Role of clinical pharmacy in Pharmacovigilance and Development of pharmacovigilance systems

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PHARM.D in therapeutic

B.S of clinical pharmacy

Clinical pharmacy

- **Clinical pharmacy** is a health science and practices of rational use of drug where the pharmacists provide patient care that optimizes medication therapy and promotes health, wellness, and disease prevention.
- **Clinical pharmacists** deal directly with physicians, other health professionals, and patients to ensure that the medications prescribed for patients contribute to the best possible health outcomes.
- **Clinical pharmacist** applies evidence-based therapeutic guidelines, evolving sciences, emerging technologies, and relevant legal, ethical, social, cultural, economic and professional principles.

Role of clinical pharmacy

1) Medication order review.
2) Patient counseling regarding safe and rational use of drugs.
3) patient education about his disease and his medications.
4) **Adverse drug reaction monitoring.**
5) Drug interactions **monitoring.**
6) Therapeutic **drug monitoring.**
7) Pharmacist **intervention and recommendation**
8) Update guideline line of disease and drugs

How Pharmacovigilance works

ADR Suspicion

ADR Reporting

ADR Analysis

Sharing of Findings

REPORTING OF ADVERSE DRUG REACTION

- Spontaneous reporting of suspected adverse drug reactions is the major source of information in pharmacovigilance. This information can be obtained from **a regional or country-wide system for reporting.**

Reporting form

1. The patient: age, sex and brief medical history
2. Adverse event: description (nature, location, severity, characteristics), investigations and tests, start date, course and outcome.
3. Suspected drug(s): name (brand or ingredient name and manufacture), daily dose, route, start/stop dates, indication for use (with particular drugs, e.g. vaccines, a batch number is important).
4. All other drugs used (including self-medication): names, doses, route, 5. Risk factors (e.g. impaired renal function, previous exposure to suspected drug, previous allergies, social drug use).
5. Name and address of reporter (to be considered confidential and to be used only for data verification, completion and case follow-up).

Republic of Yemen
Ministry of Public Health and Population
Supreme Board of Drugs
& Medical Appliances
Yemeni Center for Pharmacovigilance
and Medical Safety

الجمهورية اليمنية
وزارة الصحة العامة والسكان
الهيئة العليا للأدوية والمستلزمات الطبية
المركز اليمني للتيقظ والسلامة الدوائية

Adverse Drug Reactions(ADRs)Reporting Form
For Health Care Professionals (ADR-1)

A. Patient Details

Patient name or Initial (Optional): ------------------------ Date of birth: ----/----/---- Height: ------ Weight: ------ Health Institution: -------------------- Age: ------ Sex: ذ/أ

B. Suspected Drug(s) / Vaccine(s)/ Herbal(s) /Cosmetic(s) and all other drugs used.

		Drug name"Generic &Brand"	Manufacturer and batch No.	Dose /Route /Frequency	Start date	End date	Purpose of use
Suspected	1						
	2						
	3						
Concomitant	1						
	2						
	3						

C. Adverse Drug Reaction

Adverse event including relevant tests/lab data and dates.	Other relevant history, including preexisting medical conditions, (eg. allergies, pregnancy, hepatic, renal etc)
Date of event started:	Date of event disappeared, if applicable:

D. Action Taken

Drug withdrawn. Dose reduced. Dose increased. Dose not changed. Unknown. Not applicable.

E. Outcome of ADR (Tick all applicable)

The patient: Recovered, date: Recovering No improvement Died Unknown
Event subsided after stopping (dechallenge) No Yes Unknown
Event reappear after reintroducing (rechallenge) No Yes Not applicable
Specific antagonist or treatment used: No Yes, specify:-----------

F. Seriousness of ADR (Tick all applicable)

Patient died, date: Life threatening Permanent disability
Hospitalization Prolonged hospitalization more than 24 hr. Congenital anomaly
Required intervention to prevent permanent impairment/damage Required Emergency Room (ER) visit
Cancer Others.................

G. Reporter Details

Reporter name :	Profession (Specialty):
Address:	E-mail:
Phone /Mobile: Fax :	Date: Signature:

What to report?

