PAGE NO.:

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* Economic

S-22

Q7(c) Application of P'economics

i) P'economics can be defined as the study of how individuals & group choose to allocate ...

ii) P'economics can be defined as "the field of study that evaluate the behaviour of individual, firm & market relevant to use of pharmaceutical products, service & programs & which frequently focus on cost & consequences of use.

iii) It involve 3 analysis

(i) Perspective of Evaluation

- patient perspective :-
- Provider perspective.
- Payer perspective
- Society perspective

(ii) Cost

- Direct Medical cost
- Direct Nonmedical "
- Indirect Cost
- ~~Tang~~ Intangible cost
- Opportunity cost

(iii) Consequences.

- Economic Outcome
- Clinical "
- Humanistic "
- Positive "
- Negative "
-

iv) It is measure by 2 method.

(i) Economic

(a) Partial economic
- cost consequence analysis
- cost of illness

(b) Full economic.
- CMA
- CBA
- CEA.

(ii) Humanistic

- Quality of life year
- Patient preference

* Application of economic.

PAGE NO.:

① In formulary decision :-

(i) Cost Effective analysis :- P'economic helps assess medication for inclusion in a formulary, considering both efficacy & cost.

(ii) Resource Allocation :- It guides healthcare providers in allocating resource effectively by comparing different treatment options.

② Drug development & pricing :-

(i) Decision making :- Pharmaceutical companies leverage p'economics to determine the viability of drug development based on projected costs and potential return.

(ii) Pricing Strategies :- Economic evaluation inform drug pricing strategies by considering development cost, market competition and expected value to patients.

③ Clinical Practice & Patient Care :-

(i) Treatment Selection :- By analysing cost effectiveness clinicians can make informed decision about the most suitable medication for individual patient.

(iii) Value-Based Care :- Pharmacoeconomics supports value-based care by ensuring treatment delivers clinical benefit at a suitable cost.

(iii) Optimizing regimen :- It can help identify cost-saving opportunities while maintaining therapeutic while maintaining therapeutic efficacy within treatment plan.

④ Public health Policy.

(i) Resource Allocation :- It aids in allocating healthcare resource efficiently across different diseases area & t/t option

(ii) Cost-Benefit Analysis :- This approach help compare the broader economic impact of intervention like vaccination programs, considering social cost & benefit.

⑤ Research & development.

(i) Real world Effectiveness :- Economic evaluation can be used alongside clinical trial to assess a drug's effectiveness in real-world

(iii) Improve patient outcome :- Ensure patient recieve the most CEA effect improve their health & quality of life.

(7b) Role of p'cist in drug induced birth defect.

=> Pharmacist serve as a vital line of defense in minimizing the risk of drug-induced birth defects.

=> Their expertise in medication safety empowers them to contribute significantly to safer medication use during pregnancy.

1. Knowledge & risk assessment:

(a) Teratogenic Medication :- Pharmacist possess in depth knowledge of medication classified as teratogenic

(b) Pregnancy risk Categories :- They understand the FDA pregnancy risk categories assigned to medication, guiding safer prescribing choices for pregnant women.

(c) Drug interaction analysis :- They can identify potential interaction b/w prescribed medication

2. Patient Counselling & Communication

(d) Pregnancy Screening :- Pharmacist can incorporate pregnancy screening questions during medication dispensing, prompting further discussion if needed.

(e) Alternative Medication Suggestions :- They can propose safer medication alternative for pregnant women, considering a medical condition.

(f) Risk - Benefit communication

(g) Patient Education Material.

(3) Collaboration :

(h) Physician Collaboration :- Pharmacist can collaborate with prescribing physicians to identify safer alternative.

(i) Referal to Prenatal Care :- They can advice patients to seek comphrensive prenatal care for optimal pregnancy patient.

(j) Public Health Reporting :- Pharmacist may be required to report suspected teratogenic reaction to regulatory authorities.

(4) Inventory Managment & Dispensing.

(k) Warning label verification :- Pharmacist can verify the presence of appropriate pregnancy warning on medication labels.

(l) Prescription double - checking.

(5) Preconception & Medication Review

(m) Preconception Counselling :- Pharmacist can offer preconception counseling, advising on medication to avoid before pregnancy.

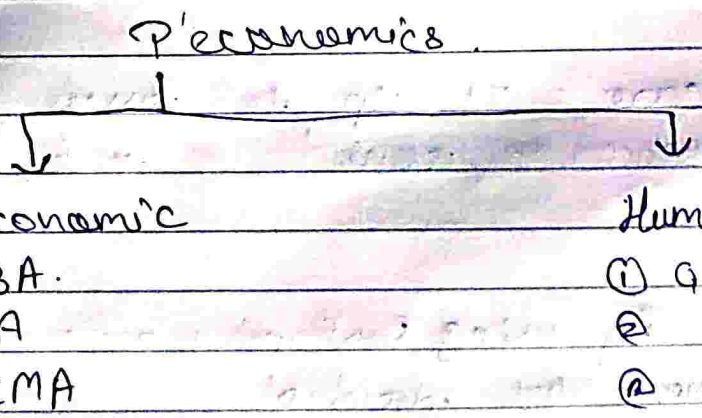
(n) Medication Review for Pregnancy planning :- They can conduct medication review for women planning pregnancy

(o) Monitoring Teratogenic Events

Q2710) Term Pheconomic, need for p'economic in india.

⇒ P'economics is a scientific discipline that evalute the economic consequences of pharmaceutical intervention alongside their clinical effect.

⇒ mainly pharmacoeconomics divided as.



ii) It mainly involve 3 analysis.

(i) Prospective
(ii) Measuring Cost
(iii) Consequences measurement.

iii) The need of p'economic in india is because.

1) Resource Allocation & Efficiency.

(a) Prioritizing T/t option :- By analyzing CEA, it help healthcare provider to choose most effective t/t.

(b) Budgetary Constrain :- In a resource-limited environment, it guide for allocation of healthcare budget across different t/t.

(c) Formulary Decision :- It inform regarding formularies, considering both effectiveness & cost factor

2) Value Based care :- It help to assess the overall value of medication, considering cost, effectiveness & safety

3) Optimizing T/t :- By using cost minimization analysis better treatment are decided.

