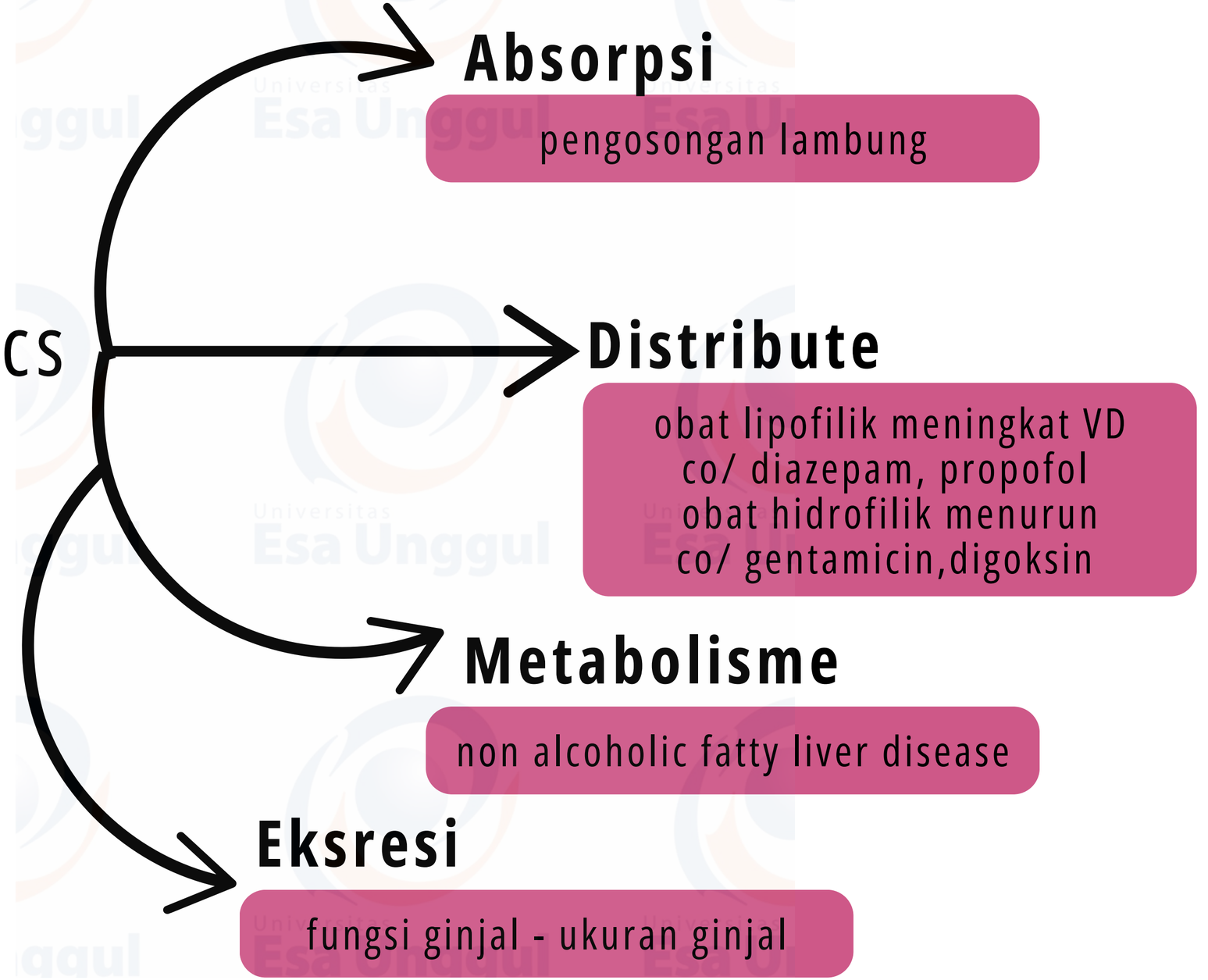
TABLE 23.2-1 Classification of Obesity Based on BMI

Classification	BMI (kg/m²)
Underweight	<18.5
Normal body weight	18.5–24.9
Overweight	25–29.9
Obese	30–39.9
Morbidly obese	≥40

Physiology changes

- **Peningkatan Massa Lemak**: Proporsi lemak tubuh yang lebih besar menyebabkan perubahan distribusi obat, terutama untuk obat yang larut dalam lemak (lipofilik). Obat-obatan ini dapat terakumulasi dalam jaringan lemak, sehingga memengaruhi durasi dan intensitas efek obat.
- **Perubahan Aliran Darah:** Obesitas dapat mengubah perfusi organ, yang dapat memengaruhi distribusi dan eliminasi obat. Perfusi jaringan adiposa lebih rendah dibandingkan jaringan otot, yang menyebabkan distribusi obat-obatan lipofilik lebih lambat.
- **Peningkatan Berat Badan Total:** Massa tubuh yang lebih besar berpotensi meningkatkan volume distribusi obat, yang mempengaruhi konsentrasi plasma dan durasi efek obat.

Pharmakokinetics



ADJUSTMENT DOSE ON OBESITY

(Total Body Weight, TBW), berat badan ideal (Ideal Body Weight, IBW), atau berat badan yang disesuaikan (Adjusted Body Weight, ABW)

1. **Obat Hidrofobik (Larut dalam Lemak)**: Obat-obatan seperti **diazepam, propofol, atau midazolam**, yang larut dalam lemak, akan memiliki volume distribusi yang lebih besar pada pasien obesitas. Dosis pemeliharaan harus disesuaikan berdasarkan TBW karena obat ini cenderung terakumulasi di jaringan lemak. Namun, dosis awal (loading dose) mungkin tidak perlu disesuaikan secara signifikan.
2. **Obat Hidrofilik (Larut dalam Air)**: Obat-obatan yang larut dalam air seperti **gentamisin, vancomisin, atau digoksin** memiliki distribusi yang lebih terbatas pada pasien obesitas. Penyesuaian dosis pada obat-obatan ini lebih baik dilakukan dengan menggunakan IBW atau ABW, karena volume distribusi untuk obat hidrofilik tidak meningkat secara signifikan pada pasien dengan berat badan berlebih.
3. **Obat yang Dimetabolisme di Hati:** Beberapa obat yang dimetabolisme di hati (**seperti atorvastatin)** mungkin memerlukan penyesuaian dosis karena perubahan fungsi metabolisme akibat obesitas dan komorbiditas yang menyertainya, seperti steatosis hepatik atau resistensi insulin.
4. **Obat yang Diekskresikan melalui Ginjal:** Untuk obat-obatan yang diekskresikan terutama melalui ginjal, seperti **aminoglikosida,** dosis pemeliharaan sering kali perlu disesuaikan dengan TBW atau ABW tergantung pada laju eliminasi ginjal pasien. Fungsi ginjal harus dinilai secara teratur untuk menentukan penyesuaian dosis yang tepat.

(Total Body Weight, TBW)

TBW adalah berat badan total seseorang saat ini, yang diukur menggunakan timbangan. TBW digunakan sebagai dasar untuk menghitung dosis beberapa obat, terutama obat yang memiliki distribusi besar dalam jaringan adiposa (lemak), karena obat-obatan ini larut dalam lemak.

Kapan menggunakan TBW?

1. Obat-obatan lipofilik (larut dalam lemak), seperti propofol, diazepam, dan midazolam, memerlukan penyesuaian dosis berdasarkan TBW karena mereka terdistribusi lebih banyak di jaringan lemak pada pasien obesitas.
2. TBW digunakan juga untuk menentukan dosis obat yang ekskresinya tergantung pada fungsi ginjal jika ginjal masih berfungsi dengan baik

Berat Badan Ideal (Ideal Body Weight, IBW)

IBW adalah berat badan "ideal" seseorang, dihitung berdasarkan tinggi badan. Konsep ini digunakan untuk memperkirakan berat badan seseorang yang memiliki proporsi normal antara lemak dan otot, sehingga lebih relevan untuk menghitung dosis obat yang memiliki distribusi terbatas dalam air tubuh dan otot.

- Kapan menggunakan IBW?
  - Obat-obatan hidrofilik (larut dalam air) seperti gentamisin atau digoksin, yang memiliki distribusi terbatas dalam air tubuh, harus disesuaikan menggunakan IBW untuk menghindari overdosis, terutama pada pasien obesitas.
  - IBW sering digunakan juga untuk menghitung dosis obat pada pasien dengan obesitas berat, di mana TBW tidak akurat karena volume distribusi obat lebih terkait dengan air tubuh daripada jaringan lemak.

Rumus IBW untuk pria:

- $IBW\ (kg) = 50 + 0{,}9 \times (\text{Tinggi badan dalam cm} - 152)$

Rumus IBW untuk wanita:

- $IBW\ (kg) = 45{,}5 + 0{,}9 \times (\text{Tinggi badan dalam cm} - 152)$

Berat Badan yang Disesuaikan (Adjusted Body Weight, ABW)

ABW adalah berat badan yang disesuaikan, digunakan untuk menghitung dosis pada pasien obesitas berat di mana penggunaan TBW bisa menyebabkan overdosis, sementara IBW mungkin terlalu rendah dari dosis yang diperlukan. ABW memberikan keseimbangan antara TBW dan IBW dengan memperhitungkan sebagian dari berat badan berlebih.

Kapan menggunakan ABW?

- ABW sering digunakan untuk obat yang larut dalam air tetapi juga memiliki distribusi yang lebih besar daripada yang dihitung dengan IBW, seperti aminoglikosida. Ini memberikan perkiraan dosis yang lebih tepat pada pasien dengan obesitas berat.
- Misalnya, jika seorang pasien memiliki berat badan 120 kg, tetapi IBW-nya hanya 70 kg, menggunakan ABW akan menghasilkan perhitungan yang lebih akurat dibandingkan menggunakan TBW sepenuhnya.

Rumus ABW:

- $\text{ABW (kg)} = \text{IBW} + 0{,}4 \times (\text{TBW} - \text{IBW})$

TABLE 23.2-2 Weight Descriptors and Related Equations

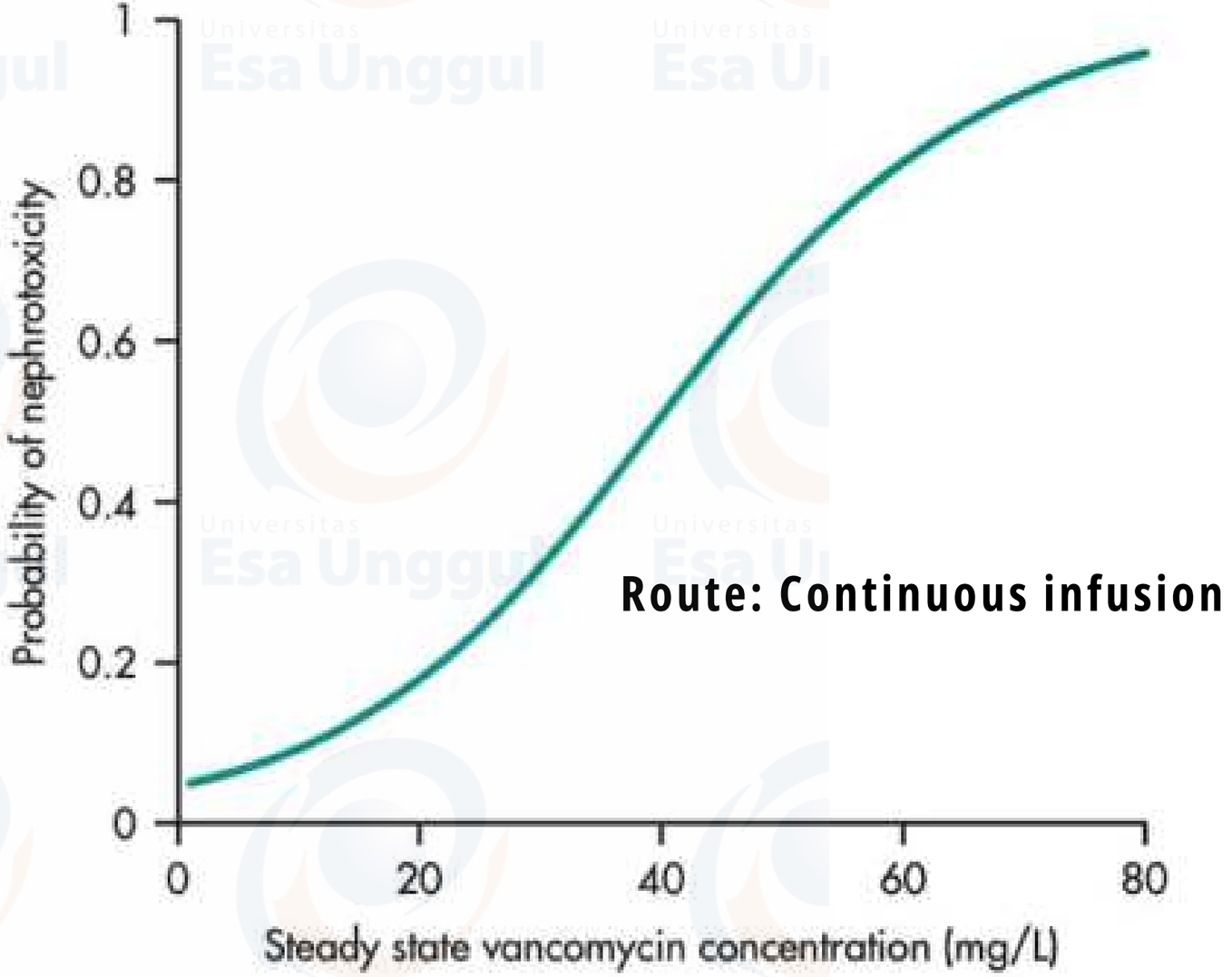
Weight Descriptor	Equation	No.	Ref.
BMI	[Weight (kg)/height (cm)^2] × 10,000 (cm^2/m^2)	23.2.1	World Health Organization (1998)
Ideal body weight (IBW), kg	Male: 50 + 2.3 × [Height (inches) – 60] Female: 45.5 + 2.3 × [Height (inches) – 60]	23.2.2	Devine (1974)
Total body weight (TBW), kg	Measured body weight	23.2.3	
Adjusted body weight (Adj. BW), kg	IBW + 0.4 × (TBW – IBW)	23.2.4	Bauer et al (1983)
Lean body weight (LBW2005), kg	Male: (9270 × TBW)/(6680 + 216 × BMI) Female: (9270 × TBW)/(8780 + 244 × BMI)	23.2.5 23.2.6	Janmahasatian et al (2005)

Case

1. **Vancomisin**: Dosis vancomisin harus disesuaikan dengan TBW karena obat ini diekskresikan melalui ginjal dan memiliki volume distribusi yang lebih besar pada pasien obesitas. Pemantauan kadar obat dalam darah juga dianjurkan untuk memastikan efektivitas terapi dan mencegah toksisitas.
2. **Propofol**: Karena propofol sangat larut dalam lemak, distribusi dan durasi aksinya dapat diperpanjang pada pasien obesitas. Dosis pemeliharaan sering kali harus disesuaikan berdasarkan TBW untuk mencapai konsentrasi plasma yang stabil, tetapi dosis induksi (loading dose) umumnya tidak terlalu berubah.
3. **Gentamisin**: Untuk gentamisin, obat yang larut dalam air dan diekskresikan melalui ginjal, dosis harus disesuaikan dengan IBW atau ABW karena volume distribusi yang tidak berubah signifikan dengan peningkatan berat badan.

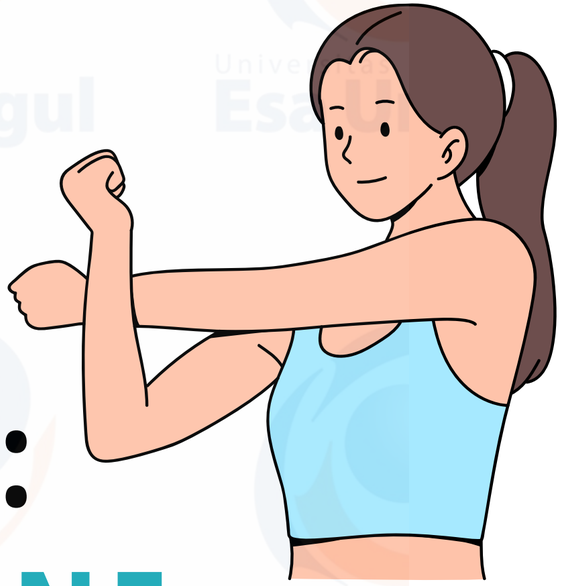
Example

Vancomycin



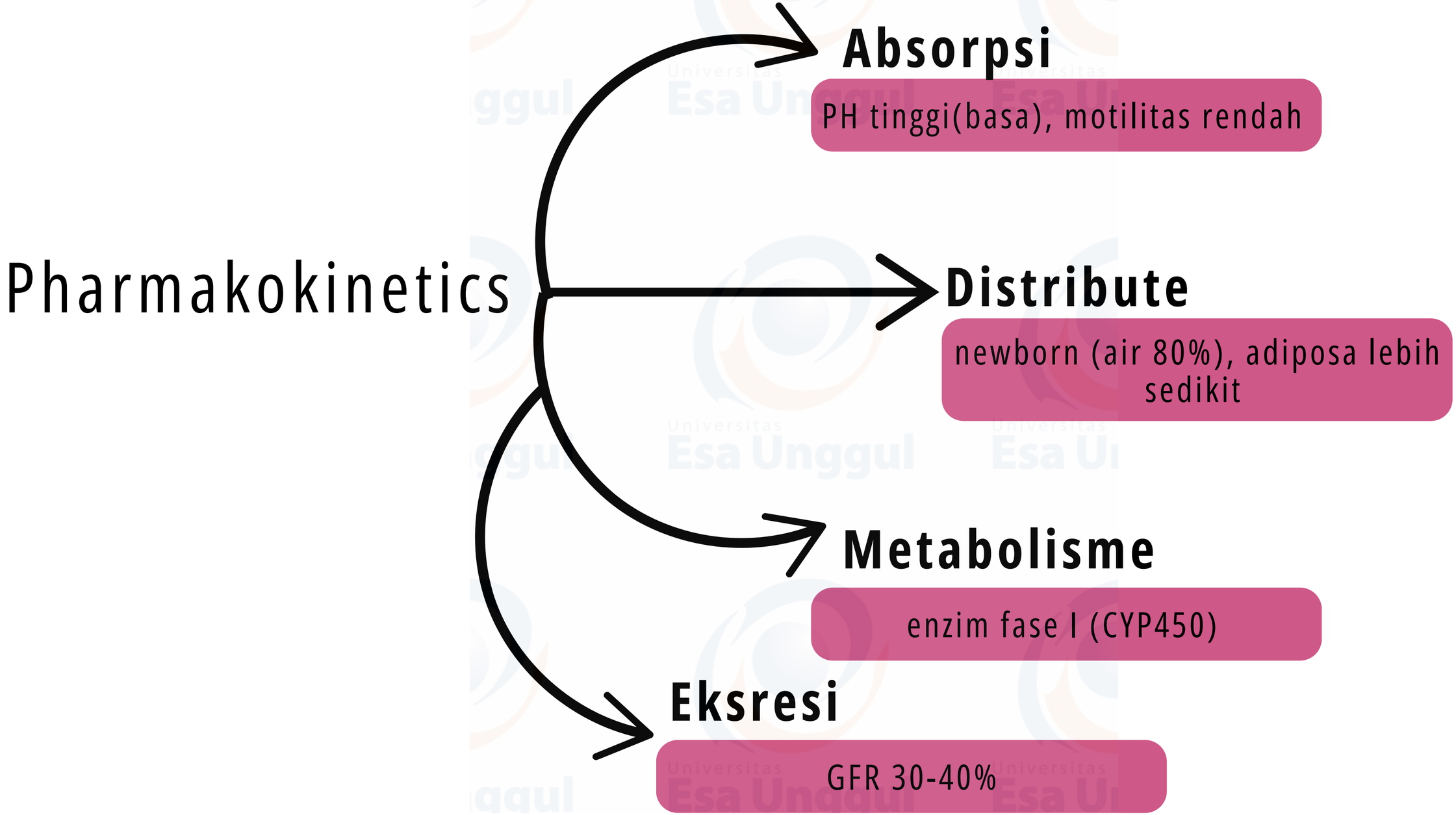
Route: Continuous infusion

EXCERCISE:
VANCOMYCINE

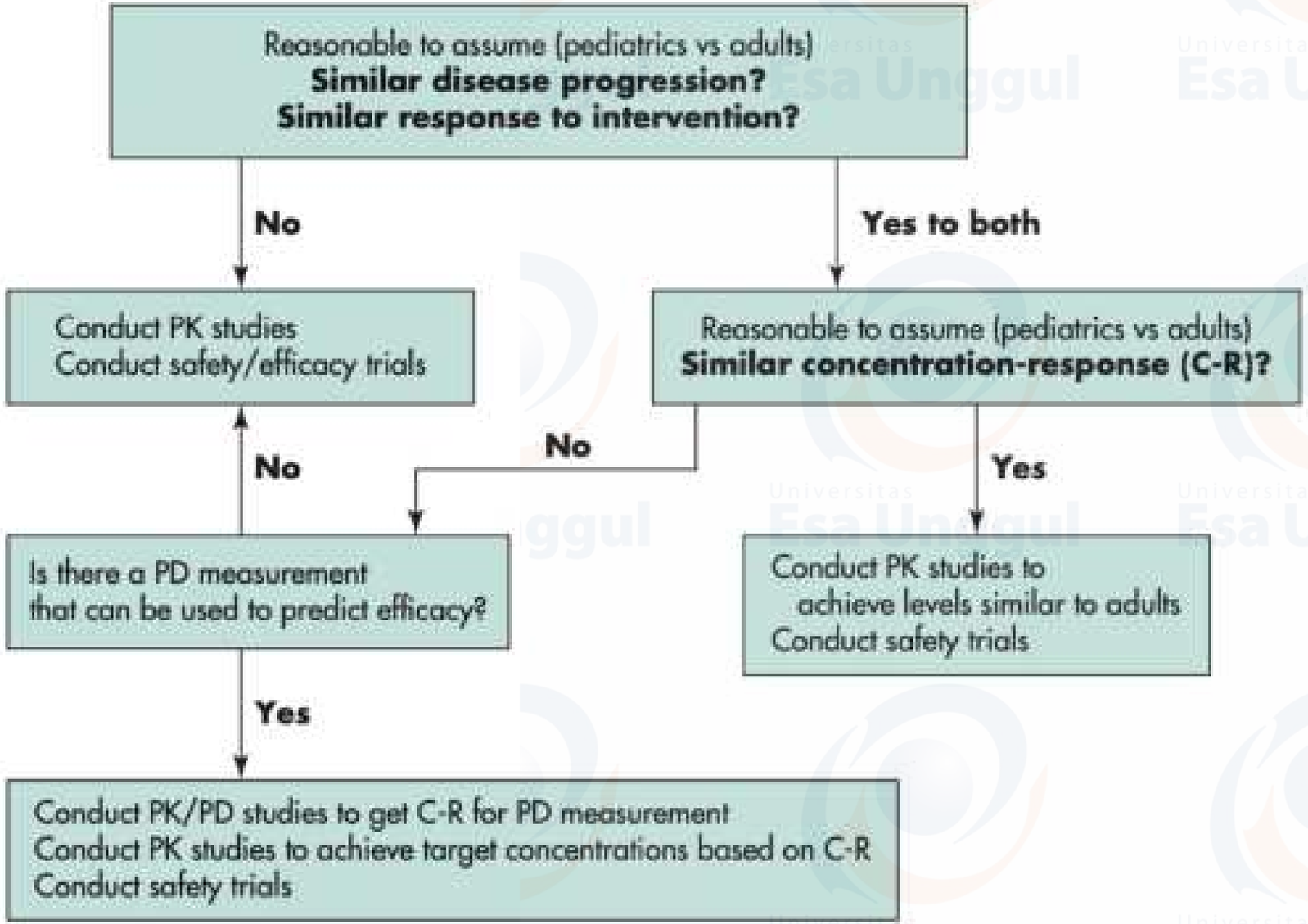


Pediatrics

Premature (preterm) neonates	Born at gestational age <38 weeks
Neonates (term newborn)	0–4 weeks postnatal age
Infants	1 month to 2 years of age (1 month to <12 months old)
Children	2–12 years of age (1–12 years old)
Adolescents	12–21 years of age (13–16, 18, or 19 years old)


Pharmakokinetics
Absorpsi
PH tinggi(basa), motilitas rendah
Distribute
newborn (air 80%), adiposa lebih sedikit
Metabolisme
enzim fase I (CYP450)
Eksresi
GFR 30-40%

Adjustment


Reasonable to assume (pediatrics vs adults)
Similar disease progression?
Similar response to intervention?
No
Yes to both
Conduct PK studies
Conduct safety/efficacy trials
Reasonable to assume (pediatrics vs adults)
Similar concentration-response (C-R)?
No
No
Yes
Is there a PD measurement
that can be used to predict efficacy?
Conduct PK studies to
achieve levels similar to adults
Conduct safety trials
Yes
Conduct PK/PD studies to get C-R for PD measurement
Conduct PK studies to achieve target concentrations based on C-R
Conduct safety trials