- For “new” drugs- report all suspected reactions, including minor ones.
- For established or well-known drugs- report all serious or unexpected (unusual) suspected ADRs Report if an increased frequency of a given reaction is observed.
- Report all suspected ADRs associated with drug-drug, drug-food or drug-food supplements (including herbal or complementary products) interactions.
- Report ADRS in special fields of interest such as drug abuse and drug use in pregnancy and during lactation.
- Report ADRs occurring from overdose or medication error.
- Report when there is a lack of efficacy or when suspected pharmaceutical defects are observed.

Case study

Lisino**pril**

- **Hypertension:** Oral: Initial: **10 mg once daily** (not maintained on a diuretic) or **5 mg once daily** (maintained on a diuretic); adjust dose according to blood pressure response. Target dose (JNC 8) 40 mg once daily; usual dosage range 10 to 40 mg daily
- **Note:** Antihypertensive effect may diminish toward the end of the dosing interval especially with doses of 10 mg daily**. An increased dose may aid in extending the duration of antihypertensive effect**.

- **Heart failure:** Oral: Initial: 2.5 to 5 mg once daily

Patients taking diuretics should have them discontinued 2 to 3 days prior to initiating lisinopril if possible. Restart diuretic after blood pressure is stable if needed. If diuretic cannot be discontinued prior to therapy, begin with 5 mg with close supervision until stable blood pressure. In patients with hyponatremia (<130 mEq/L), start dose at 2.5 mg/day.

Renal Impairment

- **Hypertension:**
- CrCl >30 mL/minute: No dosage adjustment necessary.
- CrCl 10 to 30 mL/minute: Initial: 5 mg once daily (maximum: 40 mg/day)
- CrCl <10 mL/minute: Initial: 2.5 mg once daily (maximum: 40 mg/day)
- Hemodialysis: Initial: 2.5 mg once daily (dialyzable) (maximum: 40 mg/day)
- **Administration**

Administer as a **single daily dose** and **without regard to meals.**

Equivalent Dose

Lisinopril 5 mg is equivalent to:		
benazepril 5 mg	captopril 25 mg	enalapril 2.5 mg
fosinopril 5 mg	moexipril 3.75 mg	Perindopril 2 mg
Quinapril 5 mg	ramipril 1.25 mg	Trandolapril 1 mg
Lisinopril 10 mg is equivalent to:		
benazepril 10 mg	captopril 50 mg	enalapril 5 mg
fosinopril 10 mg	moexipril 7.5 mg	Perindopril 4 mg
Quinapril 10 mg	ramipril 2.5 mg	Trandolapril 2 mg

Pharmacodynamics and Pharmacokinetics

- Onset of action: 1 hour; Peak effect: Hypotensive: Oral: ~6 hours
- Duration: 24 hours
- Half-life elimination: 12 hours
- Time to peak:
  - Pediatric patients 6 months to 15 years: Median (range): 5 to 6 hours
  - Adults: ~7 hours
- Excretion: Primarily urine (as unchanged drug)

Monitoring Parameters

- Blood pressure
- Heart rate; BUN
- Serum creatinine
- Potassium

Case study report

1) A 50-year-old Woman with hypertension and Dyslipidemia currently treated with **hydrochlorothiazide** 25 mg daily, **Lisinopril** 20 mg daily, **carvedilol** 25 mg twice daily, His BP is 135/58 mm Hg (138/86 mm Hg when repeated). He is adherent with all of these medications.

Check up Laboratory test 1 after 3 month of treatment

Serum creatinine is 0.9 mg/dL, potassium is 3.7 mEq/L, and all other laboratory values are normal.wieght 70 kg, Height 175 cm. Also Cholesterol 240 mg/dl LDL 270 mg/dl and HDL 45mg\dl

Check up Laboratory test 2 After 6 month of treatment

Serum creatinine is 4.5 mg/dL, potassium is 3.7 mEq/L, and all other laboratory values are normal.wieght 70 kg, Height 175 cm. Also Cholesterol 240 mg/dl LDL 270 mg/dl and HDL 45mg\dl

Lisinopril <1%, post marketing or case reports:Acute renal failure

hydrochlorothiazide <1%, postmarketing, and/or case reports: Allergic myocarditis, eosinophilic pneumonitis, hepatic insufficiency

carvedilol <1%, postmarketing, and/or case reports: Allergic myocarditis, eosinophilic pneumonitis, hepatic insufficiency

شكراً لحسن إستماعكم ... ☺