4) Quality of life :- The analysis (QOLY) measure the impact of treatment on quality of life.

5) Public Health Policy

(a) Cost Benefit Analysis :- It aids in assessing public health over the cost impact on public.

(b) Programms :- The vaccination program care performed to provide better treatment to large population within minimal cost of treatment.

(c) Global health consideration :- P'economic provide data for each treatment by comparing directly the cost & economic.

6) Research & Development :- P'eutical companies utilize p'economic data to determine financial viability of drug development based on projected cost.

7) Decision - Analytic Modeling :- P'economic models can predict the long-term cost & benefits of various intervention.

8) Improving Patient Access :- It aim to improve patient access the CE t/t that delives most value in terms of health outcome & quality of life.

Q6(c) Describe prescription event monitoring.

⇒ PEM is non-interventional, observational cohort form of pharmacovigilance.

⇒ It is the method of studying the safety of new medication used by the general practitioner

⇒ It is a collaborative method between Doctor, pharmacist & patient

* Evolution of PEM

⇒ The PEM ~~of~~ for drug safety came into existence after Thalidomide disaster 1961.

⇒ Professor Inam recognised the limitation of several drug & established drug safety research unit (DSRU)

⇒ Pre marketing CT care effective in studying the efficacy of medicine but are not able to define many aspect of drug safety because.

1. Small number of Patient.

2. Large number of Patient receiving the drug for small duration.

3. Dose & formulation of drug may change during drug development.

4. Exclusion special population from C.T.

* PEM process in U.K.

DSUR notify authority of new drug
↓
Patient visit Pharmacist ∑ prescription
↓
Pharmacist dispense medication & forward to authority
↓
PPA sends prescription data to DSUR
↓
DSUR questioner form
↓
Data form questioner entered in DSUR.
↓
Follow up.

* The formula for incidence density to measure number of report of each event per thousand patient are as.

$$IDt = \frac{\text{Number of event during treatment time t}}{\text{number of patient-month exposed to drug}} \times 1000$$

* Application

① Search for signal

② Assessment of important ADR
③ Medically important events
④ Reason for stopping drug
⑤ Patient Outcome

* Advantage.

① "Real world data" :- Provide an insight into safety profile of medication in real world clinical practice setting.

② Large Sample Size :- Include large patient population allow us to detect rare ADR

③ longitudinal follow up :-

Advantages of Prescription Event Monitoring:

1. **Real-world Data**: PEM provides insights into the safety profile of medications in real-world clinical practice settings, complementing pre-marketing clinical trial data.
2. **Large Sample Sizes**: PEM studies can include large patient populations, allowing for the detection of rare adverse events that may not have been identified in pre-marketing clinical trials.
3. **Longitudinal Follow-up**: PEM involves longitudinal follow-up of patients over an extended period, enabling the assessment of long-term safety outcomes and the detection of delayed adverse reactions.
4. **Diverse Patient Populations**: PEM captures data from diverse patient populations, including those with comorbidities, co-medications, and varying demographic characteristics, providing a comprehensive understanding of medication safety across different patient groups.
5. **Passive Surveillance**: PEM utilizes passive surveillance methods, such as spontaneous reporting, which allows for the continuous monitoring of medication safety without imposing additional burden on healthcare providers or patients.

Disadvantages of Prescription Event Monitoring:

1. **Underreporting**: Like other pharmacovigilance methods, PEM is subject to underreporting bias, as not all ADRs may be reported by patients or healthcare professionals, leading to an incomplete picture of medication safety.
2. **Reporting Bias**: Reporting biases, such as over-reporting of well-publicized adverse events or under-reporting of less well-known reactions, may skew the data and affect the accuracy of safety assessments.
3. **Confounding Factors**: Confounding factors, such as concomitant medications, underlying medical conditions, and patient behaviors, may influence the occurrence of adverse events, making it challenging to establish causality.
4. **Lack of Comparator Group**: PEM studies often lack a comparator group, making it difficult to determine whether observed adverse events are attributable to the medication of interest or other factors.
5. **Generalizability**: Findings from PEM studies may not always be generalizable to broader patient populations or healthcare settings, as data are typically collected from specific regions or healthcare systems.

Applications of Prescription Event Monitoring:

1. **Early Detection of Safety Signals**: PEM can identify previously unrecognized adverse reactions or safety concerns associated with newly marketed medications, leading to timely regulatory action or changes in prescribing practices.
2. **Post-marketing Surveillance**: PEM contributes to post-marketing surveillance efforts by monitoring the safety profile of medications once they are available on the market, providing ongoing reassurance of their safety and effectiveness.
3. **Risk Assessment and Management**: PEM helps assess the risk-benefit profile of medications by evaluating the incidence, severity, and clinical significance of adverse events, informing risk management strategies and regulatory decisions.
4. **Drug Labeling and Patient Information**: Findings from PEM studies may influence drug labeling and patient information materials by providing evidence-based information on potential adverse reactions, precautions, and warnings associated with medication use.
5. **Pharmacovigilance Planning**: PEM data can inform pharmacovigilance planning and prioritization by identifying medications, patient populations, or specific adverse events that warrant further monitoring and investigation.

Q6(b) Write role of record linkage in epidemiology

→ Record linkage was assigned to clerkship who would search and review list to bring together appropriate pairs of record for comparison, seek additional information when there were questionable matches, and finally make decision regarding the linkage based on established rule.

→ The need for record linkage are.

1. Researchers & community's demand for detailed statistical information.

2. In response to increasing business & health needs.

3. Improving data quality and timeliness

4. In reducing the complexity of data

5. Reducing respondent burden & costs.

→ Defination: Record linkage is the process of bringing together two or more records relating to same individual entity.

→ To find syntactially distinct data entries that refer to same entity in two or more input files.

- Part of data cleaning process, which is crucial first step in knowledge discovery process.
- There are 2 type of record linkage.
  1. Probabilistic
  2. Deterministic.
- The flow of data in record linkage are as.

Data → Standardisation → Blocking / Searching
↓
Decision Model ← Comparision ← Record Pairs
↓
Evaluation.