Adjustment

Physiological or PK Characteristic	Neonate	Infant	Child	Adolescent
Absorption				
Gastric pH	——	↑	↑	↔
GI transit time	——	↓	——	↔
Biliary function	↓	——	↔	↔
Distribution				
Total water/ECF	——	——	↓~ ↔	↔
Total body fat	↓	↓	——	——
Plasma protein	↓	——	↔	↔
Metabolism				
CYP enzymes	↓↓	——	——	↔
Phase II enzymes	↓	↓	——	↔
Excretion				
Glomerular filtration	↓	——	↔	↔
Tubular secretion	——	~ ↔	↔	↔
Tubular reabsorption				

Adjstment Dose

- Rumus dasar dosis berdasarkan berat badan
- Rumus penyesuaian dosis berdasarkan BSA (indeks terapi sempit, kemoterapi)
- Formula Khusus (Clarck, Young)

Dosis anak (mg) = Dosis dewasa (mg) × (Berat badan anak (kg) / 70 kg)

Dosis anak (mg) = Dosis dewasa (mg) × (BSA anak (m^2) / BSA dewasa (1.73 m^2))

Rumus Clark (berdasarkan berat badan):

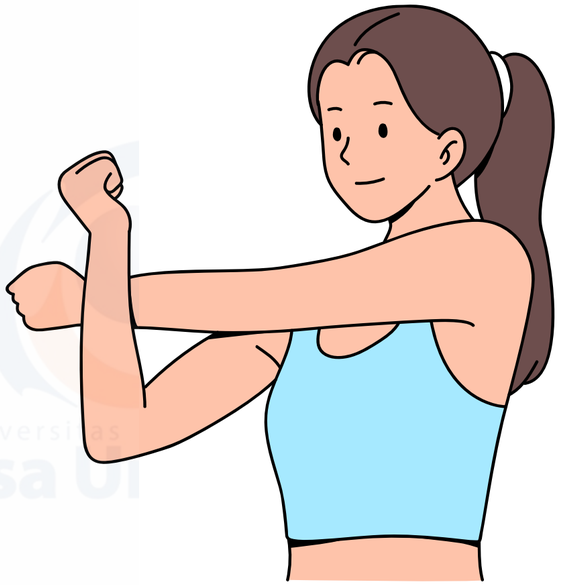
Dosis anak = (Berat badan anak (kg) / Berat badan dewasa) × Dosis dewasa

Rumus Young (berdasarkan usia):

Dosis anak = (Usia anak / (Usia anak + 12)) × Dosis dewasa

EXCERCISE:

Acetaminophen



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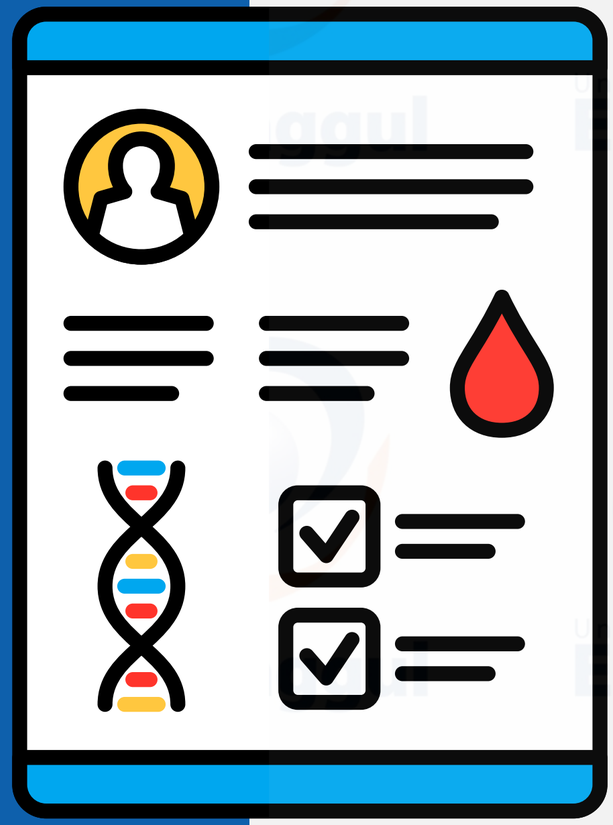
Rise your hand!

any question?



PSF426

Interpretasi Data Klinis Farmasi Klinis

Pertemuan 4

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Topik Sebelum UTS

Sesi 1

Pendahuluan Farmasi Klinis

Sesi 2

Farmakokinetika Klinis dan aplikasinya

Sesi 3

Farmakokinetika Klinis untuk populasi khusus (Geriatri, Pediatri, Ibu hamil dan menyusui)

Sesi4

Data klinis dan interpretasinya

Sesi 5

Evidence Based Medicine

Sesi 6

Adverse Drugs Reaction

Sesi 7

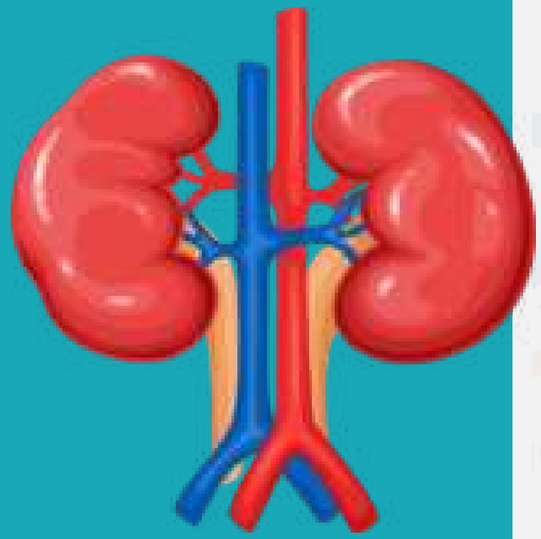
Self-Medication

Ujian Tengah Semester

Clinical Data

Data Objektif Laboratorium yang digunakan sebagai alat bantu dalam penilaian kondisi pasien

- **Skrinning** → **Deteksi dini penyakit sebelum gejala klinis muncul**
  co/kadar gula darah, kolesterol, asam urat
- **Diagnosis** → **Data penunjang penegakan diagnosa**
  co/ darah lengkap, kultur
- **Monitoring Terapi** → **Efektivitas, toksisitas**
  co/ INR, PT APTT, Natrium, Kalium, Kreatinin, SGPT/OT

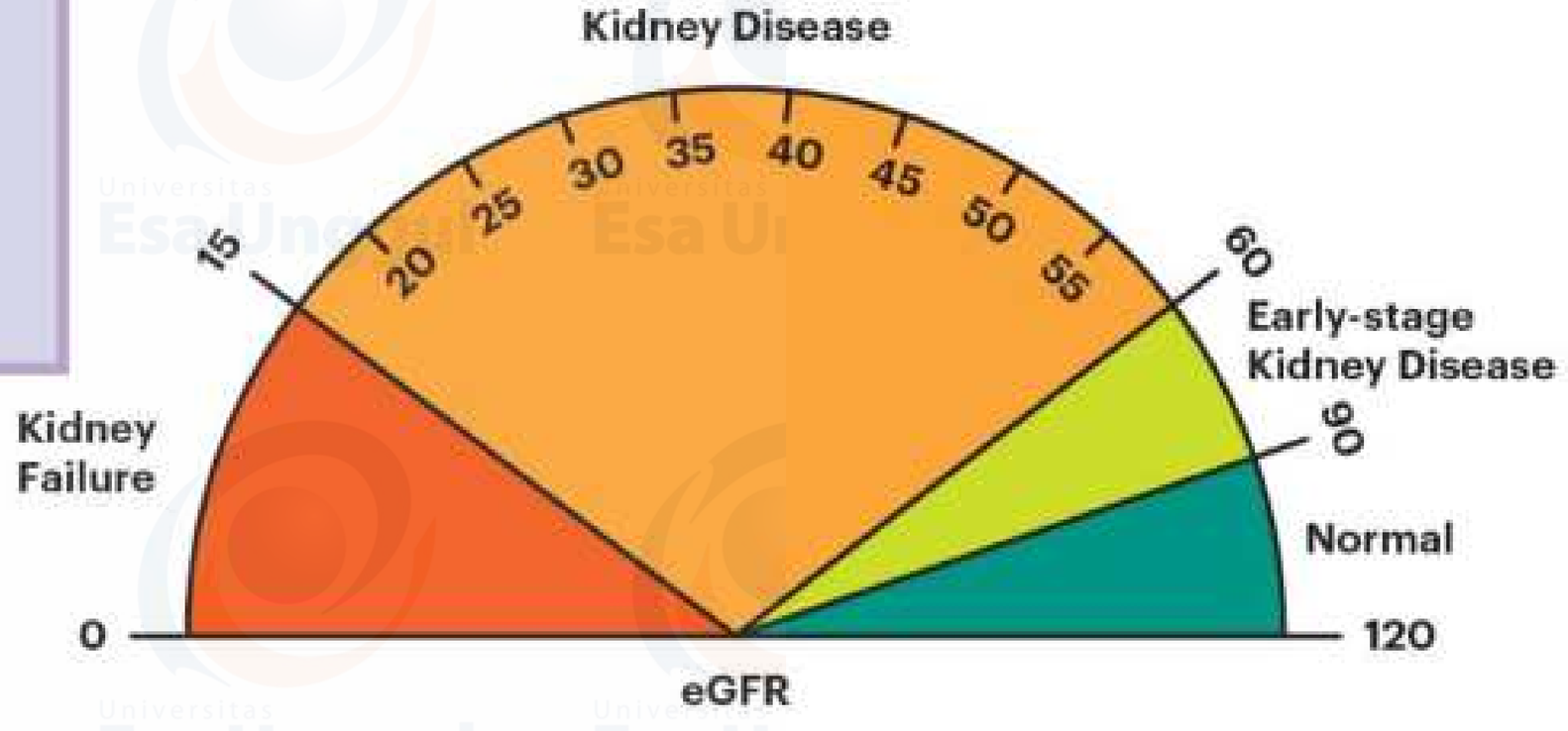


Fungsi Ginjal

<table>
<tr><th>Parameter</th><th>Definisi/ Interpretasi</th><th>Nilai Referensi</th></tr>
<tr><td>Kreatinin Serum</td><td>Kreatinin adalah produk samping metabolisme otot yang diekskresikan oleh ginjal. Peningkatan kadar kreatinin serum menunjukkan penurunan fungsi ginjal.</td><td>Men: 0.7 to 1.3 mg/dL (61.9 to 114.9 µmol/L)
Women: 0.6 to 1.1 mg/dL (53 to 97.2 µmol/L)</td></tr>
<tr><td>Urea Serum</td><td>is a waste product that your kidneys remove from your blood. Higher than normal BUN levels may be a sign that your kidneys aren't working well</td><td>5 to 20 mg/dl or
1.8 to 7.1 mmol urea per liter</td></tr>
<tr><td>Estimated GFR</td><td>Digunakan untuk menilai seberapa baik ginjal dalam menyaring darah.</td><td>
<table>
<tr><th>Stages</th><th>GFR value ml/ min/1.73m2</th><th>Classification</th></tr>
<tr><td>I</td><td>>90</td><td>Normal or High</td></tr>
<tr><td>II</td><td>60-89</td><td>Slightly decreased</td></tr>
<tr><td>III A</td><td>45-59</td><td>Mild to moderately decreased</td></tr>
<tr><td>III B</td><td>30-44</td><td>Moderately to severely de-creased</td></tr>
<tr><td>IV</td><td>15-29</td><td>Severely decreased</td></tr>
<tr><td>V</td><td><15</td><td>Kidney failure</td></tr>
</table>
</td></tr>
</table>

Panel 3: Typical adult reference ranges for tests for renal function

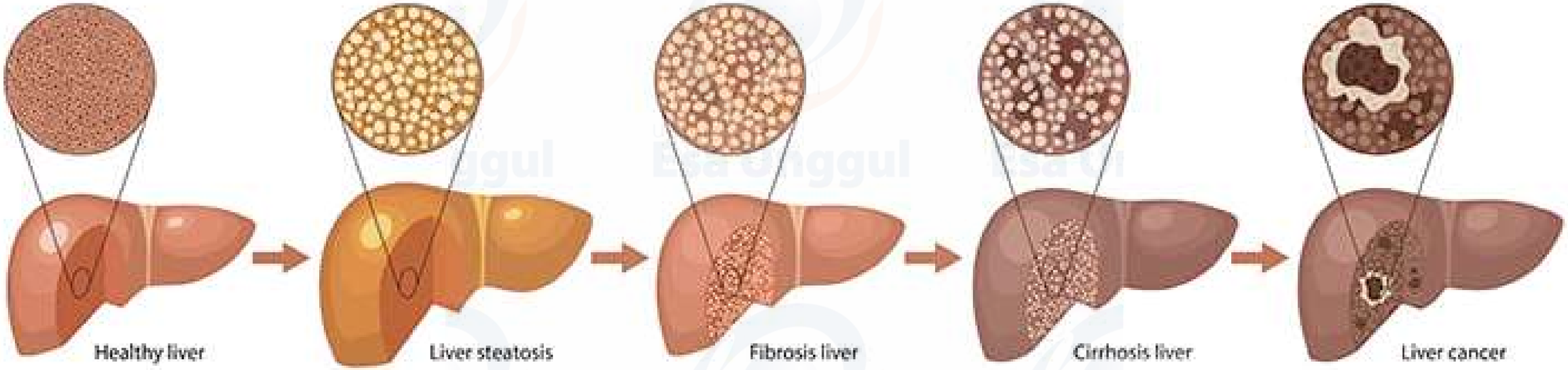
Sodium	135–148mmol/L
Potassium	3.5–5.0mmol/L
Chloride	95–105mmol/L
Serum creatinine	0.7–1.4mg/dl
Creatinine clearance	97–137ml/min ♂ 88–128ml/min ♀
Blood urea nitrogen	7–20 mg/dl



Fungsi Hati

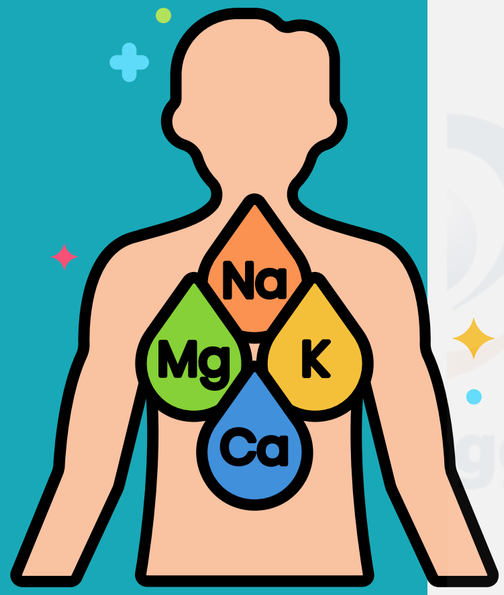
Parameter	Definisi/ Interpretasi	Nilai Referensi
AST dan ALT	Aspartate Aminotransferase dan Alanine Aminotransferase Kadar yang meningkat menunjukkan kerusakan pada sel-sel hati.	**AST: 5 to 40 units per liter** **ALT: 7 to 56 units per liter of serum**
Alkaline Phosphatase (ALP)	Enzyme that exists throughout your body. High levels of ALPin your blood may indicate liver disease or certain bone	**44 to 147 IU/L / 0.73 - 2.45 (µkat/L)**
Bilirubin	Byproduct of broken-down old red blood cells - function of hepatic	Direct (also called conjugated) bilirubin: **Less than 0.3 mg/dL (less than 5.1 µmol/L)** Total bilirubin**: 0.1 to 1.2 mg/dL (1.71 to 20.5 µmol/L)**

STAGES OF LIVER DAMAGE



Fungsi Hati (LFT)

Ukuran	Satuan	Nilai Rujukan
ALT (SGPT)	U/L	< 23 (P) < 30 (L)
AST (SGOT)	U/L	< 21 (P) < 25 (L)
Alkalin fosfatase	U/L	15 – 69
GGT (Gamma GT)	U/L	5 – 38
Bilirubin total	mg/dL	0,25 – 1,0
Bilirubin langsung	mg/dL	0,0 – 0,25
Protein total	g/L	61 – 82
Albumin	g/L	37 – 52



Kadar Elektrolit

Parameter	Definisi/ Interpretasi	Nilai Referensi
Natrium	Kadar natrium yang rendah (hiponatremia) atau tinggi (hipernatremia) dapat mempengaruhi fungsi neurologis dan kardiovaskular.	**135 - 145 mEq/L**
Kalium	Kalium penting untuk fungsi otot dan jantung. Hiperkalemia atau hipokalemia dapat menyebabkan aritmia yang berbahaya	**3.6 - 5.2 mmol/L**
Kalsium	Kalsium diperlukan untuk fungsi otot, saraf, dan tulang. Hipokalsemia atau hiperkalsemia dapat menyebabkan gejala neuromuskular atau kardiovaskular.	**8.5 - 10.5 mg/dL (2.12 to 2.62 mmol/L)**

Tes Hematologi dan Biokimia Darah

Darah Lengkap

Darah

Ukuran	Satuan	Nilai Rujukan
Eritrosit (sel darah merah)	juta/µl	4,0 – 5,0 (P) 4,5 – 5,5 (L)
Hemoglobin (Hb)	g/dL	12,0 – 14,0 (P) 13,0 – 16,0 (L)
Hematokrit	%	40 – 50 (P) 45 – 55 (L)
Hitung Jenis		
Basofil	%	0,0 – 1,0
Eosinofil	%	1,0 – 3,0
Batang[1]	%	2,0 – 6,0
Segmen[1]	%	50,0 – 70,0
Limfosit	%	20,0 – 40,0
Monosit	%	2,0 – 8,0
Laju endap darah (LED)	mm/jam	< 15 (P) < 10 (L)
Leukosit (sel darah putih)	10^3/µl	5,0 – 10,0
MCH/HER	pg	27 – 31
MCHC/KHER	g/dL	32 – 36
MCV/VER	fl	80 – 96
Trombosit	10^3/µl	150 – 400

Catatan:

1. Batang dan segmen adalah jenis neutrofil. Kadang kala dilaporkan persentase neutrofil saja, dengan nilai rujukan 50,0 – 75,0 persen

Biokimia darah

Uric acid & Lipid profile parameters

Parameter	Normal range
Uric acid (males)	3.4 – 7.0 mg/dl
Uric acid (Females)	2.4 – 5.7 mg/dl
Total Cholesterol	< 200 mg/dl
HDL - Cholesterol	40-60 mg/dl (males) 40-65 mg/dl (Females)
LDL - Cholesterol	< 100 mg/dl
VLDL - Cholesterol	15 – 40 mg/dl
Triglycerides	Less than 150 mg/dl

BLOOD GLUCOSE LEVEL CHART

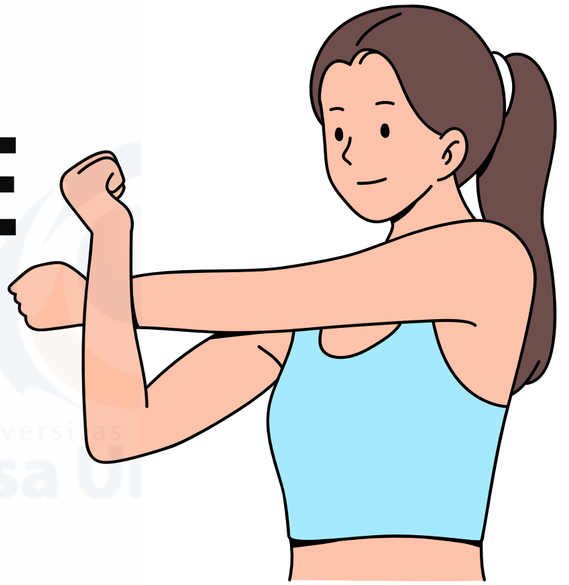
	Over 3 Month	Fasting		After meal		2-3 hrs after meal	
	HbA1c	Mg/DL	mmo/L	Mg/DL	mmo/L	Mg/DL	mmo/L
Normal	4-5.6%	80-100	4.4-5.5	170-200	9.4-11.1	120-140	6.7-7.8
Elevated	5.7-6.4%	101-125	5.8-6.9	190-230	10.6-12.8	140-160	7.8-8.9
High	> 6.5%	> 126	> 7.0	220-300	12.2-16.7	> 200	> 11.1

Notes

(US) Mg/DL: milligrams per deciliter

(UK) mmo/L : millimoles per liter

EXCERCISE



CASE 1

Seorang wanita berusia 65 tahun datang ke IGD dengan keluhan lemas, pusing, dan penurunan kesadaran. Riwayat medis menunjukkan bahwa pasien menggunakan diuretik furosemide selama 6 bulan terakhir untuk mengobati gagal jantung kongestif.

Hasil Tes Laboratorium:
Natrium (Na): 125 mmol/L (Normal: 135-145 mmol/L)
Kalium (K): 3.8 mmol/L (Normal: 3.5-5.0 mmol/L)
Kreatinin: 85 µmol/L (Normal: 50-120 µmol/L)
Urea: 7.5 mmol/L (Normal: 3.0-8.0 mmol/L)

Pertanyaan:
Bagaimana Anda menginterpretasikan hasil natrium serum pada pasien ini?
Apakah penggunaan furosemide mungkin berkontribusi terhadap kondisi pasien? Jelaskan mekanismenya.
Apa langkah manajemen yang tepat untuk menangani pasien ini?

answer

Bagaimana Anda menginterpretasikan hasil natrium serum pada pasien ini?

- Hasil natrium serum menunjukkan hiponatremia (Na = 125 mmol/L), yang berada di bawah rentang normal (135-145 mmol/L).
- Hiponatremia bisa menyebabkan gejala seperti lemas, pusing, hingga penurunan kesadaran seperti yang dialami pasien.

Apakah penggunaan furosemide mungkin berkontribusi terhadap kondisi pasien? Jelaskan mekanismenya.

- Ya, penggunaan furosemide, yang merupakan diuretik, dapat menyebabkan hiponatremia. Furosemide meningkatkan ekskresi natrium dan air melalui ginjal, yang pada akhirnya menyebabkan penurunan kadar natrium dalam darah.

Apa langkah manajemen yang tepat untuk menangani pasien ini?
Langkah manajemen:

- Stop atau sesuaikan dosis diuretik.
- Infus saline hipertonik secara hati-hati jika diperlukan untuk meningkatkan kadar natrium.
- Monitor kadar natrium serum secara berkala dan pantau status cairan pasien.
- Evaluasi tanda-tanda dehidrasi dan ketidakseimbangan elektrolit lainnya.

CASE 2

Seorang pria berusia 55 tahun dengan riwayat hipertensi datang dengan keluhan penurunan urin dan pembengkakan pada kaki selama 3 hari terakhir. Pasien juga mengonsumsi ibuprofen untuk nyeri lutut sejak 1 minggu lalu.

Hasil Tes Laboratorium:

- Kreatinin: 250 µmol/L (Normal: 50-120 µmol/L)
- Urea: 12 mmol/L (Normal: 3.0-8.0 mmol/L)
- Natrium (Na): 140 mmol/L (Normal: 135-145 mmol/L)
- Kalium (K): 5.5 mmol/L (Normal: 3.5-5.0 mmol/L)
- eGFR: 35 mL/min/1.73 m^2 (Normal: >90 mL/min/1.73 m^2)

Pertanyaan:

1. **Bagaimana interpretasi Anda terhadap hasil kreatinin dan eGFR pada pasien ini?**
2. **Apakah ada kemungkinan bahwa penggunaan ibuprofen memperburuk kondisi ginjal pasien? Jelaskan.**
3. **Langkah penanganan apa yang harus dilakukan pada pasien dengan kondisi ini?**

answer

1. **Bagaimana interpretasi Anda terhadap hasil kreatinin dan eGFR pada pasien ini?**
   - Kreatinin yang meningkat (250 µmol/L) dan eGFR yang menurun (35 mL/min/1.73 m^2) menunjukkan adanya gagal ginjal akut. Ini menunjukkan ginjal tidak berfungsi secara optimal dalam menyaring zat sisa dari darah.
2. **Apakah ada kemungkinan bahwa penggunaan ibuprofen memperburuk kondisi ginjal pasien? Jelaskan.**
   - Ya, ibuprofen, yang merupakan NSAID, dapat menyebabkan kerusakan ginjal akut. NSAID mengurangi aliran darah ke ginjal dengan menghambat prostaglandin yang menjaga perfusi ginjal, terutama pada pasien yang sudah memiliki faktor risiko seperti hipertensi.
3. **Langkah penanganan apa yang harus dilakukan pada pasien dengan kondisi ini?**
   - **Langkah manajemen:**
     - Hentikan penggunaan ibuprofen.
     - Berikan rehidrasi jika pasien mengalami dehidrasi.
     - Monitor fungsi ginjal (kreatinin dan eGFR) secara berkala.
     - Jika diperlukan, konsultasi dengan nefrologi untuk kemungkinan terapi lebih lanjut seperti dialisis.

CASE 3

Seorang wanita berusia 50 tahun dengan riwayat hepatitis B kronis datang dengan keluhan mual, muntah, dan kulit tampak kuning selama 1 minggu terakhir.

Hasil Tes Laboratorium:

- AST: 150 U/L (Normal: < 40 U/L)
- ALT: 200 U/L (Normal: < 40 U/L)
- ALP: 120 U/L (Normal: 25-100 U/L)
- Bilirubin total: 4.0 mg/dL (Normal: 0.3-1.2 mg/dL)
- Albumin: 3.2 g/dL (Normal: 3.5-5.0 g/dL)

Pertanyaan:

1. **Bagaimana interpretasi Anda terhadap hasil AST dan ALT yang tinggi pada pasien ini?**
2. **Apakah hasil bilirubin yang tinggi mengindikasikan disfungsi hati berat? Jelaskan hubungan antara peningkatan bilirubin dan kondisi pasien.**
3. **Apa langkah diagnostik atau pengobatan yang harus diambil untuk pasien dengan kondisi ini?**

answer

1. **Bagaimana interpretasi Anda terhadap hasil AST dan ALT yang tinggi pada pasien ini?**
    - Peningkatan AST (150 U/L) dan ALT (200 U/L) menunjukkan adanya kerusakan hati.
    - ALT biasanya lebih spesifik untuk kerusakan hati dibandingkan AST, terutama pada hepatitis atau peradangan hati.
2. **Apakah hasil bilirubin yang tinggi mengindikasikan disfungsi hati berat? Jelaskan hubungan antara peningkatan bilirubin dan kondisi pasien.**
    - Ya, bilirubin total yang tinggi (4.0 mg/dL) menunjukkan adanya ikterus (jaundice), yang merupakan tanda disfungsi hati berat atau obstruksi bilier. Peningkatan bilirubin terjadi karena hati tidak mampu memproses bilirubin dengan baik, menyebabkan akumulasi di darah.
3. **Apa langkah diagnostik atau pengobatan yang harus diambil untuk pasien dengan kondisi ini?**
4. **Langkah manajemen:**
        - Lakukan ultrasonografi hati atau CT scan untuk mendeteksi adanya obstruksi atau kerusakan
        - Monitor fungsi hati secara berkala (AST, ALT, bilirubin).
        - Evaluasi terapi yang mungkin memperburuk kondisi hati (seperti obat hepatotoksik).
        - Jika hepatitis teridentifikasi, berikan terapi antivirus atau imunosupresan sesuai penyebabnya.

CASE 4

Seorang pria berusia 70 tahun dengan riwayat gagal jantung dan hipertensi datang ke klinik untuk kontrol rutin. Pasien menggunakan spironolakton dan lisinopril sebagai bagian dari terapi gagal jantungnya.

Hasil Tes Laboratorium:

- Natrium (Na): 140 mmol/L (Normal: 135-145 mmol/L)
- Kalium (K): 6.2 mmol/L (Normal: 3.5-5.0 mmol/L)
- Kreatinin: 95 µmol/L (Normal: 50-120 µmol/L)
- BUN (Blood Urea Nitrogen): 8.2 mmol/L (Normal: 3.0-8.0 mmol/L)

Pertanyaan:

1. Bagaimana interpretasi Anda terhadap hasil kalium serum yang meningkat pada pasien ini?
2. Apakah penggunaan spironolakton dan lisinopril berkontribusi pada kondisi hiperkalemia ini? Jelaskan mekanismenya.
3. Langkah apa yang perlu diambil untuk menangani hiperkalemia pada pasien ini?

answer

1. **Bagaimana interpretasi Anda terhadap hasil kalium serum yang meningkat pada pasien ini?**
   - Pasien mengalami hiperkalemia (K = 6.2 mmol/L), yang berada di atas rentang normal (3.5-5.0 mmol/L). Hiperkalemia dapat menyebabkan gangguan pada fungsi jantung seperti aritmia yang berbahaya.
2. **Apakah penggunaan spironolakton dan lisinopril berkontribusi pada kondisi hiperkalemia ini? Jelaskan mekanismenya.**
   - Ya, spironolakton adalah diuretik hemat kalium yang mengurangi ekskresi kalium melalui ginjal, sedangkan lisinopril (ACE inhibitor) mengurangi produksi aldosteron yang juga menyebabkan retensi kalium. Kombinasi kedua obat ini meningkatkan risiko hiperkalemia.
3. **Langkah apa yang perlu diambil untuk menangani hiperkalemia pada pasien ini?**

Langkah manajemen:

- Hentikan atau kurangi dosis spironolakton dan lisinopril.
- Berikan resin penukar ion (seperti kayexalate) untuk mengurangi kadar kalium.
- Jika hiperkalemia berat, dapat diberikan insulin dengan glukosa atau kalsium glukonat untuk melindungi jantung.
- Monitor kadar kalium serum secara berkala.

CASE 5

Kondisi Klinis:
Seorang pria berusia 60 tahun sedang menjalani terapi warfarin setelah pemasangan katup jantung buatan. Pasien datang untuk pemantauan rutin INR.

Hasil Tes Laboratorium:

- INR: 4.5 (Normal: 2.0-3.0 untuk pasien dengan katup jantung buatan)
- Hemoglobin (Hb): 13 g/dL (Normal: 12-16 g/dL)
- Trombosit: 200 x 10^9/L (Normal: 150-400 x 10^9/L)

Pertanyaan:

1. **Bagaimana Anda menginterpretasikan nilai INR yang tinggi pada pasien ini?**
2. **Apa risiko utama yang dihadapi pasien dengan nilai INR seperti ini?**
3. **Langkah apa yang harus dilakukan untuk menurunkan INR dan menghindari komplikasi?**

answer

1. **Bagaimana Anda menginterpretasikan nilai INR yang tinggi pada pasien ini?**
    - Nilai INR yang tinggi (4.5) menunjukkan bahwa pasien berada pada risiko perdarahan yang meningkat. INR ideal untuk pasien dengan katup jantung buatan adalah 2.0-3.0, dan nilai di atas ini berarti pengenceran darah berlebihan.
2. **Apa risiko utama yang dihadapi pasien dengan nilai INR seperti ini?**
    - Risiko utama adalah perdarahan, termasuk perdarahan internal (misalnya, perdarahan gastrointestinal) atau perdarahan yang sulit berhenti akibat trauma kecil.
3. **Langkah apa yang harus dilakukan untuk menurunkan INR dan menghindari komplikasi**

Langkah manajemen:

- Hentikan sementara warfarin hingga INR kembali ke target.
- Jika diperlukan, berikan vitamin K untuk menurunkan INR lebih cepat.
- Pantau INR secara berkala sampai kembali ke target terapi yang sesuai.

CASE 6

Seorang pria berusia 45 tahun dengan riwayat diabetes tipe 2 sedang menjalani kontrol rutin di klinik. Pasien mengonsumsi metformin dan insulin basal.

Hasil Tes Laboratorium:

- Glukosa puasa: 160 mg/dL (Normal: 70-100 mg/dL)
- HbA1c: 8.5% (Normal: < 7.0%)

Pertanyaan:

1. Bagaimana interpretasi Anda terhadap hasil glukosa dan HbA1c pada pasien ini?
2. Apa yang dapat Anda simpulkan mengenai kontrol glukosa pasien berdasarkan hasil tersebut?
3. Apa rekomendasi penyesuaian terapi yang harus diberikan untuk meningkatkan kontrol diabetes pada pasien ini?

answer

1. **Bagaimana interpretasi Anda terhadap hasil glukosa dan HbA1c pada pasien ini?**
    - Glukosa puasa (160 mg/dL) dan HbA1c (8.5%) menunjukkan bahwa kontrol glukosa pasien tidak terkontrol dengan baik. HbA1c di atas 7.0% mengindikasikan bahwa kadar glukosa darah selama beberapa bulan terakhir melebihi target pengendalian.
2. **Apa yang dapat Anda simpulkan mengenai kontrol glukosa pasien berdasarkan hasil tersebut?**
    - Pasien memiliki kontrol glukosa yang buruk, yang menempatkannya pada risiko komplikasi diabetes seperti penyakit kardiovaskular, neuropati, dan nefropati.
3. **Apa rekomendasi penyesuaian terapi yang harus diberikan untuk meningkatkan kontrol diabetes pada pasien ini?**

Rekomendasi:

- Evaluasi kepatuhan pasien terhadap terapi insulin dan metformin.
- Pertimbangkan untuk meningkatkan dosis insulin atau menambah suntikan insulin prandial.
- Konseling mengenai diet, olahraga, dan perubahan gaya hidup.
- Jadwalkan pemantauan glukosa yang lebih sering dan HbA1c ulang setelah beberapa bulan.

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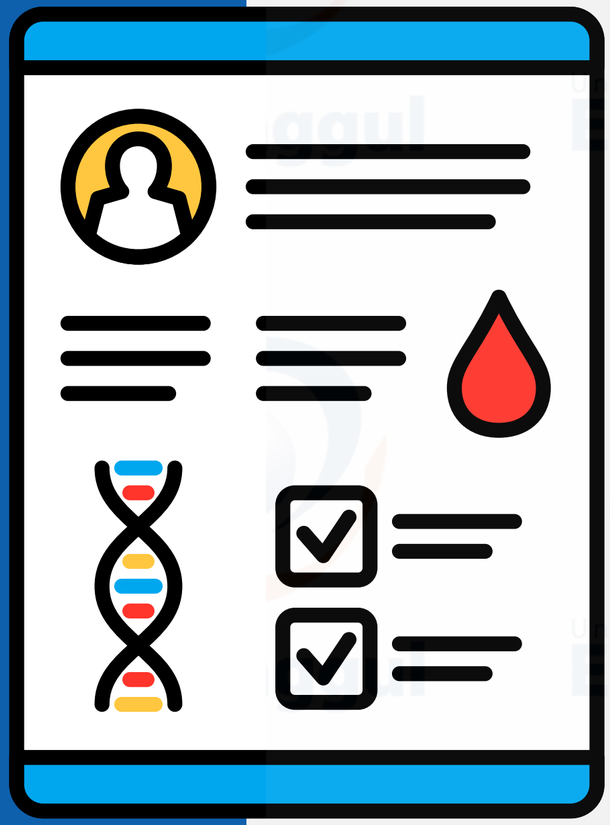
Rise your hand!

any question?



PSF426

Evidence Based Medicine

Pertemuan 5

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Topik Sebelum UTS

Sesi 1

Pendahuluan Farmasi Klinis

Sesi 2

Farmakokinetika Klinis dan aplikasinya

Sesi 3

Farmakokinetika Klinis untuk populasi khusus (Geriatri, Pediatri, Ibu hamil dan menyusui)

Sesi4

Data klinis dan interpretasinya

Sesi 5

Evidence Based Medicine

Sesi 6

Adverse Drugs Reaction

Sesi 7

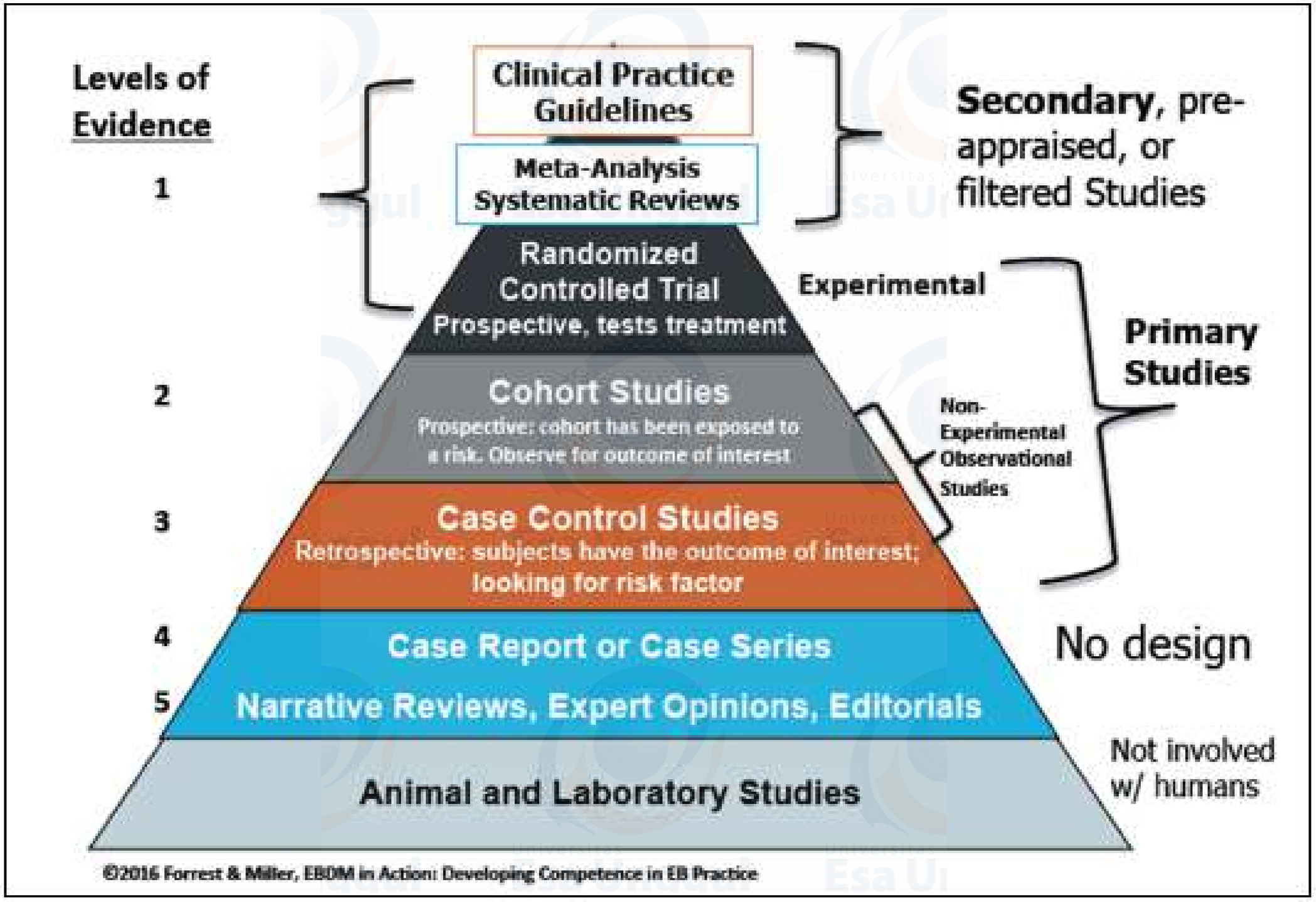
Self-Medication

Ujian Tengah Semester

What is EBM

Research Question

Evidence Based Medicine


Levels of Evidence
1
2
3
4
5
Clinical Practice Guidelines
Meta-Analysis Systematic Reviews
Randomized Controlled Trial
Prospective, tests treatment
Cohort Studies
Prospective: cohort has been exposed to a risk. Observe for outcome of interest
Case Control Studies
Retrospective: subjects have the outcome of interest; looking for risk factor
Case Report or Case Series
Narrative Reviews, Expert Opinions, Editorials
Animal and Laboratory Studies
Secondary, pre-appraised, or filtered Studies
Experimental
Non-Experimental Observational Studies
Primary Studies
No design
Not involved w/ humans
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Rise your hand!

any question?

PSF426

ADR dan Swamedikasi

Pertemuan 6&7

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Topik Sebelum UTS

Sesi 1

Pendahuluan Farmasi Klinis

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Sesi4

Data klinis dan interpretasinya

Sesi 5

Evidence Based Medicine

Sesi 6

Adverse Drugs Reaction

Sesi 7

Self-Medication

Ujian Tengah Semester

What is ADR

Therapy disadvantage

Medication Error

Adverse Drugs

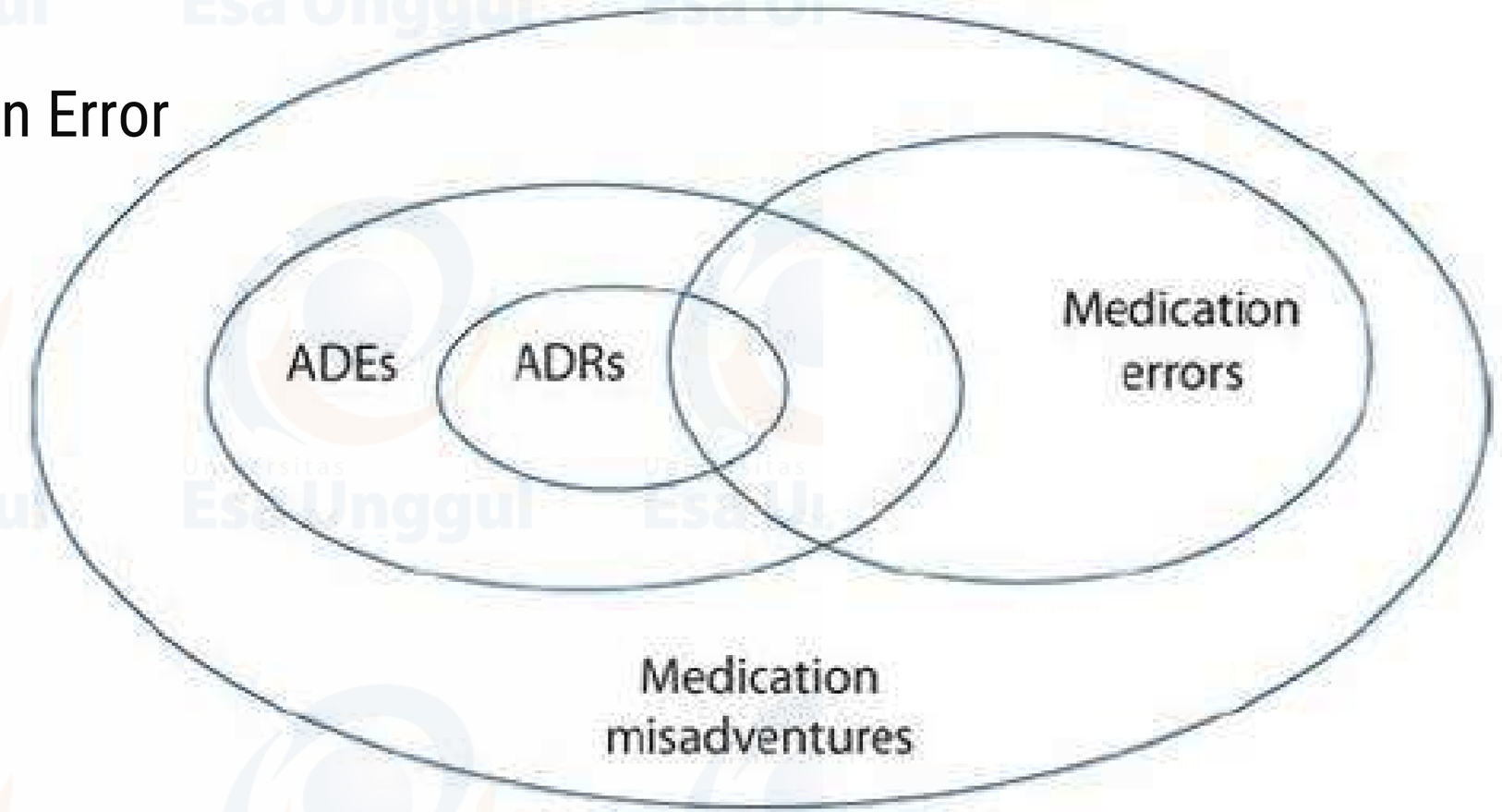
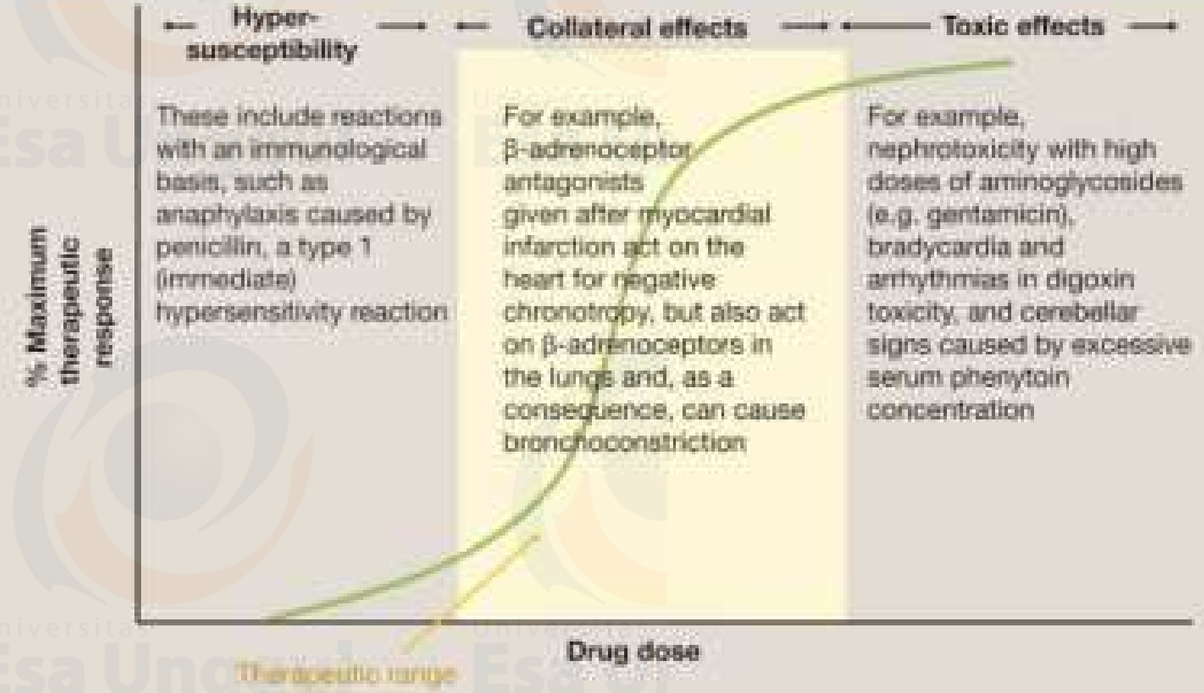


Table 12.1 Classification of adverse drug reactions

Type A	Augmented	Dose-related
Type B	Bizarre	Non-dose-related
Type C	Chronic	Dose-related and time-related
Type D	Delayed	Time-related
Type E	End of use	Withdrawal
Type F	Failure	Failure of therapy

Dose–response curve illustrating the subclasses of ADR in relation to the therapeutic window



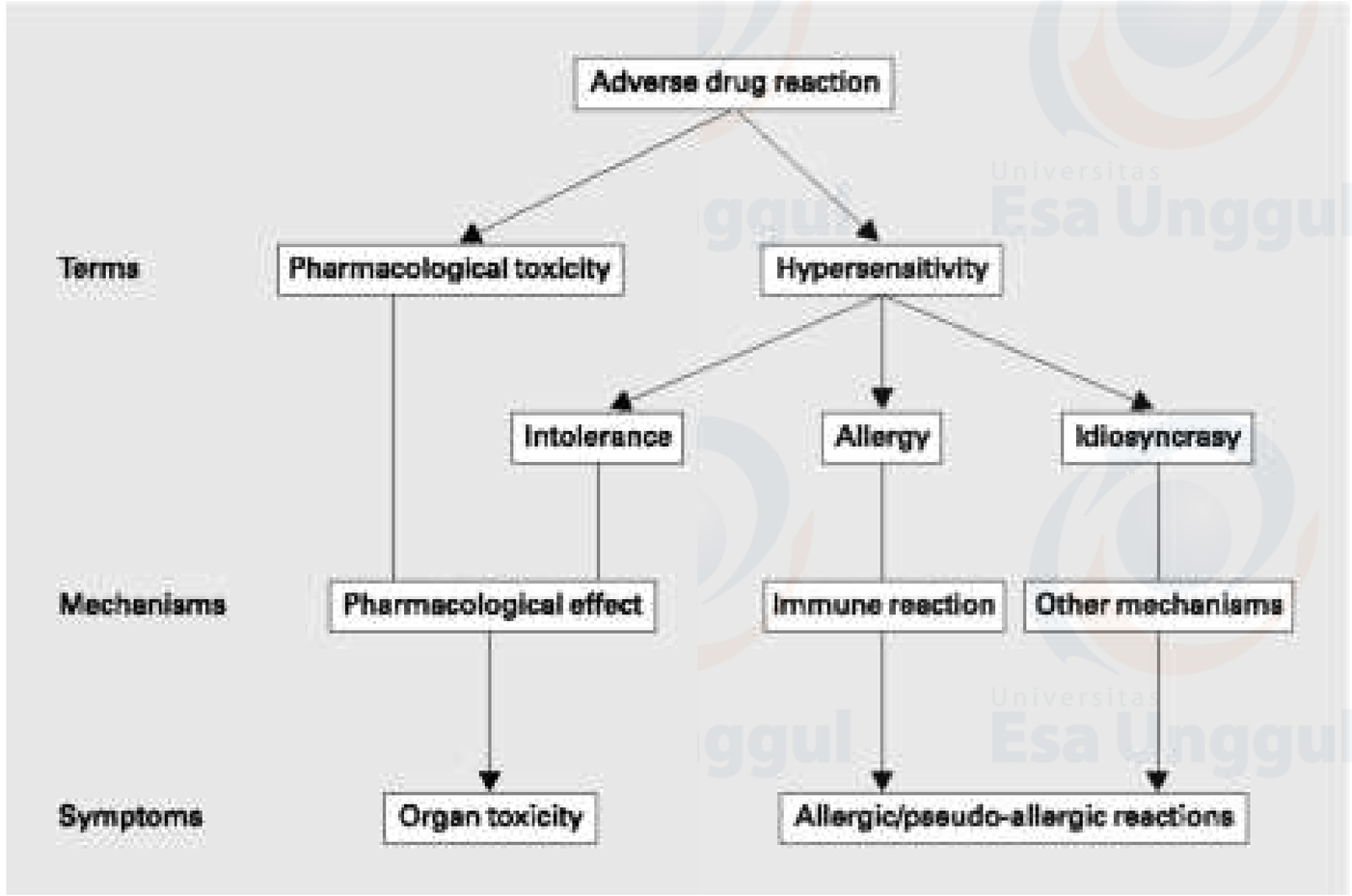


Table 4: Hartwig severity assessment scale.