- ~~Application~~: Role of record linkage
- Enhanced Patient Profiles :- Linking data from disparate source creates a more holistic view of an individual medical history, medicati use & health outcome

2. Robust Observational studies :- Medication exposure data with patient demographic & health outcome linkage provide valuable insight.

3. Improved pharmacovigilance :- Early detection of potential ADR is facilitated by linking medication use data with hospital admission & healthcare encounter.

4. long Term Outcome Evalution :- The long term effects of medication on various health condition can be assessed by linkage of medication use

5. cost Effective Analysis :- P'economic studies utilize record linkage to analyze most cost effective treatment.

6. Rare Event Analysis :- Studying ADR or drug interaction become more feasible with record linkage.

7. Risk factor identification

8. Generalized Research

9. Subgroup Analysis :- Explore treatment effect in specific patient subgroups by analysing linked database

10. Healthcare policy Development

Q6(a) Discuss vaccine safety in p'epidermology

⇒ A vaccine is a biological preparation that improve immunity to a particular diseases.

⇒ Vaccines are among the most cost-effective & prevalent public health intervention.

⇒ Morbidity & mortality declines where immunization are practised

⇒ Vaccine safety is prime fear
- Public
- Manufacturer
- Immunization provider
- Recipients of ~~various~~ vaccines.

⇒ Knowledge & research capacity has been limited by

- ~~Inadequate~~ understanding of biologic ~~mechanism~~ mechanism underlying ADR
- Insufficient information from case report & case series.
- limitation of existing surveillance system.

* Importance of Vaccine Safety.

1) Decrease in ~~decrease~~ diseases risk & increased attention on vaccine risk.

2) Public confidence in vaccine safety is critical
   - Higher standard of safety
   - Vaccines are generally healthy
   - Lower risk tolerance ~~Need~~
   - Vaccination is universally recommended.

→ There are 2 type of monitoring vaccine safety

(i) Pre-licensure

(ii) Post-licensure.

(i) Pre licensure evalute vaccines like other pharmaceutical products with safety & efficacy measuring parameter

- It carried out on Animals & humans.

→ It involve Phase I, II, III trials.

→ Common reaction are identified

Phase I :- Check the t/t is safe & find best dose
phase II :- Tests how well a t/t work
Phase III :- Compares new t/t & current t/t. on large scale

(iii) Post licensure

⇒ Identify rare reaction

⇒ Monitor increases in known reaction.

⇒ Identify risk factor for reaction.

⇒ Identify vaccine lots with unusual rates or type of event.

⇒ Phase IV studies can be FDA requirement for licensure.

⇒ Manufacturers must submit samples of each vaccine lot & results of their own test for potency & purity of FDA before releasing them for public use.

* ADE classification

⇒ Adverse drug event following vaccination can be classified by,

(i) Frequency
(ii) Extent
(iii) Severity
(iv) Causality & Preventability.

→ The ADR divided after vaccination are.

(i) Vaccine induced: Due to intrinsic characteristic of vaccine preparation & individual response of the vaccine, these events would not have occured without vaccination.

∴ e.g Oral polio vaccine → paralytic poliomyelitis.

(ii) Vaccine - potentiated.

→ Would have occured anyway, but were precipitated by vaccination.
e.g. 1st febrile seizure in child.

(iii) Programmatic error :- Due to Technical errors in vaccine preparation, handling or administration.

(iv) Coincidental :- Associated temporally ~ vaccination by chance or due to underlying illness.

* Limitation.
① Signal detection
② Assessment of causality
③ Exposure
④ Outcome
⑤ Analysis, confusion · confounding & Bias.

Q5(a) What is DUR & classify & write step in DUE.

Notes.

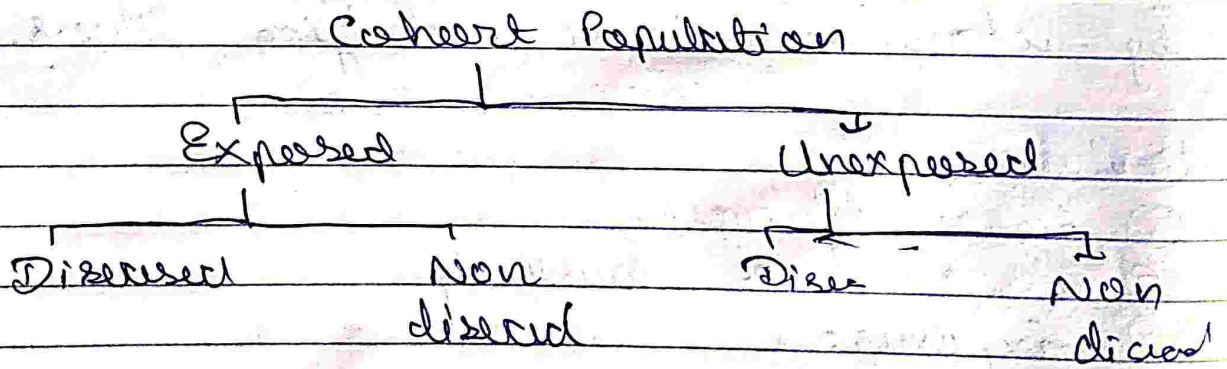
Q5(b) What is cohort study & explain it with help of case study.

→ Word cohort derived from latin "Kohort" meaning an enclosure, company or crowd.

→ In epidemiological term the cohort is a group of people with something in common usually an exposure or involvement in a defined population.

→ It is a type of analytical study which is undertaken to obtains additional evidence to refute or support existence of association b/w suspected cause & disease

→



w Certain consideration during selection of cohort.

① The cohort must be free from disease under study

② Insofar as the knowledge permits, both the group should be equally susceptible to disease under study.

③ Both group must be comparable in respect of all variable which influence the occurance of disease

④ Diagnostic & eligibility criteria of diseases must be defined beforehand.

w Types of cohort Study

Cohort Study

① Prospective ② Retrospective ③ Ambi-directional cohort study

① Prospective cohort study

=> The common strategy of cohort studies is to start with a reference population, some of whom have certain characteristic or attributes relevant to study with others who do not have these characteristic.

⇒ Both group should, at the outset of study be free from the condition under consideration.

⇒ Both group are then observed over a specific period to find out risk each group has developing condition of interest.

e.g. Framingham heart study.

⇒ The relationship of variety of factor to subsequent development of heart disease.