Level 1	An ADR occurred but required no change in treatment with the suspected drug.
Level 2	The ADR required that treatment with the suspected drug be held, discontinued, or otherwise changed. No antidote or other treatment requirement was required. No increase in length of stay (LOS).
Level 3	The ADR required that treatment with the suspected drug be held, discontinued, or otherwise changed. AND/OR an Antidote or other treatment was required. No increase in length of stay (LOS).
Level 4	Any level 3 ADR which increases length of stay by at least 1 day or The ADR was the reason for the admission.
Level 5	Any level 4 ADR which requires intensive medical care.
Level 6	The adverse reaction caused permanent harm to the patient.
Level 7	The adverse reaction either directly or indirectly led to the death of the patient.

One more thing?

Kategori	Frekuensi Kejadian ESO
Sangat umum (very common)	≥1/10
Umum (common)	≥1/100 dan <1/10
Tidak umum (uncommon)	≥1/1000 dan <1/100
Jarang (rare)	≥1/10.000 dan <1/1000
Sangat jarang (very rare)	<1/10.000

Common Terminology Criteria for Adverse Events (CTCAE) dari National Cancer Institute.

CTCAE Grade	Description of Grading Criteria
0	No adverse event (or within normal limits)
1	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
2	Moderate; minimal, local, or noninvasive intervention (eg, packing, cautery) indicated; limiting age-appropriate instrumental activities of daily living (ADL)
3	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL
4	Life-threatening consequences; urgent intervention indicated
5	Death related to adverse event

Attribute	PRO-CTCAE Response Choices and Associated Scores				
	0	1	2	3	4
Frequency	Never	Rarely	Occasionally	Frequently	Almost Constantly
Severity	None	Mild	Moderate	Severe	Very Severe
Interference	Not at all	A little bit	Somewhat	Quite a bit	Very much
Present/Absent	Absent	Present	N/A	N/A	N/A

List of Naranjo

Sr. No.	Please answer the following questionnaire and give the pertinent score	Yes	No	Do Not Know	Score
1	Are there previous *conclusive* reports on this reaction?	1	0	0	
2	Did the adverse event occur after the suspected drug was administered?	2	-1	0	
3	Did the adverse reaction improve when the drug was discontinued or a *specific* antagonist was administered?	1	0	0	
4	Did the adverse reaction reappear when the drug was readministered?	2	-1	0	
5	Are there alternative causes (other than the drug) that could have on their own caused the reaction?	-1	2	0	
6	Did the reaction reappear when a placebo was given?	-1	1	0	
7	Was the blood detected in the blood (or other fluids) in concentrations known to be toxic?	1	0	0	
8	Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	1	0	0	
9	Did the patient have a similar reaction to the same or similar drugs in *any* previous exposure?	1	0	0	
10	Was the adverse event confirmed by any objective evidence?	1	0	0	
				Total	

Interpretation of Naranjo

definite	if the overall score is 9 or greater
probable	for a score of 5-8
possible	for 1-4
doubtful	if the score is 0

1. (1) Mengikuti urutan waktu yang wajar sejak pemberian obat, atau bila kadar obat telah ditetapkan dalam cairan tubuh atau jaringan; (2) mengikuti pola respons yang diketahui terhadap obat yang diduga; (3) dikonfirmasi dengan dechallenge;
2. (1) mengikuti urutan waktu yang wajar sejak pemberian obat; (2) tidak mengikuti pola respons yang diketahui terhadap obat yang diduga
3. Reaksi yang tidak memenuhi kriteria di atas.

Seorang pasien perempuan datang ke Unit Gawat Darurat dengan keluhan pusing, gemetar, dan mual. Diketahui bahwa ia mengonsumsi produk yang disebut “XXX” yang dipasarkan untuk menurunkan berat badan. Ia mulai mengonsumsi produk tersebut 4 minggu lalu untuk membantunya menurunkan berat badan. Pada pemeriksaan fisik, pasien ditemukan mengalami peningkatan tekanan darah dan detak jantung cepat. Anda meneliti produk tersebut dan mengetahui bahwa produk tersebut mengandung keton rasberi, yang diketahui memiliki sifat stimulan. Pasien dirawat di rumah sakit dan 2 hari. Setelah ia berhenti mengonsumsi obat tersebut, gejalanya mereda dan dia diperbolehkan meninggalkan rumah sakit.

- Dalam kasus ini, apakah ada dechallenge? Jika ya, apa yang terjadi ketika produk yang diduga dihentikan?
- Apakah ada hubungan temporal antara penggunaan produk ini dan reaksi yang dialami pasien?
- Berdasarkan apa yang Anda ketahui tentang produk ini, apakah reaksinya konsisten dengan farmakologi yang diketahui?
- Seberapa besar kemungkinan produk ini menyebabkan reaksi tersebut?

What is Swamedication/ Self- Medication

Sometime called do-it-yourself medicine, is a human behavior in which an individual uses a substance or any exogenous influence to self-administer treatment for physical or psychological conditions

Self - Assessment

↓

Medication Error

Self- Medication

Role of Pharmacist

PEDOMAN

PENGGUNAAN OBAT BEBAS

DAN BEBAS TERBATAS

DIREKTORAT BINA FARMASI KOMUNITAS DAN KLINIK

DITJEN BINA KEFARMASIAN DAN ALAT KESEHATAN

DEPARTEMEN KESEHATAN RI

2007

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Rise your hand!

any question?

PSF112

Prinsip Umum Toksikologi

Sesi Ke 8

Topik Sesuai RPS:
Mahasiswa mampu menjelaskan prinsip **umum toksikologi**

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Topik Sebelum UAS

Sesi 8

Prinsip umum toksikologi

Sesi 9

efek toksik dari zat/bahan

Sesi 10

Target organ efek toksik

Sesi 11

Keamanan zat kimia/ bahan makanan

Sesi 12

toksikofarmakologi

Sesi 13

uji toksisitas konvensional

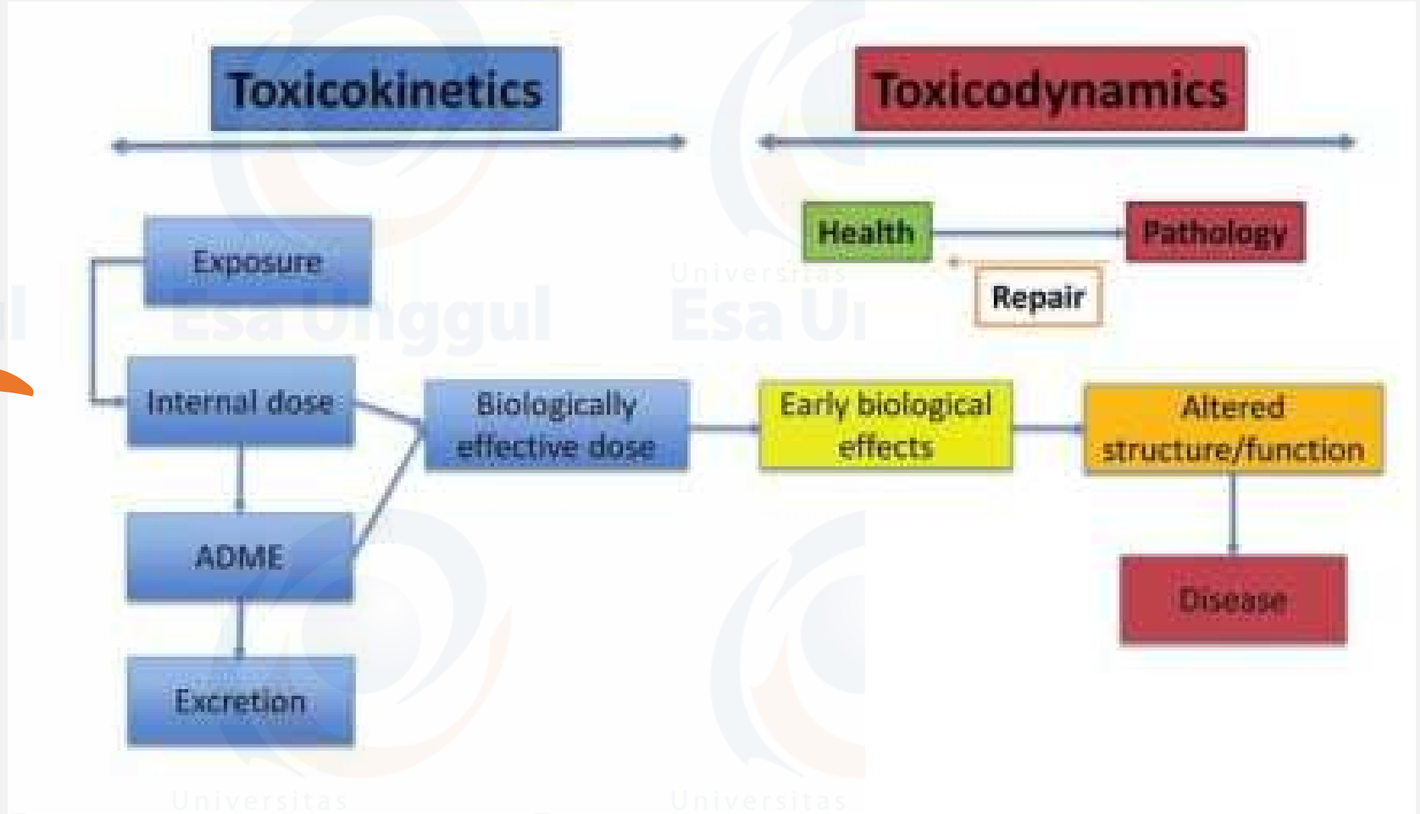
Sesi 14

uji toksisitas khusus

Ujian Akhir Semester

What is toxicology?

a field of science that helps us understand the harmful effects that chemicals, substances, or situations, can have on people, animals, and the environment.



Terjadinya keracunan ditentukan oleh dosis & cara pemberian (dosis sola facit)

Grade and incidence of toxicity

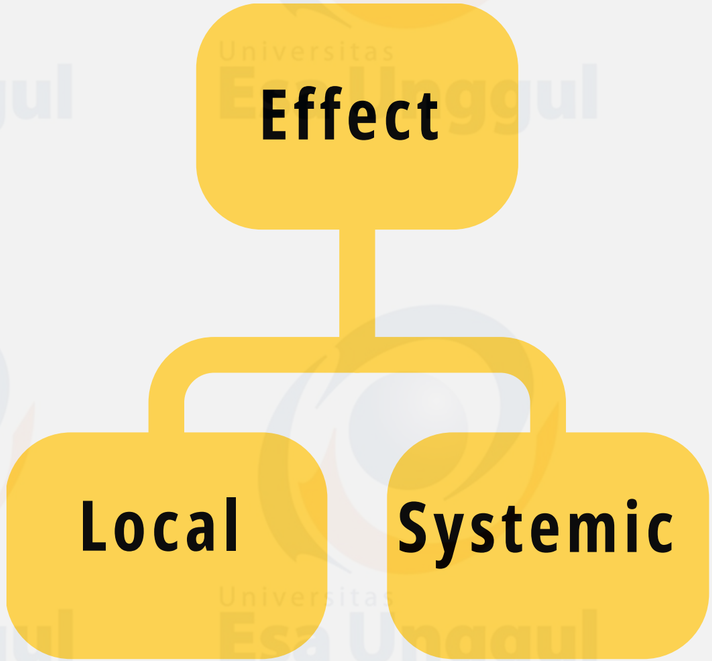
- Species: co/ methanol on human with lethal effect (methyl alcohol dehidrogenase)
- Genetic: Repair mechanism (transporter, detoxification enzyme, etc)
- Age: rate and function of metabolism
- Sex : on animals, related to lipid distribution (lethal dose on male > female)
- PK : PK profile of the compound (half life, clearance)
- Temperature: Metabolism and comorbidity
- Induction: capability oftoxic compound to induce enzymes (eg. luminal)
- Nutrition
- Patophysiology - comorbidity
- Interaction with other compound/ drugs

In general, the convention 1 — mild, 2 - moderate, 3 = severe and 4 - life-threatening is aimed for.

Grade I	Do not require treatment
Grade II	Often require symptomatic treatment but are not life-threatening
Grade III	Potentially life-threatening if untreated
Grade IV	Actually life-threatening
Grade V	Ultimately lead to patient death

Toxicity Effect

based on location



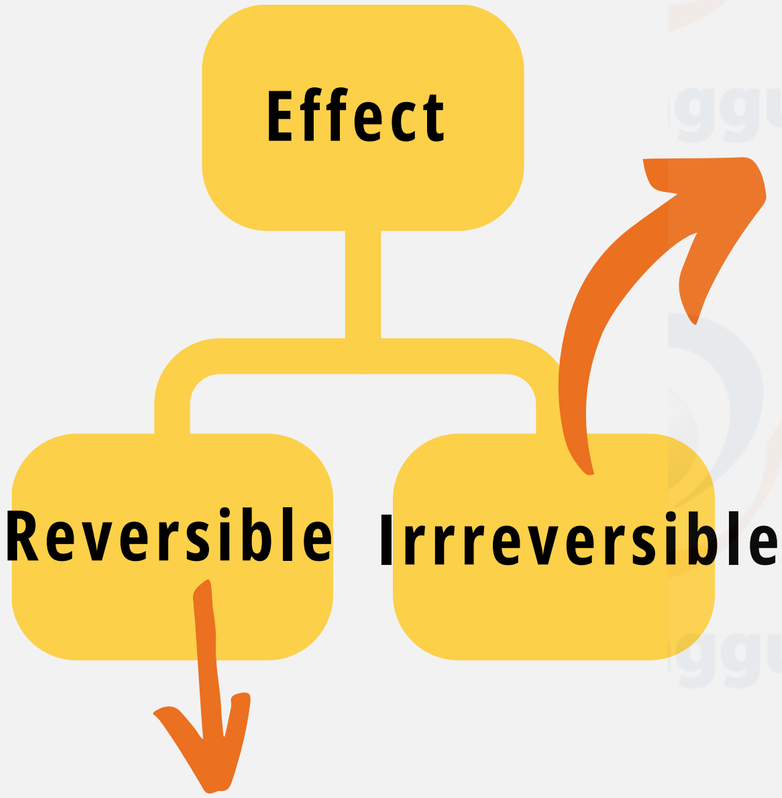
Berupa cedera pada tempat bahan itu bersentuhan dengan tubuh

co/ senyawa caustic, bahan korosif, iritasi gas, uap pada saluran nafas

Terjadi setelah seluruh compound terdistribusi ke seluruh tubuh

co/ toksisitas anastesi/ toksisitas renal, shock

based onset, and impact



jika exposure pada kadar tinggi dan waktu yang lama: Menetap dan bertambah parah setelah exposure hilang

jika exposure pada kadar rendah dan waktu singkat

Direct

- 1st attempt
- eg. sianida

Delayed

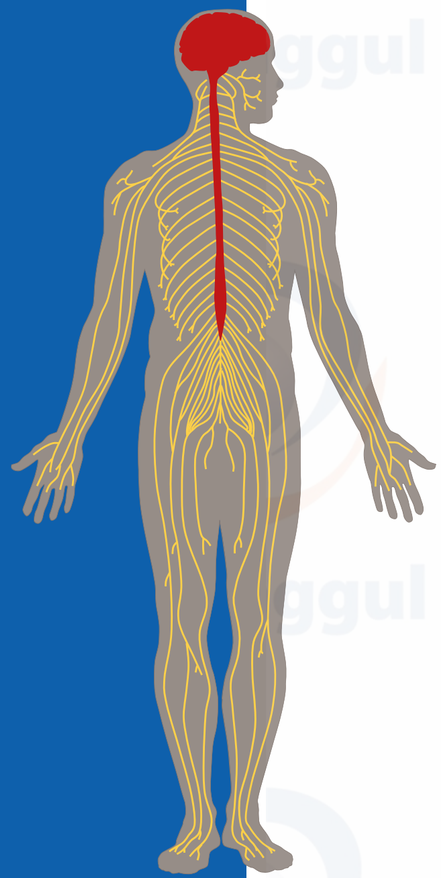
- Need times
- eg. carcinogen effect

Functional

- alteration on function/ disability
- biochemical (enzymatic)

Morphology

- external/ internal
- eg, necrosis/ neoplasm



Mechanism of actions and target organs

At a glance: alteration of cellular activity
nucleus, mitochondria, lysosome, endoplasmic reticulum, plasm membrane

Protein

- Protein struktural:

membran plasma, membran organel lebih sering dirusak.
co: heksan & silika

- Enzim

Spesifik : co/ penghambatan Asetil Cholin esterase (1 jenis enzim)
Tidak spesifik: co/ Pb dan Hg menghambat > 1 jenis enzim

Lipid : membran sel

- Anestesi umum eter & halotan dapat menumpuk di membran sel transport oksigen & glukosa ke dalam sel terganggu
- Hg dan Cd membentuk kompleks dengan fosfolipid -- fungsi membran berubah

Asam nukleat

- Alkylating agent/ carcinogenic

Ikatan kovalen dengan DNA -- adduction -- DNA damage -- cancer/ mutation/ teratogenic

Allergent

- hypersenstive reaction - shock anaphylactic

Corrosive Agent

- strong acid/ base --- coagulation of protein -- iritation/ systemic inflammation

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Drugs Related Problems

Pertemuan 8-9

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Topik Sebelum UTS

Sesi 8

Drugs Related Problemd

Sesi 9

Drugs-Induced Kidney Injury

Sesi 10

Drugs-Induced Liver Injury

Sesi 11

Toksisitas dan Kedaruratan

Sesi 12

Pendekatan Terapi Modern

Sesi 13

Project Based Discussion- Pelayanan Farmasi Klinis

Sesi 14

Presentasi Project Based Learning

Ujian Tengah Semester

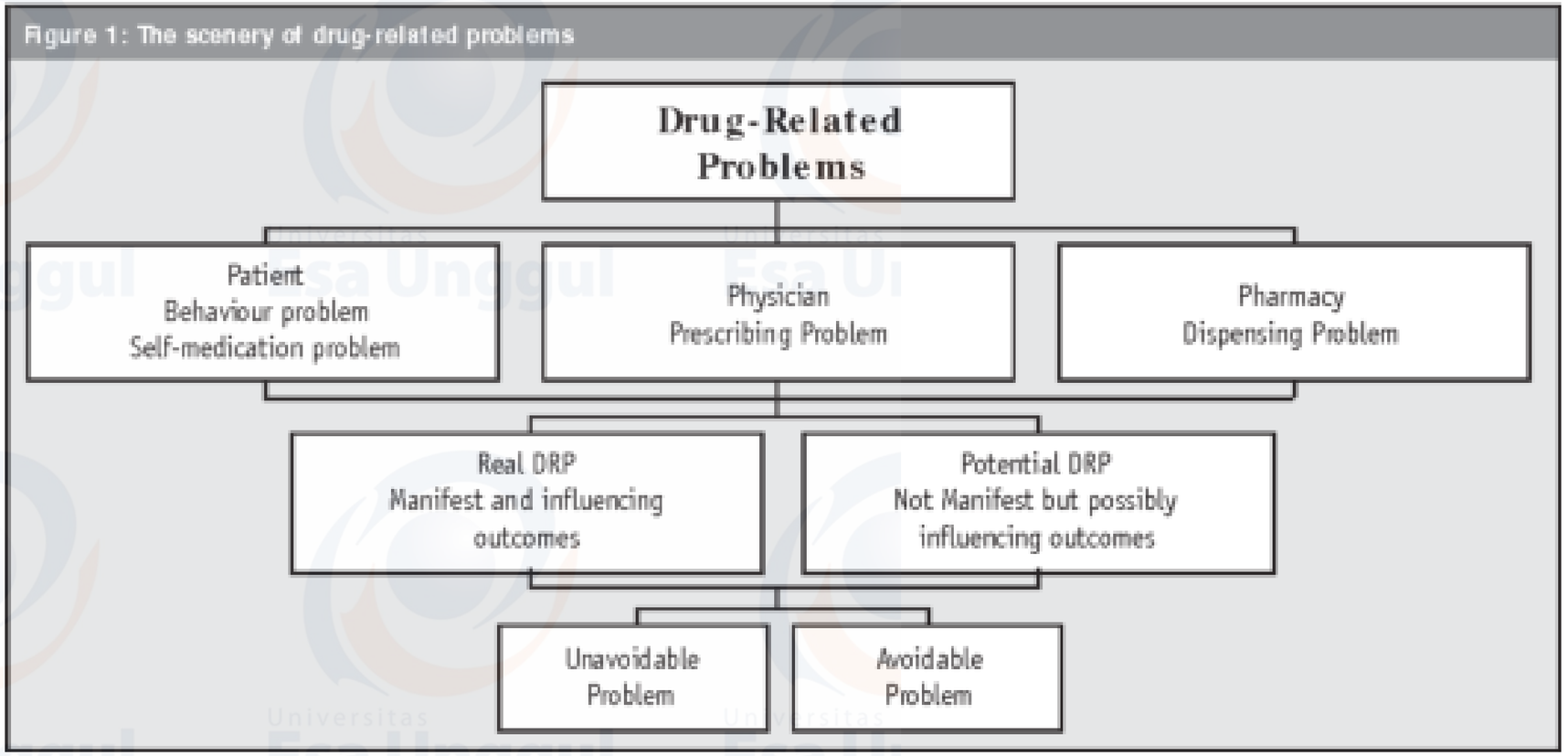
Drugs Related Problem

Assessment of therapy

Medication Error

Problem Solving

A Drug-Related Problem is an event or circumstance involving drug therapy that **actually** or **potentially** interferes with desired health outcomes.



Classification for Drug related problems

No	Items	Details	Checklist
1	Lack Of Drugs	Terdapat indikasi tidak terobati	
2	Unnecessary Drugs	Terdapat obat tanpa indikasi	
3	Wrong Medicine	Interaksi obat aktual	
		Interaksi obat potensial	
		Kontraindikasi	
		Salah obat (inappropriate)	
		Salah sediaan (inappropriate)	
4	Dosage	Dosis terlalu rendah	
		Dosis terlalu tinggi	
		Durasi terlalu pendek	
		Durasi terlalu panjang	
5	Adverse Events	Reaksi Efek Samping	
		Reaksi Obat yang Tidak Diinginkan	
6	Patients Related Problems	Masalah dalam kepatuhan	
		Kesalahan konsumsi obat	

PROBLEMS Potential Problem and Manifest Problem

Problems (also potential)	**P1**	**Treatment effectiveness** There is a (potential) problem with the (lack of) effect of the pharmacotherapy
	P2	**Treatment safety** Patient suffers, or could suffer, from an adverse drug event
	P3	**Other**

The clinical effect of the drug treatment is not as expected or there is no treatment	**See P1**
The patient suffers from an ADR at normal dose or from a toxic reaction	**See P2**
Nothing seems wrong in the treatment, but there is another problem related to the medicines in use	**See P3**

1.Treatment effectiveness There is a (potential) problem with the (lack of) effect of the pharmacotherapy.	**P1.1** **P1.2** **P1.3**	No effect of drug treatment despite correct use Effect of drug treatment not optimal Untreated symptoms or indication
2. Treatment safety Patient suffers, or could suffer, from an adverse drug event. *N.B. If there is no specific cause, skip Causes coding.*	**P2.1**	Adverse drug event (possibly) occurring
3. Other	**P3.1**	Unnecessary drug-treatment
	P3.2	*Unclear problem/complaint. Further clarification necessary (please use as escape only)*

CAUSE

1

The Causes (including possible causes for potential problems)

[N.B. One problem can have more causes]

	Primary Domain	Code V9.1	Cause
Prescribing & drug selection	**1. Drug selection** The cause of the (potential) DRP is related to the selection of the drug (by patient or health professional)	**C1.1**	Inappropriate drug according to guidelines/formulary
		C1.2	No indication for drug
		C1.3	Inappropriate combination of drugs, or drugs and herbal medications, or drugs and dietary supplements
		C1.4	Inappropriate duplication of therapeutic group or active ingredient
		C1.5	No or incomplete drug treatment in spite of existing indication
		C1.6	Too many different drugs/active ingredients prescribed for indication
	2. Drug form The cause of the DRP is related to the selection of the drug form	**C2.1**	Inappropriate drug form/formulation (for this patient)
	3. Dose selection The cause of the DRP is related to the selection of the dose or dosage	**C3.1**	Drug dose too low
		C3.2	Drug dose of a single active ingredient too high
		C3.3	Dosage regimen not frequent enough
		C3.4	Dosage regimen too frequent
		C3.5	Dose timing instructions wrong, unclear or missing
	4. Treatment duration The cause of the DRP is related to the duration of treatment	**C4.1**	Duration of treatment too short
		C4.2	Duration of treatment too long

CAUSE

2

3

Disp	**5. Dispensing** The cause of the DRP is related to the logistics of the prescribing and dispensing process	**C5.1**	Prescribed drug not available
		C5.2	Necessary information not provided or incorrect advice provided
		C5.3	Wrong drug, strength or dosage advised (OTC)
		C5.4	Wrong drug or strength dispensed
Use	**6. Drug use process** The cause of the DRP is related to the way the patient gets the drug administered ***by a health professional or other carer***, despite proper dosage instructions (on label/list)	**C6.1**	Inappropriate timing of administration or dosing intervals by a health professional
		C6.2	Drug under-administered by a health professional
		C6.3	Drug over-administered by a health professional
		C6.4	Drug not administered at all by a health professional
		C6.5	Wrong drug administered by a health professional
		C6.6	Drug administered via wrong route by a health professional
	7. Patient related The cause of the DRP is related to the patient and his behaviour (intentional or non-intentional)	**C7.1**	Patient intentionally uses/takes less drug than prescribed or does not take the drug at all for whatever reason
		C7.2	Patient uses/takes more drug than prescribed
		C7.3	Patient abuses drug (unregulated overuse)
		C7.4	Patient decides to use unnecessary drug
		C7.5	Patient takes food that interacts
		C7.6	Patient stores drug inappropriately
		C7.7	Inappropriate timing or dosing intervals
		C7.8	Patient unintentionally administers/uses the drug in a wrong way
		C7.9	Patient physically unable to use drug/form as directed
		C7.10	Patient unable to understand instructions properly

CAUSE

4

Seamless	**8. Patient transfer related** The cause of the DRP can be related to the transfer of patients between primary, secondary and tertiary care, or transfer within one care institution.	**C8.1**	Medication reconciliation problem
	9. Other	**C9.1**	No or inappropriate outcome monitoring (incl. TDM)
		C9.2	Other cause; specify
		C9.3	No obvious cause

PLANNING OF INTERVENTION

There is or can be no intervention	**See I0**
Intervention through the prescriber	**See I1**
Intervention through the patient, his carers or relatives	**See I2**
Intervention by pharmacist (dispenser) directly by changing drug or indicating change in drug use	**See I3**
Other intervention	**See I4**

Primary Domain	Code V9.1	Intervention
No intervention	**I0.1**	No Intervention
1. At prescriber level	**I1.1**	Prescriber informed only
	I1.2	Prescriber asked for information
	I1.3	Intervention proposed to prescriber
	I1.4	Intervention discussed with prescriber
2. At patient level	**I2.1**	Patient (drug) counselling
	I2.2	Written information provided (only)
	I2.3	Patient referred to prescriber
	I2.4	Spoken to family member/caregiver
3. At drug level	**I3.1**	Drug changed to …
	I3.2	Dosage changed to …
	I3.3	Formulation changed to …
	I3.4	Instructions for use changed to …
	I3.5	Drug paused or stopped
	I3.6	Drug started
4. Other intervention or activity	**I4.1**	Other intervention (specify)
	I4.2	Side effect reported to authorities

STATUS OF PLANNING AND/INTERVENTION

Acceptance of the Intervention proposals

N.B. One status of acceptance per intervention proposal

Primary domain	Code 9.1	Implementation
1. Intervention accepted (by prescriber or patient)	**A1.1**	Intervention accepted and fully implemented
	A1.2	Intervention accepted, partially implemented
	A1.3	Intervention accepted but not implemented
	A1.4	Intervention accepted, implementation unknown
2. Intervention not accepted (by prescriber or patient)	**A2.1**	Intervention not accepted: not feasible
	A2.2	Intervention not accepted: no agreement
	A2.3	Intervention not accepted: other reason (specify)
	A2.4	Intervention not accepted: unknown reason
3. Other (no information on acceptance)	**A3.1**	Intervention proposed, acceptance unknown
	A3.2	Intervention not proposed

Status of the DRP

N.B. This domain depicts the outcome of the intervention. One problem (or the combination of interventions) can only lead to one level of solving the problem

Primary Domain	Code V9.1	Outcome of intervention
0. Not known	**O0.1**	Problem status unknown
1. Solved	**O1.1**	Problem totally solved
2. Partially solved	**O2.1**	Problem partially solved
3. Not solved	**O3.1**	Problem not solved, lack of cooperation of patient
	O3.2	Problem not solved, lack of cooperation of prescriber
	O3.3	Problem not solved, intervention not effective
	O3.4	No need or possibility to solve problem

Descriptive Analysis of Patient Readmissions Within 60 Days Due to Medication-Related Events

Julin Thomas [*,✉], Aida Coralic [*], Melanie Ruegger [*], Nathaniel Thompson-Moore [*]

Background: Hospital readmissions have become a marker for quality health care. Readmissions secondary to failures of the medication use process are poorly documented and underrecognized.
Objective: To identify the incidence of readmissions related to the medication use process and identify associated patient- and therapy-related risk factors.
Methods: A prospective observational cohort study including patients discharged from an acute care medicine unit and readmitted within 60 days. The primary outcome was percentage of readmissions related to drug-related problems (DRPs) as defined by Pharmaceutical Care Network Europe (PCNE). Secondary outcomes included classification of problems using PCNE criteria, type and extent of pharmacist involvement in patient care, and identification of variables associated with a readmission related to a DRP.
Results: One hundred patients provided informed consent and were included for analysis. A DRP associated with readmission was identified in 64 patients. Sixty-one percent were classified as a potential problem with effect or lack of effect of pharmacotherapy. Patients who had a pharmacy consult were less likely to have a DRP (27% vs 47%; $P = .04$), and patients who missed follow-up appointments were more than 3 times as likely to have a DRP (20% vs 4%; $P = .03$). Presence of a pharmacy consult (odds ratio [OR], 0.38; 95% CI, 0.15-0.99; $P = .05$) and missed follow-up appointments (OR, 5.63; 95% CI, 1.52-20.86; $P = .01$) remained significant in a multivariate regression model.
Conclusion: DRPs were frequent in patients who were readmitted within 60 days. Clinical pharmacist involvement in care and support for appropriate patient follow-up may reduce unnecessary admissions.

Table 1. Pharmaceutical Care Network Europe classification of problems and causes[a]

Causes	Treatment effectiveness ($n = 60$)	Adverse reactions ($n = 32$)	Treatment costs ($n = 4$)	Others ($n = 1$)
Drug use/administration process	15 (25)	4 (13)	1 (20)	0
Drug selection	13 (22)	8 (25)	3 (60)	0
Dose selection	12 (20)	9 (28)	0	1 (100)
Patient	8 (13)	4 (13)	0	0
Logistics	5 (8)	1 (3)	0	0
Treatment duration	2 (3)	0	1 (20)	0
Drug form	1 (2)	0	0	0
Other	4 (7)	6 (19)	0	0

Note: Values given as *n* (%).
[a]Patients had more than 1 problem and cause identified.

- For the primary outcome, 64 patients were clas- sified as having a readmission related to a DRP.
- Nine of 64 patients had more than 1 problem identified.

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Profil *Drug Related Problems* (DRPs) pada Pasien Hipertensi di Instalasi Rawat Jalan Rumah Sakit Pemerintah di Kota Mataram Tahun 2018

Profile of Drug Related Problems (DRPs) on Hypertension in Outpatients Installation at one of Mataram Government Hospital in 2018

Candra Eka Puspitasari[1,5*], Royani Widiyastuti[2], Ni Made Amelia Ratnata Dewi[1,4], Oci Qonita Londo Woro[5], Arfi Syamsun[1]

Tabel 5. Profil Jumlah Obat Antihipertensi

No	Jenis DRPs	Kode V8.03	Jumlah Kejadian	Persentase (%)
1	Gejala atau indikasi tidak diterapi	P1.3	4	3.53
2	Kejadian efek buruk obat mungkin terjadi	P2.1	57	50.44
3	Obat tidak tepat menurut pedoman/formularium	C1.1	39	34.51
4	Obat kontra-indikasi	C1.2	0	0
5	Obat tanpa indikasi	C1.3	9	7.96
6	Kombinasi obat atau obat dengan herbal tidak tepat	C1.4	0	0
7	Duplikasi terapi	C1.5	0	0
8	Terlalu banyak obat yang diresepkan untuk indikasi	C1.7	4	3.53
9	Bentuk sediaan obat tidak tepat (untuk pasien)	C2.1	0	0
10	Dosis obat terlalu rendah	C3.1	0	0
11	Dosis obat terlalu tinggi	C3.2	0	0
12	Frekuensi penggunaan dosis tidak mencukupi	C3.3	0	0
13	Frekuensi penggunaan dosis terlalu sering	C3.4	0	0
Total			113	100

Tabel 6. Kategori Interaksi Obat

Kategori DRPs	Interaksi Obat-obat	Jumlah	Persentase (%)
Major	Amlodipin-simvastatin	9	8.25
	Amlodipin-Phenitoin	1	0.91
Moderate	Amlodipin-Aspirin	16	14.67
	Amlodipin-Meloxicam	8	7.33
	Metformin-Glimepirid	7	6.42
	Amlodipin-Bisoprolol	6	5.50
	Candesartan-Aspirin	5	4.59
	Sukralfat-Lansoprazole	3	2.75
	Valsartan-Meloxicam	3	2.75
	Valsartan-Aspirin	2	1.83
	Amlodipine-Voltadex	2	1.83
	Valsartan-Voltadex	2	1.83
	Valsartan-Bisoprolol	2	1.83
	Bisoprolol-Meloxicam	2	1.83
	Clopidogrel-Meloxicam	2	1.83
	Amlodipine-Diclofenac	2	1.83
	Candesartan-Levemir	1	0.91
	Captopril-Glimepirid	1	0.91
	Candesartan-Meloxicam	1	0.91
	Metformin-Meloxicam	1	0.91
	Valsartan-Ibuprofen	1	0.91
	Adalat oros (Nifedipine)-Meloxicam	1	0.91
	Candesartan-Pregabalin	1	0.91
	Aspirin-Glimepirid	1	0.91
	Bisoprolol-Glimepirid	1	0.91
	Lansoprazol-clopidogrel	1	0.91
	Amlodipin-Propranolol	1	0.91
	Glimepirid-Meloxicam	1	0.91
	Captopril-Metformin	1	0.91
	Hydrochlorothiazide-Bisoprolol	1	0.91
Minor	Bisoprolol-Aspirin	3	2.75
	Glimepirid-Clopidogrel	2	1.83
	Phenitoin-Aspirin	1	0.91
	Amlodipin-Hydrochlorothiazide	1	0.91
	Vitamin B12 (Cyanocobalamin)-Lansoprazol	1	0.91
	Total	109	100

Contoh Kasus

1

- Kondisi: Seorang pasien lansia dengan hipertensi dan asma mengalami eksaserbasi asma setelah menerima beta-blocker propranolol untuk hipertensi.

- Tentukan DRP: Problem, Causa, dan Intervention
- Jika Status Intervensi A1.1 Maka Status DRP?

2

- Kondisi: Seorang pasien dengan diabetes mellitus tipe 2 tidak mencapai kontrol glukosa darah yang baik meskipun sudah menggunakan metformin. Setelah dilakukan Homecare, diketahui bahwa terdapat masalah kepatuhan terapi, dan kesalahan dalam penyimpanan obat.

- Tentukan DRP: Problem, Causa, dan Intervention
- Jika Status Intervensi A1.3 Maka Status DRP?

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Drugs Related Problems

Pertemuan 8-9

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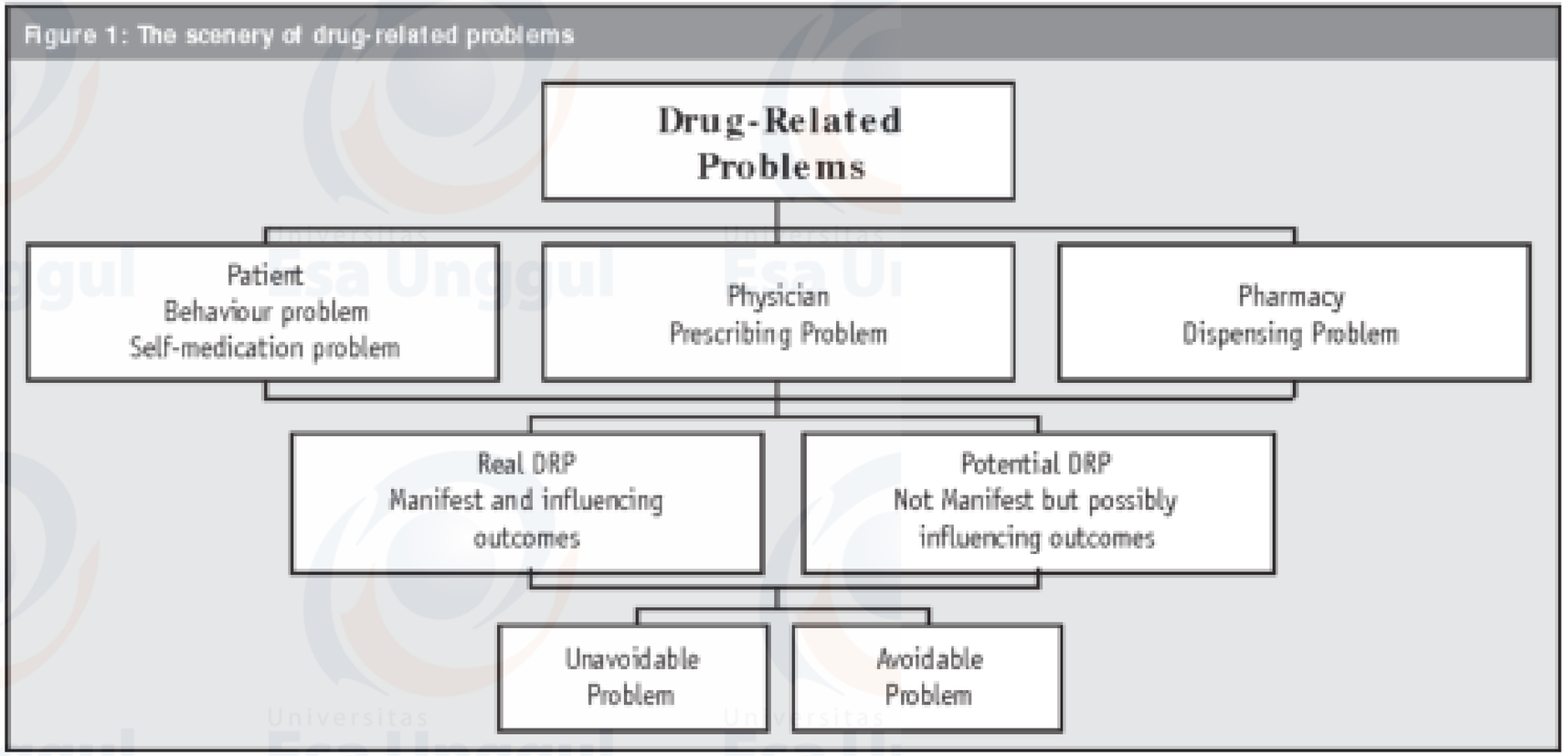

Classification for Drug related problems

No	Items	Details	Checklist
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		Salah obat (inappropriate)	
		Salah sediaan (inappropriate)	
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		Durasi terlalu pendek	
		Durasi terlalu panjang	
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6	Patients Related Problems	Masalah dalam kepatuhan	
		Kesalahan konsumsi obat	

PROBLEMS Potential Problem and Manifest Problem

Problems (also potential)	**P1**	**Treatment effectiveness** There is a (potential) problem with the (lack of) effect of the pharmacotherapy
	P2	**Treatment safety** Patient suffers, or could suffer, from an adverse drug event
	P3	**Other**

The clinical effect of the drug treatment is not as expected or there is no treatment	**See P1**
The patient suffers from an ADR at normal dose or from a toxic reaction	**See P2**
Nothing seems wrong in the treatment, but there is another problem related to the medicines in use	**See P3**

1.Treatment effectiveness There is a (potential) problem with the (lack of) effect of the pharmacotherapy.	**P1.1** **P1.2** **P1.3**	No effect of drug treatment despite correct use Effect of drug treatment not optimal Untreated symptoms or indication
2. Treatment safety Patient suffers, or could suffer, from an adverse drug event. *N.B. If there is no specific cause, skip Causes coding.*	**P2.1**	Adverse drug event (possibly) occurring
3. Other	**P3.1**	Unnecessary drug-treatment
	P3.2	*Unclear problem/complaint. Further clarification necessary (please use as escape only)*

CAUSE

1

The Causes (including possible causes for potential problems)

[N.B. One problem can have more causes]

	Primary Domain	Code V9.1	Cause
Prescribing & drug selection	**1. Drug selection** The cause of the (potential) DRP is related to the selection of the drug (by patient or health professional)	**C1.1**	Inappropriate drug according to guidelines/formulary
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		C1.3	Inappropriate combination of drugs, or drugs and herbal medications, or drugs and dietary supplements
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		C1.6	Too many different drugs/active ingredients prescribed for indication
	2. Drug form The cause of the DRP is related to the selection of the drug form	**C2.1**	Inappropriate drug form/formulation (for this patient)
	3. Dose selection The cause of the DRP is related to the selection of the dose or dosage	**C3.1**	Drug dose too low
		C3.2	Drug dose of a single active ingredient too high
		C3.3	Dosage regimen not frequent enough
		C3.4	Dosage regimen too frequent
		C3.5	Dose timing instructions wrong, unclear or missing
	4. Treatment duration The cause of the DRP is related to the duration of treatment	**C4.1**	Duration of treatment too short
		C4.2	Duration of treatment too long

CAUSE

2

3

Disp	**5. Dispensing** The cause of the DRP is related to the logistics of the prescribing and dispensing process	**C5.1**	Prescribed drug not available
		C5.2	Necessary information not provided or incorrect advice provided
		C5.3	Wrong drug, strength or dosage advised (OTC)
		C5.4	Wrong drug or strength dispensed
Use	**6. Drug use process** The cause of the DRP is related to the way the patient gets the drug administered ***by a health professional or other carer***, despite proper dosage instructions (on label/list)	**C6.1**	Inappropriate timing of administration or dosing intervals by a health professional
		C6.2	Drug under-administered by a health professional
		C6.3	Drug over-administered by a health professional
		C6.4	Drug not administered at all by a health professional
		C6.5	Wrong drug administered by a health professional
		C6.6	Drug administered via wrong route by a health professional
	7. Patient related The cause of the DRP is related to the patient and his behaviour (intentional or non-intentional)	**C7.1**	Patient intentionally uses/takes less drug than prescribed or does not take the drug at all for whatever reason
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		C7.8	Patient unintentionally administers/uses the drug in a wrong way
		C7.9	Patient physically unable to use drug/form as directed
		C7.10	Patient unable to understand instructions properly

CAUSE

4

Seamless	**8. Patient transfer related** The cause of the DRP can be related to the transfer of patients between primary, secondary and tertiary care, or transfer within one care institution.	**C8.1**	Medication reconciliation problem
	9. Other	**C9.1**	No or inappropriate outcome monitoring (incl. TDM)
		C9.2	Other cause; specify
		C9.3	No obvious cause

PLANNING OF INTERVENTION

There is or can be no intervention	**See I0**
Intervention through the prescriber	**See I1**
Intervention through the patient, his carers or relatives	**See I2**
Intervention by pharmacist (dispenser) directly by changing drug or indicating change in drug use	**See I3**
Other intervention	**See I4**

Primary Domain	Code V9.1	Intervention
No intervention	**I0.1**	No Intervention
1. At prescriber level	**I1.1**	Prescriber informed only
	I1.2	Prescriber asked for information
	I1.3	Intervention proposed to prescriber
	I1.4	Intervention discussed with prescriber
2. At patient level	**I2.1**	Patient (drug) counselling
	I2.2	Written information provided (only)
	I2.3	Patient referred to prescriber
	I2.4	Spoken to family member/caregiver
3. At drug level	**I3.1**	Drug changed to …
	I3.2	Dosage changed to …
	I3.3	Formulation changed to …
	I3.4	Instructions for use changed to …
	I3.5	Drug paused or stopped
	I3.6	Drug started
4. Other intervention or activity	**I4.1**	Other intervention (specify)
	I4.2	Side effect reported to authorities

STATUS OF PLANNING AND/INTERVENTION

Acceptance of the Intervention proposals

N.B. One status of acceptance per intervention proposal

Primary domain	Code 9.1	Implementation
1. Intervention accepted (by prescriber or patient)	**A1.1**	Intervention accepted and fully implemented
	A1.2	Intervention accepted, partially implemented
	A1.3	Intervention accepted but not implemented
	A1.4	Intervention accepted, implementation unknown
2. Intervention not accepted (by prescriber or patient)	**A2.1**	Intervention not accepted: not feasible
	A2.2	Intervention not accepted: no agreement
	A2.3	Intervention not accepted: other reason (specify)
	A2.4	Intervention not accepted: unknown reason
3. Other (no information on acceptance)	**A3.1**	Intervention proposed, acceptance unknown
	A3.2	Intervention not proposed

Status of the DRP

N.B. This domain depicts the outcome of the intervention. One problem (or the combination of interventions) can only lead to one level of solving the problem

Primary Domain	Code V9.1	Outcome of intervention
0. Not known	**O0.1**	Problem status unknown
1. Solved	**O1.1**	Problem totally solved
2. Partially solved	**O2.1**	Problem partially solved
3. Not solved	**O3.1**	Problem not solved, lack of cooperation of patient
	O3.2	Problem not solved, lack of cooperation of prescriber
	O3.3	Problem not solved, intervention not effective
	O3.4	No need or possibility to solve problem

Descriptive Analysis of Patient Readmissions Within 60 Days Due to Medication-Related Events

Julin Thomas [*,✉], Aida Coralic [*], Melanie Ruegger [*], Nathaniel Thompson-Moore [*]

Background: Hospital readmissions have become a marker for quality health care. Readmissions secondary to failures of the medication use process are poorly documented and underrecognized.
Objective: To identify the incidence of readmissions related to the medication use process and identify associated patient- and therapy-related risk factors.
Methods: A prospective observational cohort study including patients discharged from an acute care medicine unit and readmitted within 60 days. The primary outcome was percentage of readmissions related to drug-related problems (DRPs) as defined by Pharmaceutical Care Network Europe (PCNE). Secondary outcomes included classification of problems using PCNE criteria, type and extent of pharmacist involvement in patient care, and identification of variables associated with a readmission related to a DRP.
Results: One hundred patients provided informed consent and were included for analysis. A DRP associated with readmission was identified in 64 patients. Sixty-one percent were classified as a potential problem with effect or lack of effect of pharmacotherapy. Patients who had a pharmacy consult were less likely to have a DRP (27% vs 47%; $P = .04$), and patients who missed follow-up appointments were more than 3 times as likely to have a DRP (20% vs 4%; $P = .03$). Presence of a pharmacy consult (odds ratio [OR], 0.38; 95% CI, 0.15-0.99; $P = .05$) and missed follow-up appointments (OR, 5.63; 95% CI, 1.52-20.86; $P = .01$) remained significant in a multivariate regression model.
Conclusion: DRPs were frequent in patients who were readmitted within 60 days. Clinical pharmacist involvement in care and support for appropriate patient follow-up may reduce unnecessary admissions.

Table 1. Pharmaceutical Care Network Europe classification of problems and causes[a]

Causes	Treatment effectiveness ($n = 60$)	Adverse reactions ($n = 32$)	Treatment costs ($n = 4$)	Others ($n = 1$)
Drug use/administration process	15 (25)	4 (13)	1 (20)	0
Drug selection	13 (22)	8 (25)	3 (60)	0
Dose selection	12 (20)	9 (28)	0	1 (100)
Patient	8 (13)	4 (13)	0	0
Logistics	5 (8)	1 (3)	0	0
Treatment duration	2 (3)	0	1 (20)	0
Drug form	1 (2)	0	0	0
Other	4 (7)	6 (19)	0	0

Note: Values given as *n* (%).
[a]Patients had more than 1 problem and cause identified.

- For the primary outcome, 64 patients were clas- sified as having a readmission related to a DRP.
- Nine of 64 patients had more than 1 problem identified.

Jurnal Sains dan Kesehatan (J. Sains Kes.)