Sample size 5127 at Framingham having population age 30 to 59 years.

* limits.
  - Take long duration
  - Sufficient amount of funding for long period
  - Missing of study subjects.

(ii) Retrospective.

⇒ A cohort study is one in which the outcome have all occured before the start of investigation

⇒ Investigator go back to past to select study group from existing record of past employment, medical & other records & traces them.

→ The case study in 2008 b/w smoking & lung cancer begin.

→ Now they find an old roaster of elementary school children from 1998 available in community & surveyed available regarding that is 1998.

(iii) Ambi-directional Cohort Study

→ Elements of prospective & retrospective are combined.

→ The cohort is identified from past records & assess of date for the outcome.

→ The same cohort is followed up prospectively into future for further assessment.

e.g. Curt-Brown & Dolls study on effect of radiation Began in 1955 with 13,000 patients received large dose of radiation therapy for ankylosing spondylitis b/w 1934 to 1954.

* Steps of Cohort Study

- Selection of Study population
↓
Obtaining data on exposure
↓
Selection of comparison grp
↓
follow up → Analysis.

further note example

* Examples can be
① Pharm D student of particular college
② Patient coming to a particular hospital
③ People with a particular genetic trait or adult admitted in speciality.

→ Just a hypothetical example of smoking & cancer of pancreas for a 1 year.

	Pancreatic Cancer	No disease	Total	Incidence rate
Smoker	42	27,000	27,042	1.5/1000/yr
Non-Smoker	07	63,000	63007	0.1/1000/yr
Total	49	90,000	90,049	

Rate Ratio = $\frac{\text{Incidence rate in exposed grp}}{\text{Incidence rate in unexposed grp}}$

$= 1.5/0.1 = 15$

→ The relative risk of 15 indicate that it risk of cancer of pancreas is 15 times higher among smokers than non-smokers.

Q5(a) Define Medication Adherence & explain it & ~~example~~ method to evalute medication adherence.

i) Medication Adherence :- The patient's conformance with provider's recommendation with respect to timing, dosage & frequency of medication-taking during the prescribed length of time.

ii) It is a factor that determine the therapeutic outcome in a patient suffering from chronic illness / diseases.

iii) Various causes of medication non-adherance

① Socio-economic.
- Poor socio economic Status
- lack of family support.
- lack of financial resource

② Health care system.
- Doctor-patient relationship
- Poor or lack of communication regarding beneficial effect of taking medication
- Poor medication distribution.

③ Therapy related
- Complex regimen.
- longer duration of t/t

④ Condition related
- Severity of symptoms or few neglegible symptoms

⑤ Patient related
- Impairment of visual, hearing & swallowing problems
- Stress, anxiety.

~ Typically, adherence rate of 80% or more are needed for optimal therapeutic efficacy.

~ Formula for calculation of medication adherence

$$\text{Percentage adherence} = \frac{\text{Total number of actual dose patient consumed}}{\text{Total number of calculated dose to be consumed.}} \times 100$$

~ There are 2 basic method for medication adherence

(i) Direct measurement.

(ii) Indirect measurement.

(i) Direct method.

- It has 3 sub methods

(a) Directly observed therapy :- most accurate method.
- Patient can hide pills in mouth & then discard are noticable by observing & asking them

- This method take place in presence of interviewer or caretaker.

(b) Measurement of level of drug or metabolite in Blood or Urine.

- Biological assays measures the conc^n of drug or tracer compound in blood or urine of patient.

- Patient who know that they will be tested may consciously take medication that they had been skipping so; the test will not detect individuals who has been nonadherent.

(c) measurement of a Biological Marker.
- Not suitable for all medication.
- For example, riboflavin, a biological marker in which nonquantitative is used for detection

(ii) Indirect methods.

→ It include 6 submethods.

(i) Patient interview :- ~~Interview~~ by clinicians is generally an easy-to-use, less cost subjective method to assess patient's adherence.

- Questions can ~~also estimate their~~ based on patient's knowledge on personal prescribed regimen includ drug name, schedule etc.

(ii) Self reports :- Self-report methods such as diaries & questionnaires, are fairly simple to administer.

→ Although diaries are less influenced by recall bias.

(iii) Pill counts :- Counting number of pills in a strip & calculating the number of pills that patient has taken since filling prescription is useful method.

→ It has several disadvantages that patient switch medicines b/w bottles & may even discard pills.

(iv) Prescription refills :- It is assumed that patient administer the medication b/w day of dispensation & the day of refills.

(v) Assessment of Patient Clinical Response

- measurement of clinical response can be performed during regular visit of health care provider & may already constitute the standard of care for monitoring of disease being treated.

(vi) Electronic Medication Monitoring

- Electronic drug monitoring, include medication event monitoring system (MEMS), consist of specialized microchips incorporated into medication bottles that catalogue every opening of bottle.
- The MEMS cream tube & pill bottles are available.

~~Common Questions~~

Q4(c) Explain about daily doses & prescribed daily doses.

- Defined daily dose also indicated by DDD.
- It assumed average maintance dose per day for a drug used for its main indication in adult.
- DDDs are only assigned for medicines given on ATC codes.
- The DDDs are allocated to drug by WHO collaborating Centre in Oslo, working in close association with WHO.
- The DDD sometimes a dose that is rarely or never prescribed because it is own drug of two or more commonly used dose.
- It normally expressed as DDD/1000 patient/day

$$\text{Drug usage} = \frac{\text{Item used amount of drug per item}}{\text{DDD}}$$

- The DDD is a unit of measurement & does not necessarily correspond to the recommended or Prescribed Daily Dose.

classmate
Date
Page

- Drug utilization data presented in DDDs give a rough estimate of consumption & not an exact picture of actual use.

- DDD for children :- For medical product approved for use in children, the dose recommendation will differ based on age & body weight.

- Paediatric DDDs are challenging to assign and problem related to drug utilization research.

- ~~Eg~~. Advantages.

① It is helpful in describing & comparing patterns of drug use & provides denominator data for estimation of ADR rates.

② It allows comparisons b/w drugs in same therapeutic class.

- Disadvantages.