Journal homepage: https://jsk.farmasi.unmul.ac.id

Profil *Drug Related Problems* (DRPs) pada Pasien Hipertensi di Instalasi Rawat Jalan Rumah Sakit Pemerintah di Kota Mataram Tahun 2018

Profile of Drug Related Problems (DRPs) on Hypertension in Outpatients Installation at one of Mataram Government Hospital in 2018

Candra Eka Puspitasari[1,5*], Royani Widiyastuti[2], Ni Made Amelia Ratnata Dewi[1,4], Oci Qonita Londo Woro[5], Arfi Syamsun[1]

Tabel 5. Profil Jumlah Obat Antihipertensi

No	Jenis DRPs	Kode V8.03	Jumlah Kejadian	Persentase (%)
1	Gejala atau indikasi tidak diterapi	P1.3	4	3.53
2	Kejadian efek buruk obat mungkin terjadi	P2.1	57	50.44
3	Obat tidak tepat menurut pedoman/formularium	C1.1	39	34.51
4	Obat kontra-indikasi	C1.2	0	0
5	Obat tanpa indikasi	C1.3	9	7.96
6	Kombinasi obat atau obat dengan herbal tidak tepat	C1.4	0	0
7	Duplikasi terapi	C1.5	0	0
8	Terlalu banyak obat yang diresepkan untuk indikasi	C1.7	4	3.53
9	Bentuk sediaan obat tidak tepat (untuk pasien)	C2.1	0	0
10	Dosis obat terlalu rendah	C3.1	0	0
11	Dosis obat terlalu tinggi	C3.2	0	0
12	Frekuensi penggunaan dosis tidak mencukupi	C3.3	0	0
13	Frekuensi penggunaan dosis terlalu sering	C3.4	0	0
Total			113	100

Tabel 6. Kategori Interaksi Obat

Kategori DRPs	Interaksi Obat-obat	Jumlah	Persentase (%)
Major	Amlodipin-simvastatin	9	8.25
	Amlodipin-Phenitoin	1	0.91
Moderate	Amlodipin-Aspirin	16	14.67
	Amlodipin-Meloxicam	8	7.33
	Metformin-Glimepirid	7	6.42
	Amlodipin-Bisoprolol	6	5.50
	Candesartan-Aspirin	5	4.59
	Sukralfat-Lansoprazole	3	2.75
	Valsartan-Meloxicam	3	2.75
	Valsartan-Aspirin	2	1.83
	Amlodipine-Voltadex	2	1.83
	Valsartan-Voltadex	2	1.83
	Valsartan-Bisoprolol	2	1.83
	Bisoprolol-Meloxicam	2	1.83
	Clopidogrel-Meloxicam	2	1.83
	Amlodipine-Diclofenac	2	1.83
	Candesartan-Levemir	1	0.91
	Captopril-Glimepirid	1	0.91
	Candesartan-Meloxicam	1	0.91
	Metformin-Meloxicam	1	0.91
	Valsartan-Ibuprofen	1	0.91
	Adalat oros (Nifedipine)-Meloxicam	1	0.91
	Candesartan-Pregabalin	1	0.91
	Aspirin-Glimepirid	1	0.91
	Bisoprolol-Glimepirid	1	0.91
	Lansoprazol-clopidogrel	1	0.91
	Amlodipin-Propranolol	1	0.91
	Glimepirid-Meloxicam	1	0.91
	Captopril-Metformin	1	0.91
	Hydrochlorothiazide-Bisoprolol	1	0.91
Minor	Bisoprolol-Aspirin	3	2.75
	Glimepirid-Clopidogrel	2	1.83
	Phenitoin-Aspirin	1	0.91
	Amlodipin-Hydrochlorothiazide	1	0.91
	Vitamin B12 (Cyanocobalamin)-Lansoprazol	1	0.91
	Total	109	100

Contoh Kasus

1

- Kondisi: Seorang pasien lansia dengan hipertensi dan asma mengalami eksaserbasi asma setelah menerima beta-blocker propranolol untuk hipertensi.

- Tentukan DRP: Problem, Causa, dan Intervention
- Jika Status Intervensi A1.1 Maka Status DRP?

2

- Kondisi: Seorang pasien dengan diabetes mellitus tipe 2 tidak mencapai kontrol glukosa darah yang baik meskipun sudah menggunakan metformin. Setelah dilakukan Homecare, diketahui bahwa terdapat masalah kepatuhan terapi, dan kesalahan dalam penyimpanan obat.

- Tentukan DRP: Problem, Causa, dan Intervention
- Jika Status Intervensi A1.3 Maka Status DRP?

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PSF426

Drugs Induced Kidney Injury

Pertemuan 9

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Topik Sebelum UTS

Sesi 8

Drugs Related Problemd

Sesi 9

Drugs-Induced Kidney Injury

Sesi 10

Drugs-Induced Liver Injury

Sesi 11

Toksisitas dan Kedaruratan

Sesi 12

Pendekatan Terapi Modern

Sesi 13

Project Based Discussion- Pelayanan Farmasi Klinis

Sesi 14

Presentasi Project Based Learning

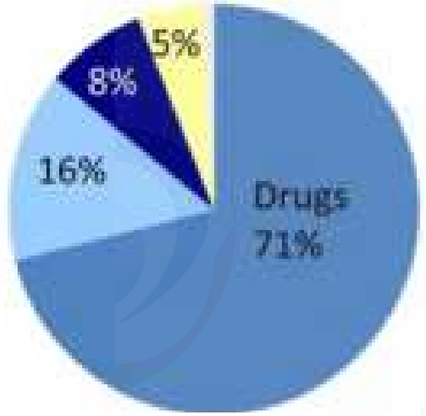
Ujian Tengah Semester

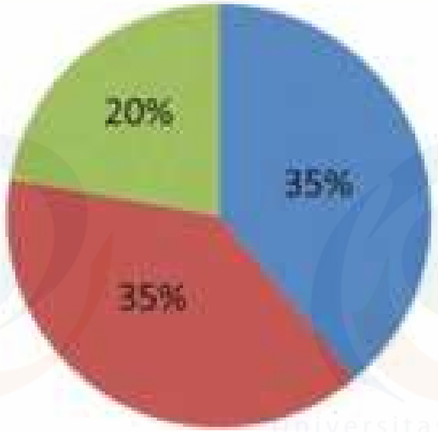
Facts!

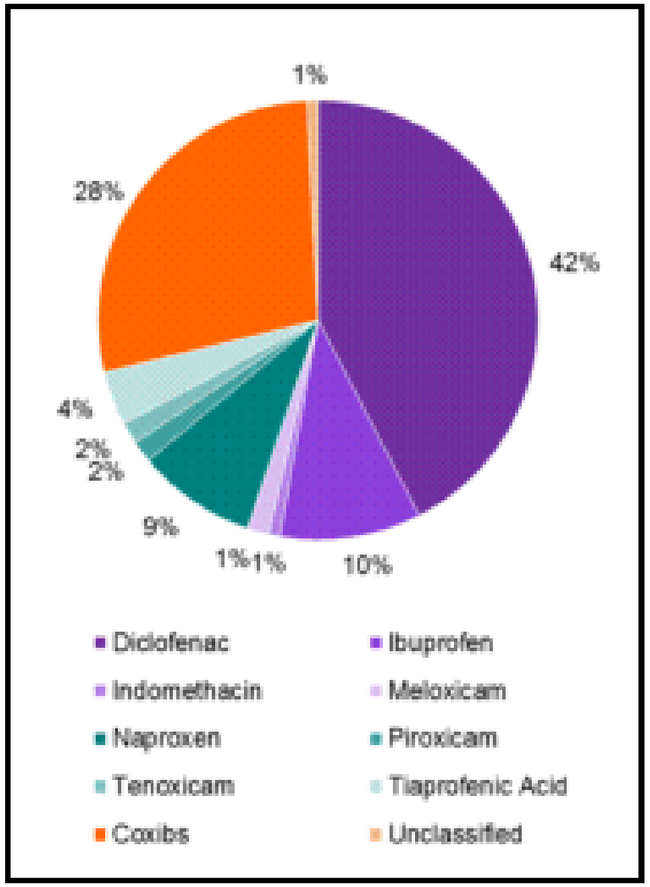
Common Causes of AIN	
Drugs	71%
Infection-Associated	16%
Idiopathic/unknown	8%
TINU	5%
Sarcoidosis	1%

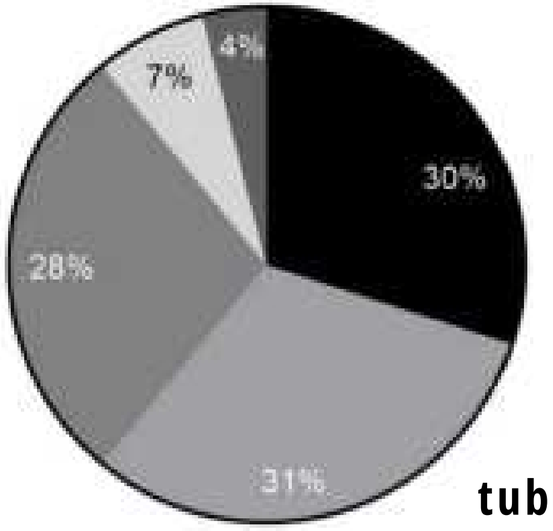
https://link.springer.com/article/10.1007/s00467-019-04207-9

Top Three Drugs
Antibiotics
Proton Pump Inhibitors (PPIs)
NSAIDs





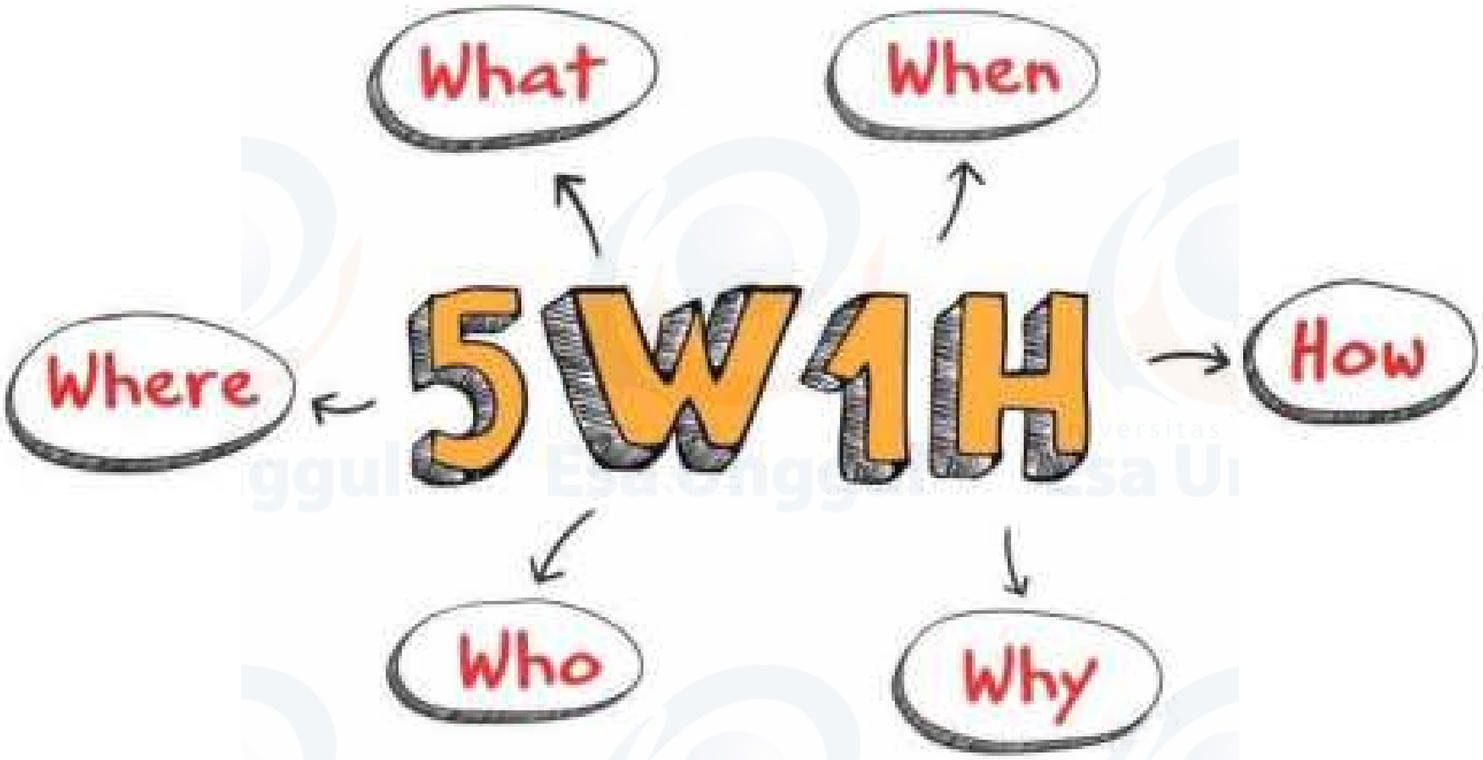




- drug-induced
- TINU
- idiopathic
- systemic disease
- infectious

tubulointerstitial nephritis

Drugs Induced Kidney Injury

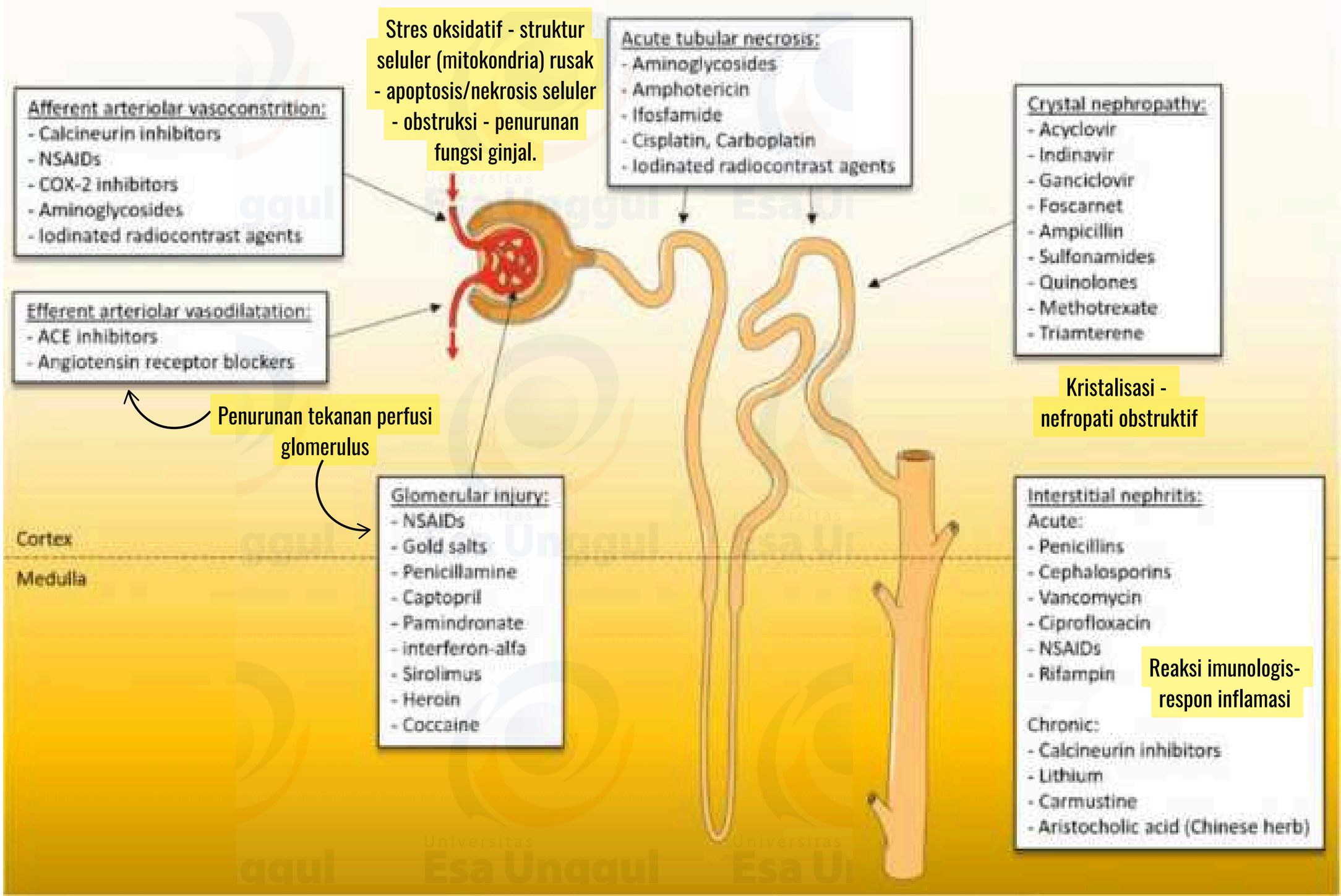


Key Concept

1. The initial diagnosis of drug-induced kidney disease (DIKD) typically involves detection of elevated serum creatinine and blood urea nitrogen, for which there is a temporal relationship between the toxicity and use of a potentially nephrotoxic drug.
2. DIKD is best prevented by avoiding the use of potentially nephrotoxic agents for patients at increased risk for toxicity. However, when exposure to these drugs cannot be avoided, recognition of risk factors and specific techniques, such as hydration, may be used to reduce potential nephrotoxicity.
3. Acute tubular necrosis is the most common presentation of DIKD in hospitalized patients. The primary agents implicated are aminoglycosides, radiocontrast media, cisplatin, amphotericin B, and osmotically active agents.
4. Angiotensin-converting enzyme inhibitors and nonsteroidal antiinflammatory drugs are associated with hemodynamically mediated kidney injury, the pathogenesis of which is a decrease in glomerular capillary hydrostatic pressure.
5. Acute allergic interstitial nephritis is observed in up to 27% of kidney biopsies performed for hospitalized patients with unexplained acute kidney injury. Clinical manifestations of AIN typically present approximately 14 days after initiation of therapy and include fever, maculopapular rash, eosinophilia, arthralgia, often with pyuria, hematuria, proteinuria, and oliguria.

WHAT
WHEN
WHO

WHY
HOW
WHERE



1 RISK FACTOR

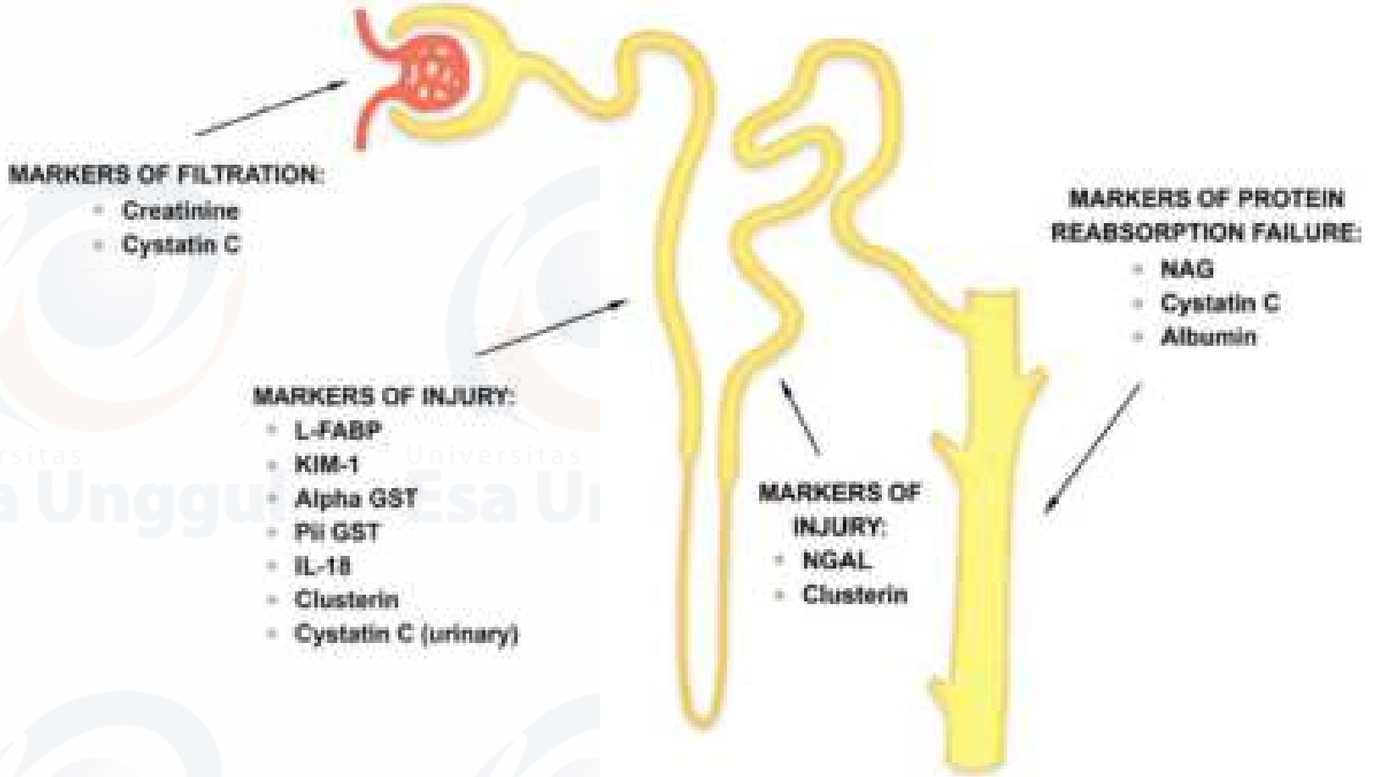
- **Usia lanjut:** Penurunan fungsi ginjal secara fisiologis terjadi seiring bertambahnya usia, yang membuat ginjal lebih rentan terhadap toksisitas obat. Pada orang lanjut usia, penurunan laju filtrasi glomerulus (GFR) seringkali tidak disadari sehingga dosis obat yang digunakan tidak disesuaikan.
- **Dehidrasi:** Volume cairan yang rendah meningkatkan risiko iskemia ginjal dan memperburuk nefrotoksisitas, terutama pada pasien yang menerima agen kontras radiologi.
- **Penyakit Ginjal Kronis (CKD):** Pasien dengan CKD memiliki kapasitas kompensasi ginjal yang terbatas, sehingga lebih rentan terhadap kerusakan lebih lanjut jika terpapar obat nefrotoksik.
- **Penggunaan Bersamaan Obat Nefrotoksik:** Penggunaan bersamaan beberapa obat nefrotoksik, seperti aminoglikosida, NSAID, dan cisplatin, dapat meningkatkan risiko terjadinya nefrotoksisitas.

2 MANIFESTASI KLINIS

- **Penurunan laju filtrasi glomerulus (GFR)**: Ini ditandai dengan peningkatan kadar kreatinin serum (Scr) dan nitrogen urea darah (BUN).
- **Gejala umum malaise:** Termasuk kelelahan, mual, muntah, dan nyeri tubuh.
- **Penurunan output urin:** Dalam beberapa kasus, terutama pada nefropati obstruktif, pasien mungkin mengalami oliguria atau anuria.
- **Gejala khas AIN:** Termasuk demam, ruam kulit, dan nyeri sendi.

3 LABORATORY TEST

Parameter	Nilai Referensi Abnormal
Kreatinin Serum	Peningkatan ≥ 0,3 mg/dL dalam 48 jam atau ≥ 50% peningkatan dalam 7 hari
Output Urin	<0,5 mL/kg/jam selama lebih dari 6 jam
Elektrolit	Hiperkalemia, hiponatremia, dan hiperfosfatemia
Acid-base	Metabolic acidosis



4 STRATEGIES

- AVOID/WITHDRAWAL RELATED TO RISK FACTOR
- ADJUSTMENT DOSAGE AND MONITORING
- ADEQUATE HYDRATION AND HEMODIALYSE/ TRANSPLANT

LIST OF DRUGS

Drugs Associated with Acute Renal Failure

Prerenal	Intrinsic	Postrenal
Diuretics	Radiocontrast dye	Indinavir
ACE inhibitors	Aminoglycosides	Acyclovir
ARBs	Foscarnet	Sulfonamides
NSAIDs	Amphotericin B	
Cyclosporine	Penicillins	
Interferon	Rifampin	
Interleukin-2	Immunoglobulin	
Tacrolimus	Methotrexate	
	Lithium	
	Tetracyclines	
	Phenytoin	
	Cimetidine	
	Cocaine	
	Mannitol	
	Statins	
	Cidofovir	
	Pentamidine	
	Fluoroquinolones	
	Allopurinol	
	Cisplatin	
	Cephalosporins	
	Thiazide diuretics	
	Ifosfamide	
	Indinavir	
	Gold	
	Mesalamine	

ACE: angiotensin-converting enzyme; ARBs: angiotensin II receptor blockers; NSAIDs: nonsteroidal anti-inflammatory drugs.

ERXERCISE

- Seorang pria berusia 60 tahun dengan ISPB- infeksi gram negatif, menjalani terapi gentamisin selama 7 hari. Setelah terapi dimulai, pasien mengalami penurunan output urin, dan kadar kreatinin serum meningkat dari 1,0 mg/dL menjadi 2,5 mg/dL.
- Diagnosis: Nefrotoksisitas akibat aminoglikosida.

Apa parameter objektif yang mendukung diagnosa tersebut?
Bagaimana mekanisme nefrotoksik gentamisin?
Apa plan dari kamu sebagai apoteker?

ERXERCISE

- Seorang wanita berusia 35 tahun menerima sulfasalazin untuk mengobati kolitis ulseratif. Setelah beberapa hari, pasien mengalami nyeri punggung bawah yang signifikan dan oliguria. Pemeriksaan urin menunjukkan kristal sulfonamid.

Drug induced Kidney Injury apa yang terjadi pada kondisi Pasien tersebut?
Bagaimana mekanisme DIKI tersebut?
Bagaimana plan dari kamu sebagai apoteker?

ERXERCISE

- Seorang pria berusia 50 tahun dengan riwayat hipertensi mengeluh nyeri sendi akibat osteoartritis dan menggunakan ibuprofen selama beberapa minggu. Pasien mengalami penurunan output urin, edema, dan peningkatan berat badan. Kreatinin serum meningkat dari 1,1 mg/dL menjadi 3,0 mg/dL.

Drug induced Kidney Injury apa yang terjadi pada kondisi Pasien tersebut?
Bagaimana mekanisme DIKI tersebut?
Bagaimana plan dari kamu sebagai apoteker?

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PSF426

Drugs Induced Liver Injury

Pertemuan 10

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Topik Sebelum UTS

Sesi 8

Drugs Related Problemd

Sesi 9

Drugs-Induced Kidney Injury

Sesi 10

Drugs-Induced Liver Injury

Sesi 11

Toksisitas dan Kedaruratan

Sesi 12

Pendekatan Terapi Modern

Sesi 13

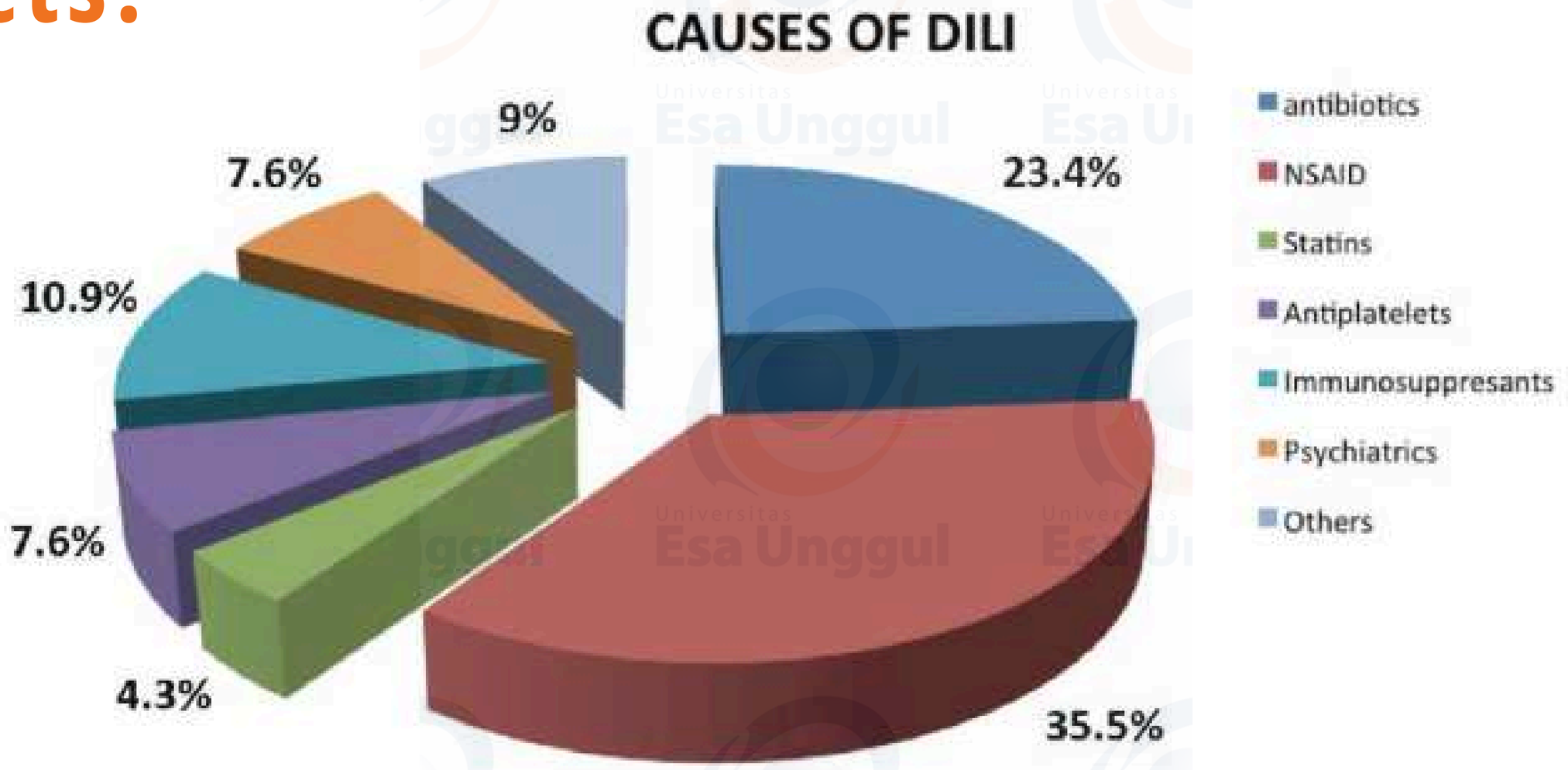
Project Based Discussion- Pelayanan Farmasi Klinis

Sesi 14

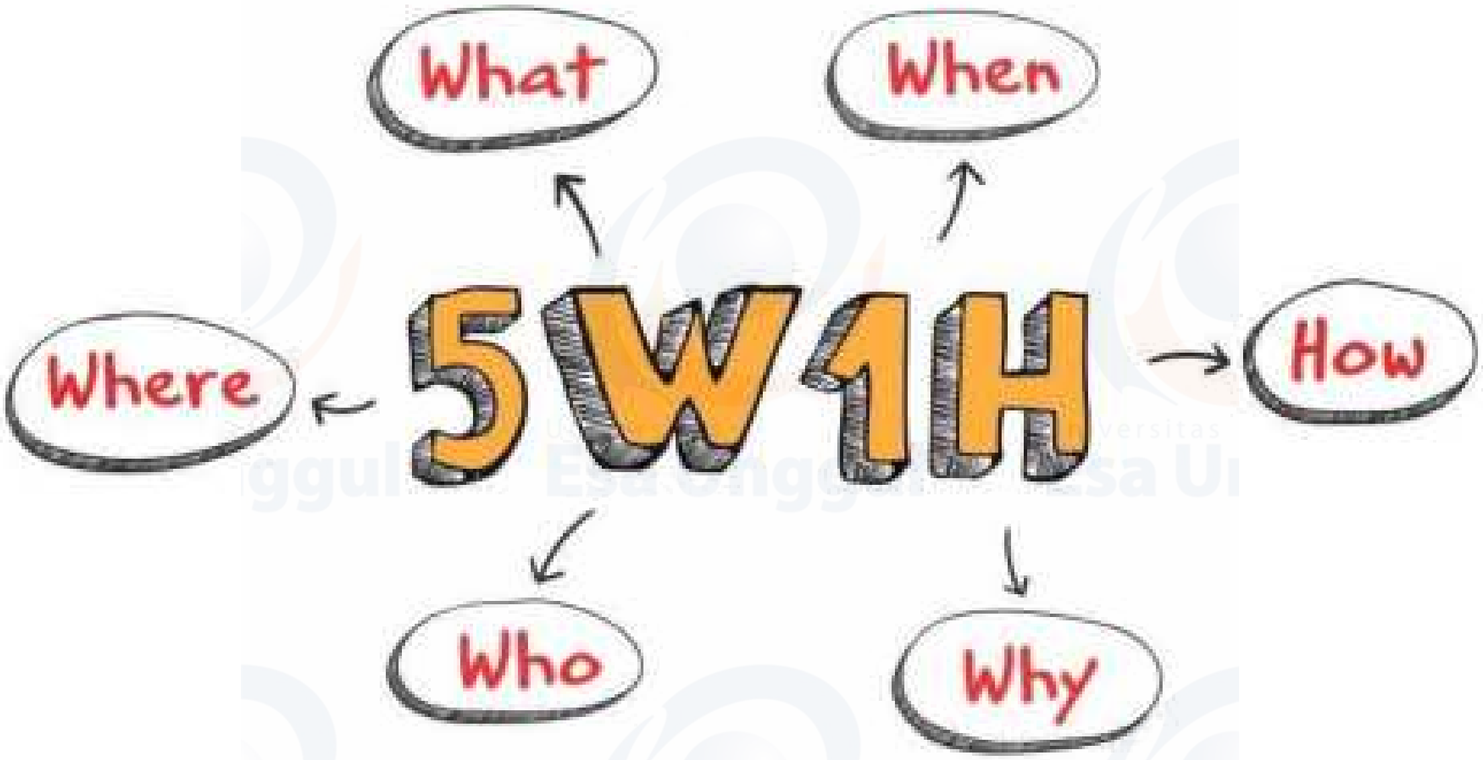
Presentasi Project Based Learning

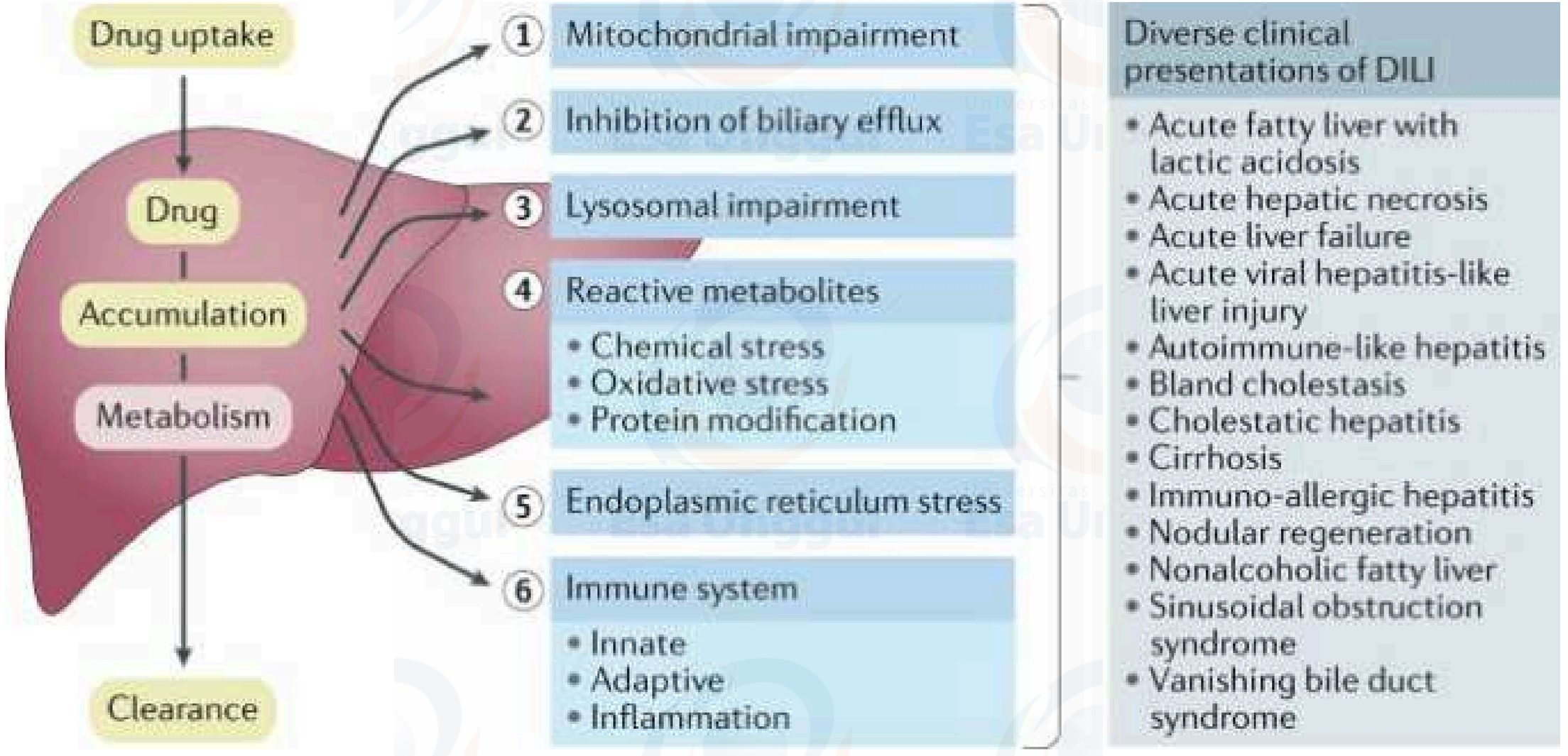
Ujian Tengah Semester

Facts!


CAUSES OF DILI
9%
7.6%
23.4%
10.9%
7.6%
4.3%
35.5%
antibiotics
NSAID
Statins
Antiplatelets
Immunosuppresants
Psychiatrics
Others

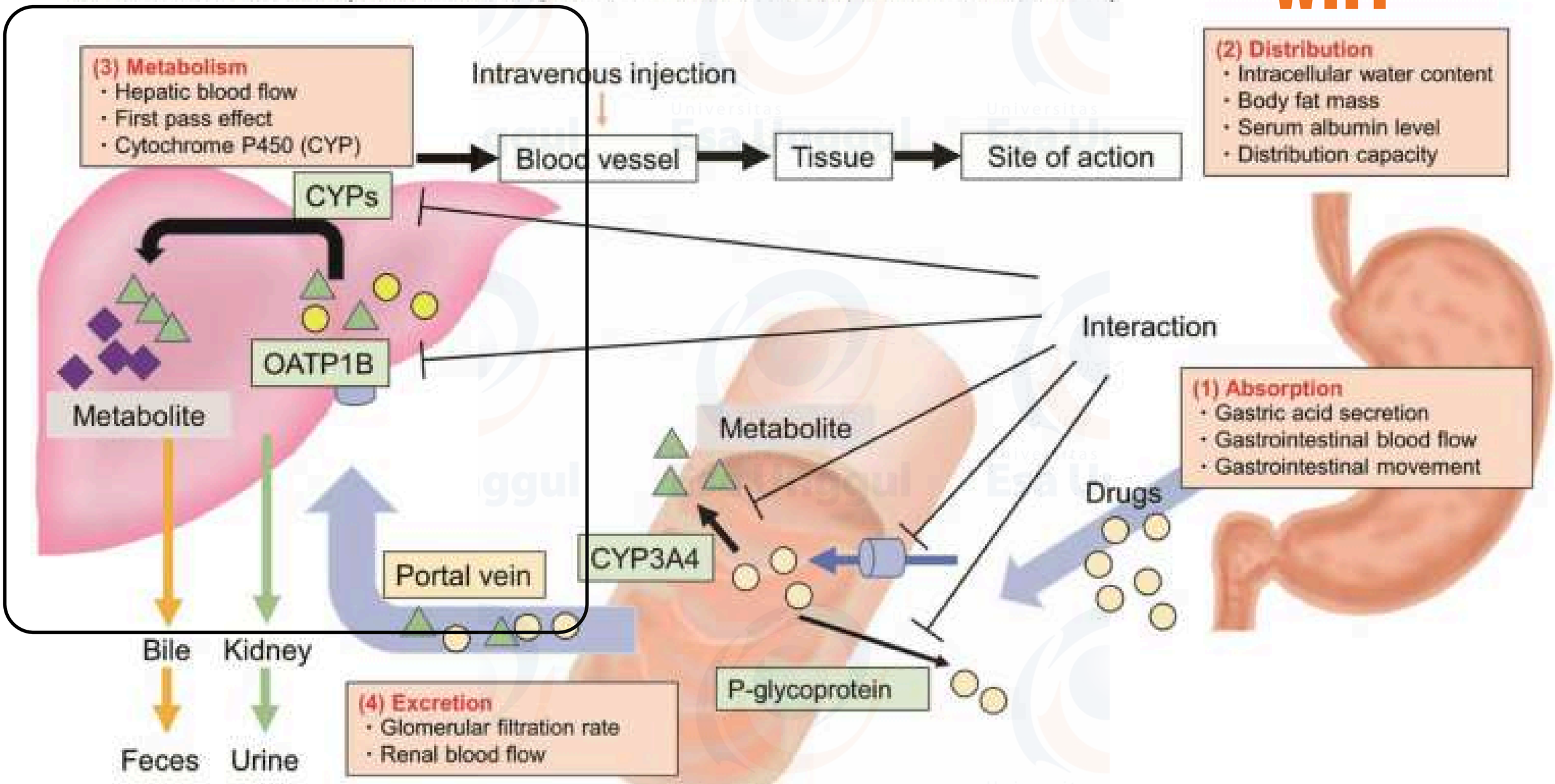
Drugs Induced Liver Injury




Drug uptake
Drug
Accumulation
Metabolism
Clearance
1 Mitochondrial impairment
2 Inhibition of biliary efflux
3 Lysosomal impairment
4 Reactive metabolites
• Chemical stress
• Oxidative stress
• Protein modification
5 Endoplasmic reticulum stress
6 Immune system
• Innate
• Adaptive
• Inflammation
Diverse clinical presentations of DILI
• Acute fatty liver with lactic acidosis
• Acute hepatic necrosis
• Acute liver failure
• Acute viral hepatitis-like liver injury
• Autoimmune-like hepatitis
• Bland cholestasis
• Cholestatic hepatitis
• Cirrhosis
• Immuno-allergic hepatitis
• Nodular regeneration
• Nonalcoholic fatty liver
• Sinusoidal obstruction syndrome
• Vanishing bile duct syndrome

Pharamacokinetics (ADME: Absorption, Distribution, Metabolism, Excretion)

WHY



Key Concept

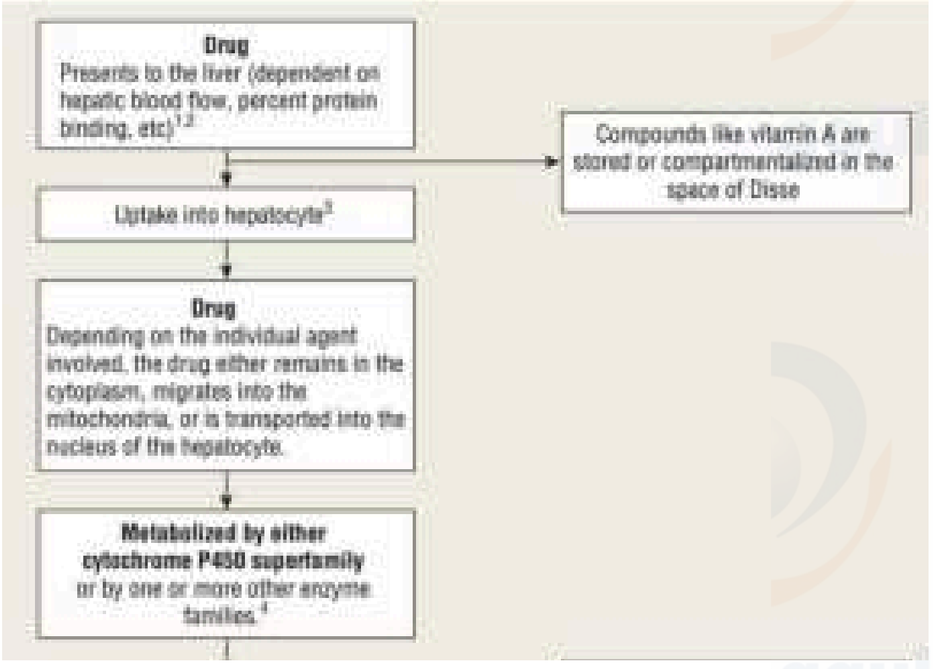
KEY CONCEPTS

1. The liver itself through its normally functioning enzymes and processes often causes a drug to become toxic through a process known as bioactivation.
2. Drug-induced liver disease occurs as several different clinical presentations: idiosyncratic reactions, allergic hepatitis, toxic hepatitis, chronic active toxic hepatitis, toxic cirrhosis, and liver vascular disorders.
3. The mechanisms of drug-induced liver disease are diverse, representing many phases of biotransformation, and are susceptible to genetic polymorphism.
4. A fulminant or severe drug-induced reaction within the liver usually involves the immune system and is marked by large scale cell necrosis.
5. The assessment of a possible liver injury caused by drugs should include what is known in the literature, the timing involved, the clinical course, and, always, an exploration for preexisting conditions that may have encouraged the lesion's development.
6. Liver enzyme assays can help to determine if a particular type of liver damage is present.
7. Monitoring for drug-induced liver disease must be tailored to the drug and the patient's potential risk factors.

HOW

WHEN

HOW


Drug
Presents to the liver (dependent on hepatic blood flow, percent protein binding, etc)[1,2]
Compounds like vitamin A are stored or compartmentalized in the space of Disse
Uptake into hepatocyte[3]
Drug
Depending on the individual agent involved, the drug either remains in the cytoplasm, migrates into the mitochondria, or is transported into the nucleus of the hepatocyte.
Metabolized by either cytochrome P450 superfamily or by one or more other enzyme families.[4]

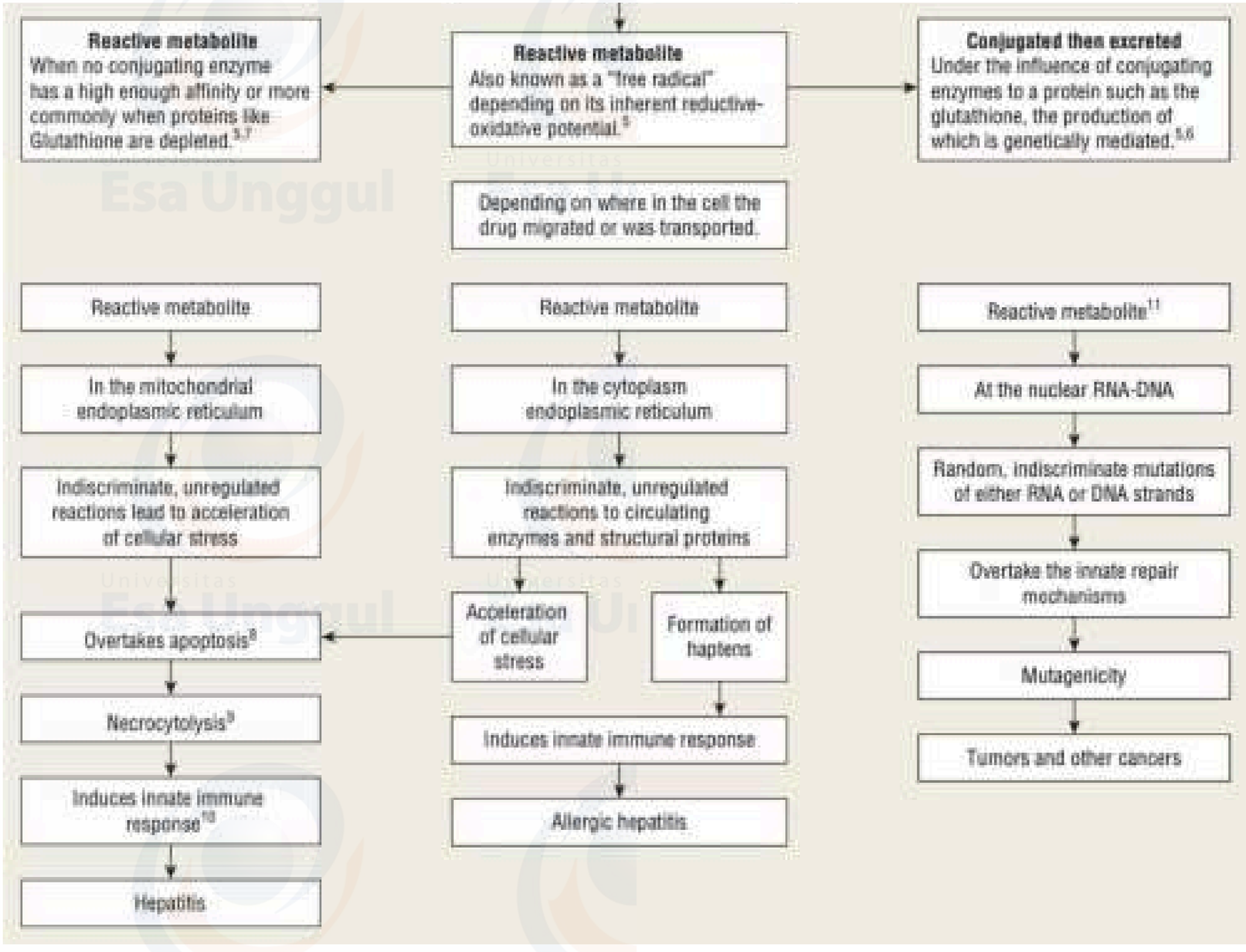

Reactive metabolite
When no conjugating enzyme has a high enough affinity or more commonly when proteins like Glutathione are depleted.[5,7]
Reactive metabolite
Also known as a "free radical" depending on its inherent reductive-oxidative potential.[5]
Conjugated then excreted
Under the influence of conjugating enzymes to a protein such as the glutathione, the production of which is genetically mediated.[5,6]
Depending on where in the cell the drug migrated or was transported.
Reactive metabolite
In the mitochondrial endoplasmic reticulum
Indiscriminate, unregulated reactions lead to acceleration of cellular stress
Overtakes apoptosis[8]
Necrocytolysis[9]
Induces innate immune response[10]
Hepatitis
Reactive metabolite
In the cytoplasm endoplasmic reticulum
Indiscriminate, unregulated reactions to circulating enzymes and structural proteins
Acceleration of cellular stress
Formation of haptens
Induces innate immune response
Allergic hepatitis
Reactive metabolite[11]
At the nuclear RNA-DNA
Random, indiscriminate mutations of either RNA or DNA strands
Overtake the innate repair mechanisms
Mutagenicity
Tumors and other cancers

TABLE 45-1 An Approach to Evaluating a Suspected Hepatotoxic Reaction Using a Clinical Diagnostic Scale

Patient Presents with Elevated Liver Enzymes	Score	Component Subscore
Literature		
Literature supports this drug (drug combination) and pattern of liver enzyme elevation	+2	
No literature supports this, but the drug has been on the market less than 5 years	+0	–
No literature supports this and the drug has been on the market for 5 years or more	–3	
Alternative causes		
Alternative causes (e.g., viral, alcohol) are completely ruled out	+3	
Alternative causes are partially ruled out	+0	–
Alternative causes cannot be ruled out and are possible or even probable	–1	
Presentation		
The presentation includes 4 or more extrahepatic (fever, malaise, etc.) symptoms	+3	
The presentation includes 2–3 extrahepatic symptoms	+2	–
The presentation includes only 1 identifiable extrahepatic symptom	+1	
The presentation is essentially a laboratory abnormality, with no extrahepatic symptoms	+0	
Temporality		
Initiation of drug therapy to onset is 4–56 days	+3	
Initiation of drug therapy to onset is <4 or >56 days	+1	
Discontinuance of therapy to onset is 0–7 days	+3	–
Discontinuance of therapy to onset is 8–15 days	+0	
Discontinuance of therapy to onset is >15 days	–1	
Rechallenge		
Rechallenge was positive	+3	–
Rechallenge was negative or not attempted	+0	
Total Score		–

1 DILI ASSESSMENT

- The likelihood that this presentation is an adverse reaction in the liver increases linearly with an increasing score.
- The maximum score is 14, and scores below 7 are associated with an ever decreasing likelihood that the drug or drug combination in question caused the problem.
- This approach is not designed for the assessment of hepatic cancers or cirrhotic conditions.