① Problems arises when dose vary widely like with Antibiotics or if the drug has more than one major indication.

e.g. Aspirin :- Low dose → cardiac use
moderate → Pain management
High dose → Inflammatory use.

* Prescribed daily dose.

- It is important to underline that DDD is a technical unit & does not necessarily correspond to the recommended or PDD.
- The PDD can be determined from studies of prescription, medical or pharmacy record, & it is important to related the PDD to diagnosis on which the drug is used.
- The PDD is defined as the average dose prescribed according to representative sample of prescription.
- For drugs where the recommended dosage differ for different indications it is important that diagnosis is linked to PDD.
- Epidermiological information is also imp in order to interpret PDD.
- The PDD can vary according to both illness treated & national policies & practices.
- For e.g. Anti infectives.

* common question

Q4(b) Write about relative risk & attributable risk & example. W-22, 2C, S-23 5c.

ans

S-23

Q4(c). Describe Ad HOC data source & automated data system.

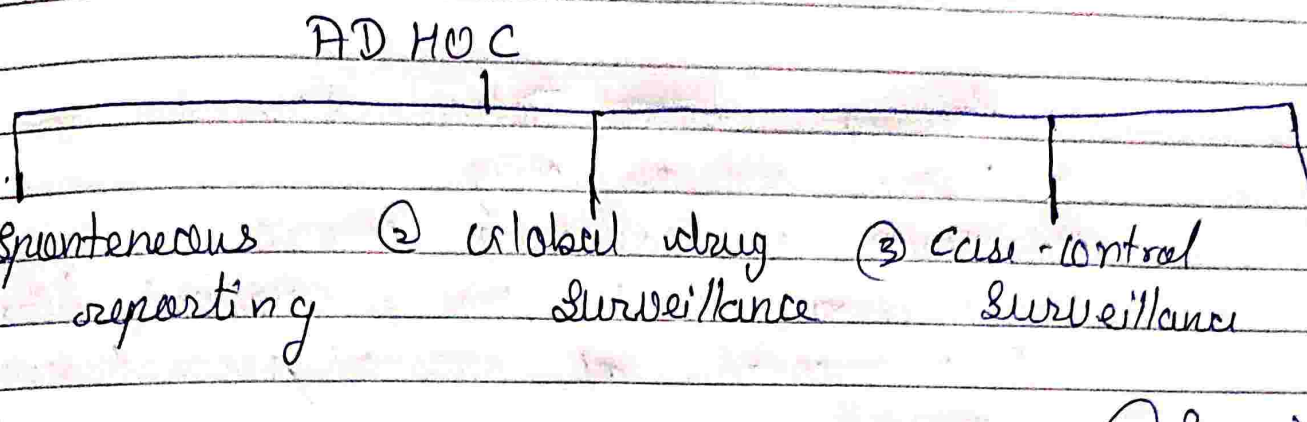
ans Ad hoc is a latin phrase meaning "for this".

ans It generally signifies a solution designed for a specific problem or task.

ans In Epidermological study, the data source available as Ad hoc source as these that are collected during p-Marketing survey studies.

ans Ad hoc is concerned mainly with one specific purpose i.e. providing data regarding drug safety in long term use or about the drug aspect in large population which is seen in PMS studies compared to pre marketing studies.

There are various data sources of Ad hoc.



(1) Spontaneous reporting :- It is the most common method used in Pharmacovigillance to generate signals on new or rare ADR, which is not discovered during C.T.

- Very useful in generating hypothesis, & to find possible outcome of ADR event.
- FDA relies on.
  - Voluntary reporting by healthcare profession or consumer
  - Mandatory reporting of ADR by manufacturers as required by law & regulation.

⇒ After confirmation of 'signal', FDA can initiate regulatory action like:-

(a) Labeling "~~boxed~~ Boxed Warning".
(b) Restrict use of drug
(c) Name or packaging change.
(d) A "Dear Health Care professional" letter
(e) Withdrawal of medical product from market.

e.g. Phenylpropanolamine used as decongesant & in OTC weight loss product.

(2) Global drug surveillance :- Global reporting of concerns about suspected ADR is a vital alterting tool.

⇒ Today 73 countries are full official members.

⇒ There has been international effort to:
- Harmonization the term used to describe ADR.
- To set criteria & definitation for atleast the major serious type of reaction.

-Main agencies involved in this are WHO, CIOMS, ICH & EU.

③ Case Control Surveillance :-

like prescription drugs, non-prescription drug can also have serious ADR

→ Here multiple case-control studies conducted simultaneously in order to monitor effect of prescription & OTC medications

④ PEM :- It is a prescription event monitoring & it is p'epidemiology study in which a cohort of users of a medicine is defined from prescription & followup for a defined period so as to identify all ADR occurring in early post-treatment period.

→ It is one form of Pharmacovigilance & it complementary to spontaneous reporting of suspected ADRs.

* Automated data System

→ Automated data is creation & implementation of technology that automatically process data.

→ The technology includes computers & other electronic communication that gather, store, process & prepare data.

⇒ Various Automated data sources are used world wide for conducting Epidemiological research.

Automated data System.

① Group health cooperative

② Health Monitoring Organization HMO

③ Medicaid Database

④ Kaiser Permanent Medical care program

⑤ United Health group etc

⇒ The useful data is via database, here various databases are:

① IDeal data base
② Claims "
③ Medical record "
④ Group health cooperative "
⑤ HMO Research network
⑥ United health group.

(1) Ideal database :-

~> It includes records from :-
(a) IP (inpatient & OP (out patient care.
(d) Emergency care
(c) mental health care
(d) OTC medicine
(e) laboratory tests.

~> The population covered databases would be large enough to permit discovery of rare event.

~> The drugs under investigation must be present in formulary & prescribed in sufficient quantity to provide adequate power of analysis.

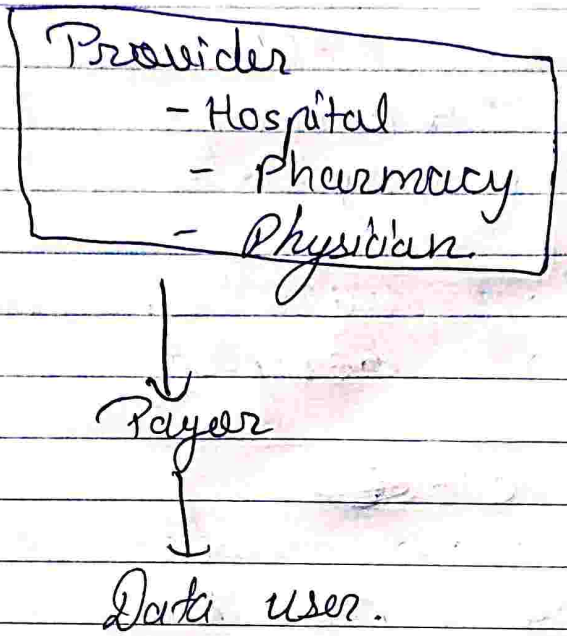
(2) Claims Database.

~> Claims data arises from a person's use of healthcare system.

~> When a patient goes to pharmacy & get a drug dispensed, the pharmacy bills the insurance carriers for the cost of that drug & has to identify which medication was dispensed, the mg per tablet, number of tablet etc.

~> If there is common patient identification number for both pharmacy & medical claim

Than these elements could be linked & analysed as longitudinal medical record.



③ Medical record database (MRD).

- MRD are more recent development arising out of increasing use of computerization in medical care.

- The validity of diagnosis data in these database is better than that in claims database.

④ Group health cooperative :- Data from HMO (health maintainance organization has been used extensively to evaluate drug usage & the Adverse & beneficial effect of marketed drug & medical procedure.

(5) HMO Research network :- Include large sample size with a wide range of comorbid condition & concomitant medication to evalute the benficial & ADR.

(6) United Health group.

⇒ These database have been used extensively to study drug safety & ADR.

Q7 (b) Differentiate cost effective & cost utility analysis also CBA & CEA in detail.

⇒ CBA is a method that allows for the identification, measurement, and comparison of the benfit & costs of a program or treatment alternative.

⇒ The benefit realized from a program or Rx alternative are compared with cost providing it.

⇒ These cost & benefit are measured and converted into equivalent dollars in year in which they will occur.

⇒ The cost & benefit ratio are expressed in ratio, a net benfit or net cost.

⇒ If B:C ratio >1 than treatment is of value or if equal than either continue or alternative choose or if less than 1 than alternative is applied.

w) CBA should be employed when comparing b/t alternative in which the cost & benefit do not occur simultaneously

e.g.

Cost.	Drug A	Drug B
Medication	200	300
Administering	50	0
ADR	150	0
Total	400	300
Benefit.		
- Days at work	1000	1000
- Extra month of life	2000	3000
Total	3000	4000
cost output ratio.	3000/400	4000/300
Ratio	7 : 1	13 : 1

Hence Drug B is suitable.

+ cost ~~Benefit~~ Effective

↳ The most commonly employed

↳ CBA: also can be used to evaluate a single program or compare multiple programs.

↳ However, valuing health benefits & in monetary term can be difficult & controversial.

↳ The expression of some health benefits as monetary unit is neither appropriate nor widely accepted.

Steps of CBA

1. Specifying the project clearly
2. Describe quantitatively the input & output of program
3. Estimate the social cost & benefits of these input & output of program
4. Compare these benefits & cost

	Advantages.	Disadvantage.
①	The CBA analysis may be applicable for both the new as well as old projects.	1) The gauerment is not completely aware of all the cost & benefit associate with program
②	It is based of accepted social principle that is an individual preference.	2. This approach does not clearly states that who should bear the population control cost.
③	This method encourage development for new techniques for the evaluation of social benefits	3. This method of collecting data for this analysis is generally biased.
④	Monetary measurement provides comparison	④. Probability of hazard

Cost Effective Analysis.

- The most commonly employed method is cost effective analysis.
- Measure effectiveness in natural units e.g. years of life saved & the costs in monetary unit.
- It compares therapies with qualitatively similar outcome in a particular therapeutic area.
- For instance, in severe reflux oesophagitis, using a proton pump inhibitor compared to using H_2 blocker.
- CEA does not allow comparision to be made b/w two totally different areas of medicine with different outcomes.
- The result of CEA are expressed as a ratio either as an average - cost effectiveness ratio. (ACER) or as an incremental cost effectiveness ratio (ICER)
- An ACER represents the total cost of program or treatment alternative divided by it clinical outcome to yield a ratio representing the dollar cost per specific outcome gained independent of comparators.

$$ACER = \frac{\text{Net Cost}}{\text{Net health Benefit}}$$

» The key measure of CEA is incremental cost effectiveness ration. (ICER).

$$ICER = \frac{(\text{cost of drug A} - \text{cost of drug B})}{(\text{Benefit of drug A} - \text{Benefits of drug B})}$$

$$\therefore ICER = \frac{\text{Difference in cost (A-B)}}{\text{Difference in benefit (A-B)}}$$

for e.g.