Roussel Uclaf Causality Assessment Method (RUCAM)

2 LAB TEST

TABLE 45-3 Relative Patterns of Hepatic Enzyme Elevation versus Type of Hepatic Lesion

Enzyme	Abbreviations	Necrotic	Cholestatic	Chronic
Alkaline phosphatase	Alk Phos, AP	↑	↑↑↑	↑
5′-Nucleotidase	5-NC, 5NC	↑	↑↑↑	↑
γ-Glutamyltransferase	GGT, GGTP	↑	↑↑↑	↑↑
Aspartate aminotransferase	AST, SGOT	↑↑↑	↑	↑↑
Alanine aminotransferase	ALT, SGPT	↑↑↑	↑	↑↑
Lactate dehydrogenase	LDH	↑↑↑	↑	↑

↑, <100% of normal; ↑↑, >100% of normal, ↑↑↑, >200% of normal.

3 MANAGEMENT

TABLE 45-4 An Approach to Determining a Drug-Monitoring Plan to Detect Hepatotoxicity in Patients Initiated on Hepatotoxic Drugs

Draw a baseline set of blood samples for liver enzymes, bilirubin, and albumin before beginning the drug

↓

Is the patient pregnant?
Is the patient older than age 60 years?
Is the patient exposed to an environmental hepatotoxin at work or at home?
Is the patient drinking more than one alcoholic beverage per day or bingeing?
Is the patient using any injected recreational drug?
Is the patient using herbal remedies or tisanes that are associated with hepatic damage?
Is the patient's diet deficient in magnesium, vitamin E, vitamin C, or α- or β-carotenes?
Is the patient's diet excessive in vitamin A, iron, or selenium?
Does the patient have hypertriglyceridemia or type 2 diabetes mellitus?
Does the patient have juvenile arthritis or systemic lupus erythematosus?
Does the patient have chronic or chronic remitting viral hepatitis (hepatitis B or C)?

↓

Yes to one to two risk factors → Redraw liver enzymes every 180 days depending on the drug, for the first year

No → Redraw liver enzymes if other signs or symptoms manifest

Does the patient have more than two risk factors?
Is the drug identified as one that may cause a predictable hepatotoxic reaction?[a]

Yes → Redraw liver enzymes every 60–90 days depending on the drug, for the first year

No → Redraw liver enzymes every 180 days as directed above for the first year

No → Redraw liver enzymes if other signs or symptoms manifest

If no toxicity is manifested during the first year of therapy, then redraw liver enzymes every 6–12 months; assess liver for cirrhosis every 1–2 years by ultrasound and every 4–6 years by CT or MRI scan; biopsy as directed by other findings

TABLE 45-2 Environmental Hepatotoxins and Associated Occupations at Risk for Exposure

Hepatotoxin	Associated Occupations at Risk for Exposure
Arsenic	Chemical plant, agricultural workers
Carbon tetrachloride	Chemical plant workers, laboratory technicians
Copper	Plumbers, sculpture artists, foundry workers
Dimethylformamide	Chemical plant workers, laboratory technicians
2,4-Dichlorophenoxyacetic acid	Horticulturists
Fluorine	Chemical plant workers, laboratory technicians
Toluene	Chemical plant, agricultural workers, laboratory tech
Trichloroethylene	Printers, dye workers, cleaners, laboratory technicians
Vinyl chloride	Plastics plant workers; also found as a river pollutant

4 STRATEGIES

AVOID/WITHDRAWAL RELATED TO RISK FACTOR

ADJUSTMENT DOSAGE AND MONITORING

SUPPORTING AGENT:
N-ACETYLCYSTEIN
GLUCOCORTICOID

LIST OF DRUGS

TABLE I: CLASSIFICATION OF DILI ACCORDING TO PATTERN OF INJURY

HEPATOCELLULAR *(ALT ELEVATED)*	CHOLESTATIC *(ALP AND BILIRUBIN ELEVATED)*	MIXED *(ELEVATED ALP AND ALT)*
Aspirin	Chlorpromazine	Amitriptyline
Allopurinol	Clopidogrel	Azathioprine
Amiodarone	Amoxicillin/clavulanic acid	Cyclosporine
Bupropion	Co-trimoxazole	Carbamazepine
Ciprofloxacin	Efavirenz	Clindamycin
Isoniazid	Erythromycin	Co-trimoxazole
Ketoconazole	Nevirapine	Enalapril
Losartan	Oral contraceptives	Erythromycin
Methotrexate	Phenothiazines	Phenobarbital
Nevirapine	Terbinafine	Phenytoin
NSAIDs		Sulphonamides
Paracetamol		Trazodone
Protease inhibitors		Verapamil
Pyrazinamide		
Rifampicin		
Risperidone		
Sertraline		
Statins		
Valproic acid		
Venlafaxine		

Adopted and expanded from: Navarro VJ, Senior JR. Drug-related hepatotoxicity. N Engl J Med 2006;16;354(7):731-739.

EXERCISE

- Usia 50 tahun (pria), tidak terdapat riawayat penyakit hati, dan rutin mengonsumsi alkohol 3-4 kali perminggu.
- Telah menggunakan paracetamol 3 gram/ hari untuk mengatasi nyeri sendi selama 2 minggu.
- Gejala klinis berupa: mual, muntah, nyeri perut bagian atas, ada kekuningan pada kulit (ikterus)
- Pemeriksaan Lab menunjukkan kenaikan ALT (600 IU/L), AST (520 IU/L), dan bilirubin total (3 mg/dL).

Berapa total skor RUCAM?

Plan asuhan kefarmasian yang direncanakan adalah?

EXERCISE

- Usia 35 tahun (wanita), Alergi terhadap antibiotik penisilin
- Mengalami ISPB dan diberikan amoksisilin-klavulanat.
- Gejala klinis berupa: setelah 10 hari penggunaan amoksiklav, demam, ruam, mual, nyeri di perut kanan atas. Pada hari ke 12 ikterus muncul nampak
- Pemeriksaan laboratorium menunjukkan peningkatan ALT (700 IU/L), AST (650 IU/L), alkali fosfatase (400 IU/L), dan bilirubin total (5 mg/dL).

Berapa total skor RUCAM?
Plan asuhan kefarmasian yang direncanakan adalah?

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Rise your hand!

any question?

PSF426

Toxicity and Emergency

Pertemuan 11

Dosen Pengampu:

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Topik Sebelum UTS

Sesi 8

Drugs Related Problemd

Sesi 9

Drugs-Induced Kidney Injury

Sesi 10

Drugs-Induced Liver Injury

Sesi 11

Toksisitas dan Kedaruratan

Sesi 12

Pendekatan Terapi Modern

Sesi 13

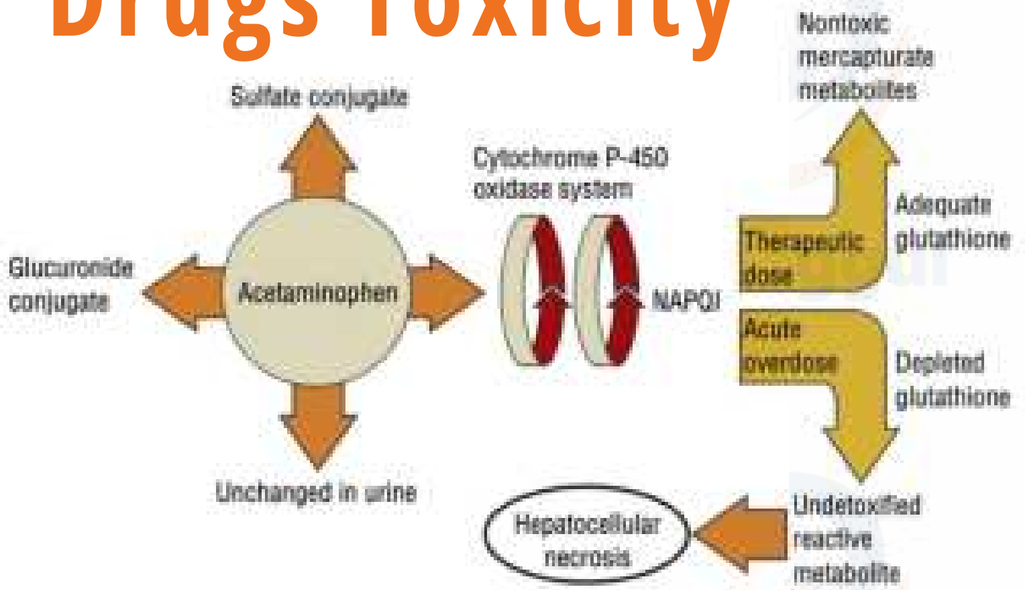
Project Based Discussion- Pelayanan Farmasi Klinis

Sesi 14

Presentasi Project Based Learning

Ujian Tengah Semester

Drugs Toxicity



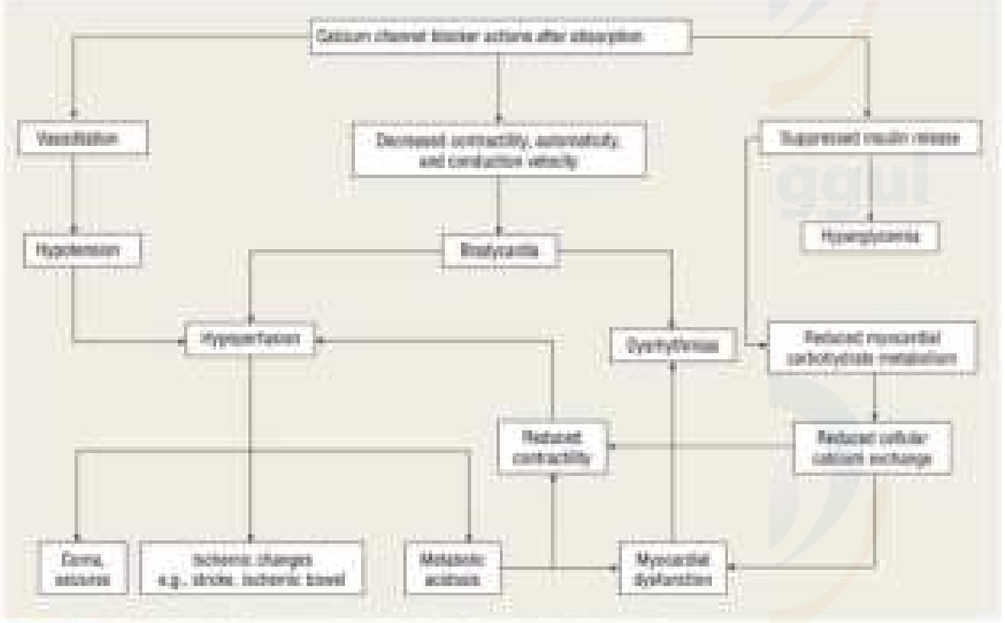


FIGURE 14-5. Pathophysiologic changes associated with calcium channel blocker poisoning.

Other Toxicity

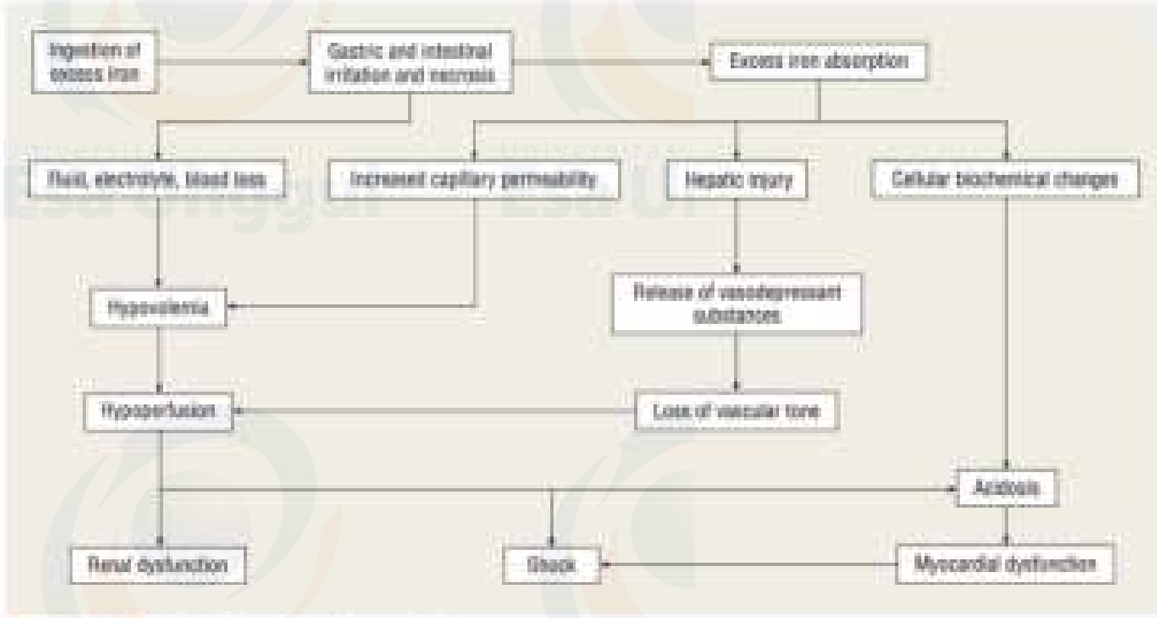


FIGURE 14-6. Pathophysiology of acute iron poisoning.

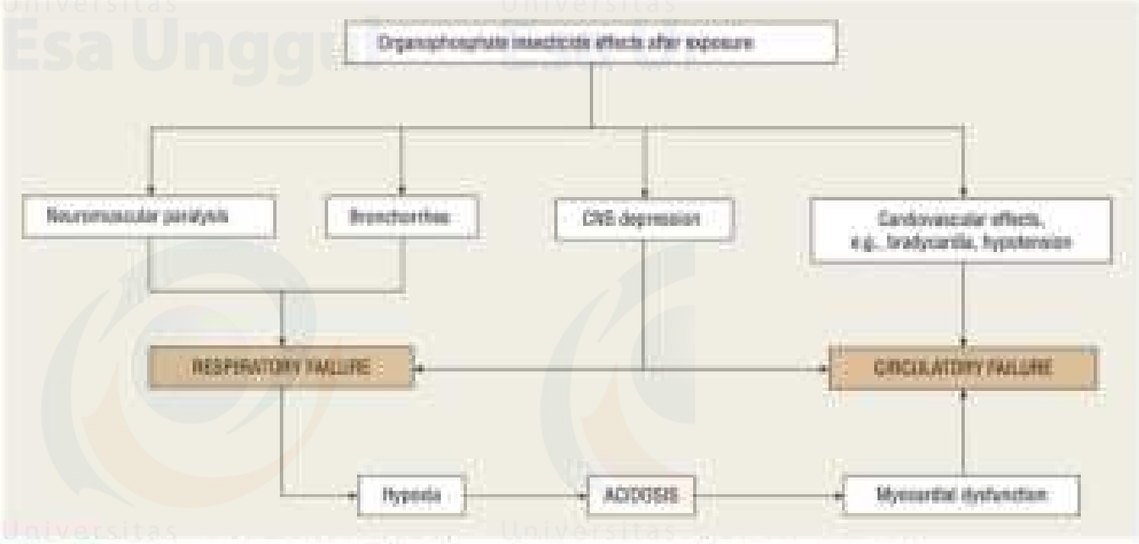
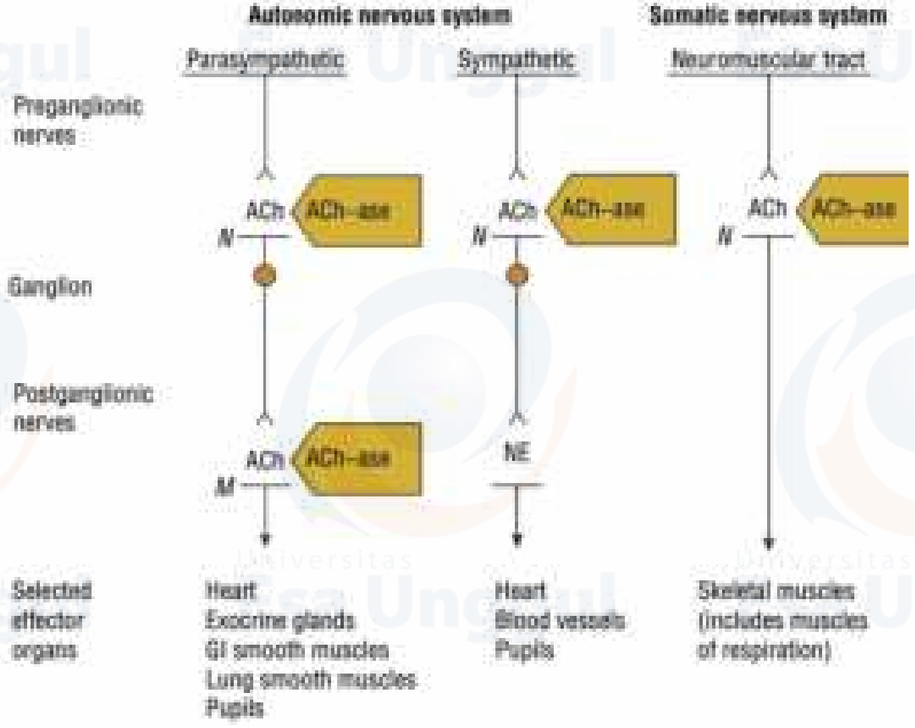


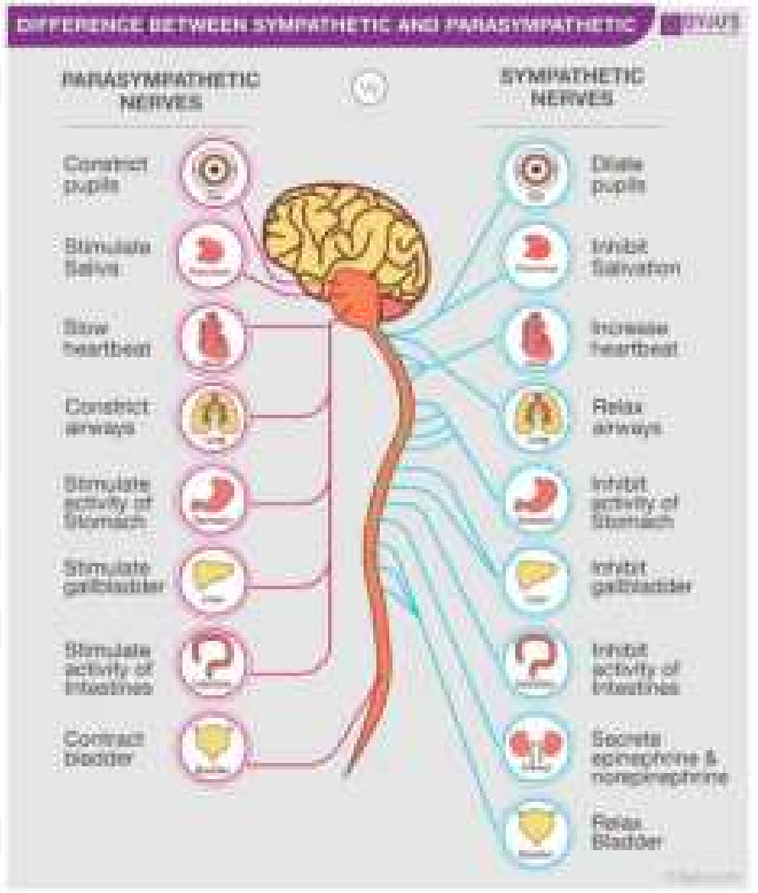
FIGURE 14-3. Pathogenesis of life-threatening effects of organophosphate poisoning. (CNS, central nervous system.)

Principle of Antidotes

TABLE 14-10 Comparison of Intravenous and Oral Regimens for Acetylcysteine in the Treatment of Acute Acetaminophen Poisoning

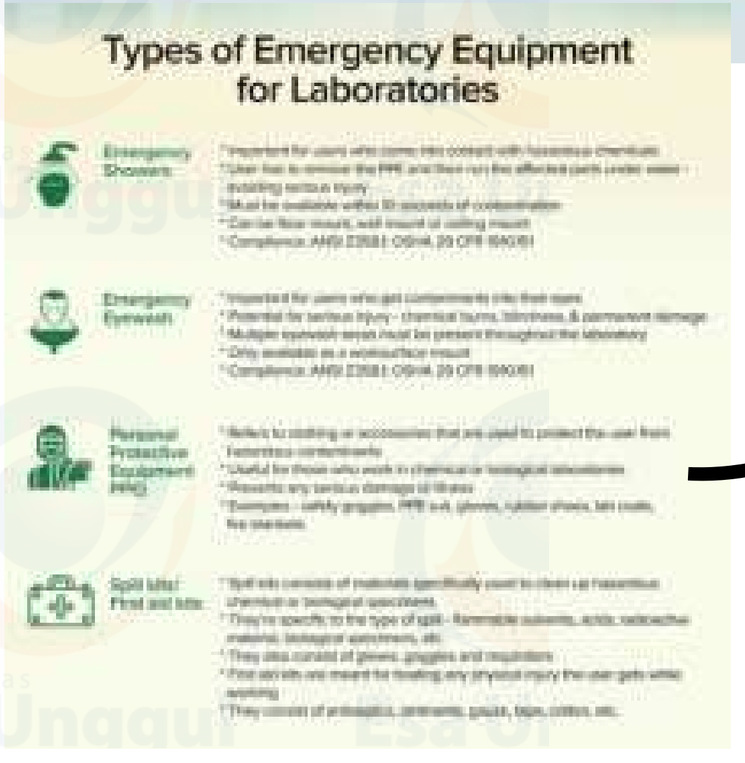
Characteristic	Intravenous	Oral
Regimen	150 mg/kg in 200 mL D_5W infused over 1 hour, then 50 mg/kg in 500 mL D_5W over 4 hours, followed by 100 mg/kg in 1,000 mL D_5W over 16 hours[a]	140 mg/kg, followed 4 hours later by 70 mg/kg every 4 hours for 17 doses diluted to 5% with juice or soft drinks
Total dose (mg/kg)	300	1,330
Duration (h)	21	72
Adverse effects	Anaphylactoid reactions (rash, hypotension, wheezing, dyspnea); acute flushing and erythema in first hour of the infusion that typically resolves spontaneously	Nausea, vomiting
Ancillary therapy, if needed	Antihistamines and epinephrine for severe anaphylactic reactions	Antiemetics, e.g., metoclopramide, ondansetron, or droperidol
Trade name	Acetadote	Mucomyst
Available strength	20%	10%, 20%






serenity S-ET54
Emergency trolley
Drawers (three different height small, medium and large)
Central locking
Hidden telescopic deputy working table
ABS double dirt buckers


BIOHAZARD SPILL KIT
DISINFECTION GRANULES
CHLORINE DISINFECTION TABLETS
DILUTION BOTTLE
APRONS
SCOOP AND SCRAPERS
Biohazard Spill Kit
WALL BRACKET
LOGGING CARD
NITRILE GLOVES
CLINICAL WASTE BAGS
1 X INSTRUCTION POSTER
PAPER TOWELS


Types of Emergency Equipment for Laboratories
Emergency Showers
Emergency Eyewash
Personal Protective Equipment (PPE)
Spill kits/ First aid kits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Crash Cart Management in Emergency Situations
Understand the importance of crash carts and managing emergency supplies effectively. Ensure...
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