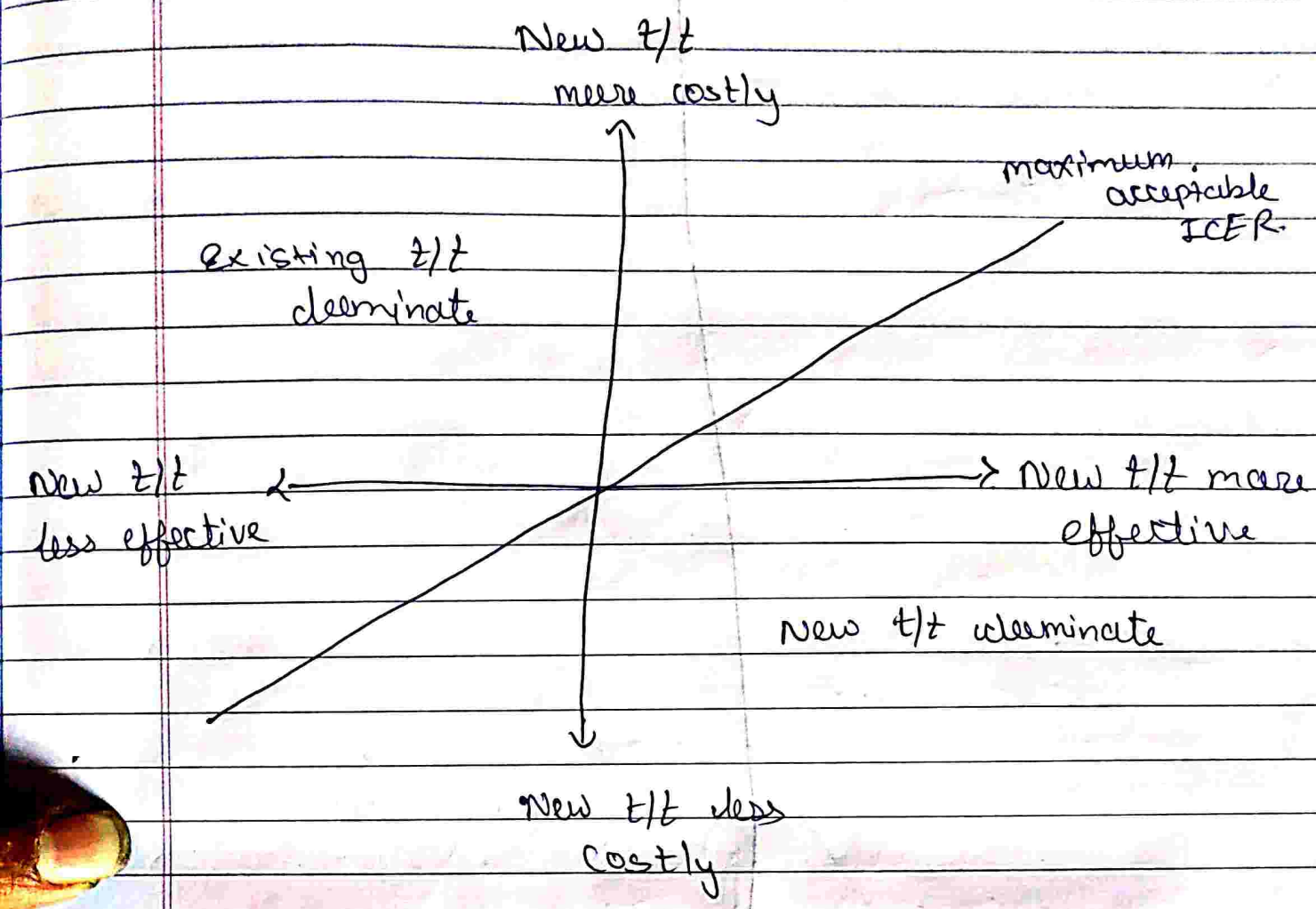
Cost	Drug A	Drug B
Medication	300	400
Administration	50	0
Monitoring	50	0
ADR	100	0
Total	500	400

- Output

Extra life	2.22	1.6
CER	500/2.22 = 225 ₹	400/1.6 ₹ 250.

∴ Hence Drug A is best choice of treatment.

+ CEA plan.



+ Advantage

① Health unit are common outcome measured in C.T

② Outcome are easier to quantify CUA or CBA.

Disadvantage

① Intervention is difficult

② Can't combine more than 1 Imp outcome

③ Difficult to calculate effectiveness & side effect into one unit.

④ Inconsistency methodology

+ Different.

	CBA	CEA
Outcome	- Money gained - Ratio of cost to all outcome	- Health unit used. - Ratio of cost & 1 intervention of outcome.
Indices	- CBR (cost benefit ratio)	- Health unit per unit cost.
Used in healthcare	- At executive level of goverment considering proposal i.e. ranking during budgeting in health seactor.	- Selecting most cost effective t/t - Evaluation of activities under program.
Advantage	can be used to evaluate public expenditure program aimed at producing different outcomes, even different sectors.	- Comparing various clinical strategies aiming to deliver the same outcome.
Disadv	① Every health benefit is not measurable in terms of money. ② CBA is comparatively more complex as every matter needs to quantified & it also consider oppurunity cost & time factor	① Useful even when the health benefit cannot be converted in monetary unit. ② CEA is relatively easier to as all the matters need not be quantified in monetary value.

Q7(a) What is prescription event monitoring, adv, dis; appl

Further.

Q6(c) Note on case reports.

Course.

INTRODUCTION:

- Case report is an example of observational descriptive study in Pharmaco-epidemiology.
- It is a non experimental method, and is one of the simplest methods in Pharmaco-epidemiology.
- Quite often, experts consider it as one of the weakest form of evidence for causation.
- Case reports are simply reports of events observed in single patients. A case report describes a single patient who was exposed to a drug and experiences a particular, usually adverse outcome.
- Case reports are useful for raising hypothesis about drug effects, which should be tested with more rigorous study designs.
- However, in a case report, one cannot know, if the patient reported is either "typically of those with the exposure" or "typically of those with the disease".
- In a case report one cannot usually determine whether the adverse outcome was due to the drug exposure or would have would have happened anyway.
- Case reports are hypothesis generating reports. A case report is not ordinarily used to make a report (or) statement on causation of an event.
- But it gives a signal that can make others, alert to the possibility of casual association.
- The strength of a case report rests on its ability to produce signals. But case reports are very weak in causation. It is to be noted that Pharmaco-epidemiology evolved with the publication of case reports in USA in 1960s, mostly by hospital pharmacists & clinical pharmacist.

Case Study - Case reports

Example:

- Dr. William McBride of Sydney, Australia, who published the first report indicating that thalidomide, might be a human-teratogen, as a letter in the Lancet on 16th of December 1961.

  - The signal generated letter helped to confirm that thalidomide could produce fetal abnormalities. It was in fact responsible for the origin of teratology as a discipline.
- The case report of "Hyper-trichosis" with the use of "Minoxidil" for hypertension also helpful for developing minoxidil as a topical preparation for baldness.

Advantages:

- They serve as an alerting mechanism for clinician's, investigators and others that a drug (or) group of drugs could produce a given effect.
- It prompts clinicians to be aware of the potential problems and to report other such occurrences.
- They may directly lead to hypothesis generation that can guide research.
- The most serious adverse drug reactions have been detected by a collection of single case reports.

Disadvantages:

- Case reports are the weakest form of evidence for causation. It is very rare that a case report can be used to make a statement about causation.

Q6(b) Application of hospital epidemiology.

- Hospitals are complex institution where patients go to have their health problem diagnosed & treated.
- But hospitals and medical/surgical intervention introduce risk that may harm a patient's health.
- Main application ~~of~~ in role of hospital epidemiology are

1. Identify risk to patient's health.
   - Find nosocomial infection.
   - Identify & study risk factor for nosocomial infection.

- Understand epidemiological principle & methods
- case control & cohort studies, bias.

- Understand nosocomial pathogens.

2. Eliminate or minimize risk to a patient

- Organize care to minize risk
- (a) Eliminate risk factor
  (b) Work around risk factors.
  (c) Develop improved policies & procedure.
- Educate physicians & nurses regarding risk
- Study risk factor to learn more about them and how to eliminate them.

• The main Applications of hospital epidemiology.

Q.6 (B) Write applications of hospital pharmaco epidemiology.

→ Hospital pharmacoepidemiology involves the study of medication use & its effects within hospital setting. some key appⁿ include:

(1) Drug utilization studies
→ Analyzing patterns of medication use within hospitals to optimize prescribing practices, reduce medication errors, & improve patient outcomes.

(2) medication safety
→ investigating adverse drug events (ADEs) medication errors, & their causes to enhance patient safety protocols & minimize risks associated with medication use.

(3) Pharmacovigilance
→ monitoring & reporting of ADRs within hospital populations to identify potential safety concerns associated with specific

PAGE:
DATE: / /

medication or drug classes.

(4) Antibiotic stewardship
- Implementing strategies to promote appropriate antibiotic use, reduce antimicrobial resistance, & prevent health care-associated infections.

(4) Antibiotic stewardship
- Implementing strategies to promote appropriate antibiotic use, reduce antimicrobial resistance, & prevent health care - associated infections.

(5) clinical decision support.
- developing & implementing clinical decision support systems to provide evidence - based recommendations for medication management, dosing & monitoring.

(6) Formulary management
- Assessing the effectiveness & safety of medications included in hospital formularies & making evidence - based decisions regarding formulary additions, deletions or restrictions.

(7) Health outcomes Research
→ Investigating the impact of medications on patient outcomes, such as length of hospital stay, readmission rates, mortality & quality of life.

(8) Economic evaluation.
- medication interventions, including drug therapies, medication management programs, & pharmacy services in hospital setting.

PAGE:
DATE: / /

(9) Quality Improvement initiatives.
- using pharmacoepidemiological data to identify areas for improvement in medication related processes.

(10) Education & training
- providing education & training to health care professionals on medication safety, rational prescribing practices, & the use of pharmacoepidemiological data to optimize patient care.

Q6(a) Short note on Meta-Analysis.

⇝ The statistical analysis of a large collection of analysis result for the purpose of integrating the findings.

⇝ The basic purpose of meta-analysis is to provide the same methodological rigor to a literature review that we require from experimental research.

⇝ Providing a report of primary research using statical methodological & analysis called "quantitative synthesis" or "meta analysis".

⇝ A report of primary research using traditional, literacy method is called a "narrative review".

⇝ Meta-analyses are generally centered on the relationship b/w one explanatory and one response variable.

⇝ This relationship, ie "the effect of X on Y", define the analysis.

⇝ Meta analyses are most easily performed with the assistance of computer database (Microsoft Access, Paradox) & statistical software (DSTAT, SAS).

- Some people consider Meta-analysis as "conducting research about previous research".

- It is a low statistical analysis of a large collection of analytical result from individual studies for purpose of integrating the finding.

- It is of is a stage of sort review of literature employing statistical methods in conjunction with a ~~thorough~~ thorough & systematic qualitative review.

- Meta analysis can be applied to RCT, Case control or Cohort studies.

- Meta-analysis combines the result of several studies that address a set of related research hypothesis.

- For e.g. meta-analysis could be performed on a collection of studies each of which attempt to estimate the incidence of left handedness in various group of people.

- The 1st meta-analysis was performed by karl Pearson in 1904.

- It was an attempt to overcome the problem of reduced statistical power in studies with small sample size.

* Types of meta-analysis.

(1) Meta-analysis has been in quantitative literature reviews.

(2) Traditional Meta-Analysis

(3) Replication Analysis

(4) Second order meta-Analysis.

* Steps to perform meta analysis.

① Define ~~theory~~ theoretical relationship interest.

↓

② Collect population of studies that provide data on relationship

↓

③ Code the studies and compute effect size

↓

④ Examine the distribution of effect size and analyze the impact of moderating variables.

↓

⑤ Interpret & report the result.

Uses

- To establish statistical significance of studies that has conflicting results.
- To develop a more correct estimate of effect magnitude.
- To provide a more complex analysis of harms, safety data, & benefits.
- To examine subgroups with individual numbers those are not statistically significant.
- If the individual studies utilized randomized controlled trials (RCT), combining several selected RCT results would be the highest-level of evidence on the evidence hierarchy, followed by systemic reviews, which analyze all available studies on a topic.

PAGE: 43
DATE: / /

Advantages

- Greater statistical power
- Confirmatory data analysis
- Greater ability to extrapolate to general population affected.
- Considered an evidence-based resource

Disadvantages

- Difficult & time consuming to identify appropriate studies.
- Not all studies provide adequate data for inclusion & analysis
- Require advanced statistical techniques.
- Heterogeneity of study populations.

Gtu - summer - 2023

PAGE :
DATE : / /

Q:-1(A) Define pharmacoepidemiology & write its application.

→ It is the study of distribution & resultant determinants of disease on population.

→ Epidemiology: The science concerned with the benefits & risk of drugs, used in popⁿ & the analysis of the outcomes of drug therapies.

- Epidemiology borrows from both "Pharmacology & "Epidemiology."

Application of pharmacoepidemiology.

(1) Estimation of the risks of drug use:
- The risk involved in drug use can be estimated.
- Risks & benefits of use of a drug may be weighed.

Ex :- case reports of Trazodum induced CNS disturbances appear soon after its introduction to market.

- The drug was withdrawn in some countries The reaction was likely due to "dose related." Hence the problem was solved by recommending a lower dose.

PAGE :
DATE : / /

(2) Use in Patient counselling:
- collection & analysis of observational data from other studies may help to address certain issues through counselling the patient.

(3) Ex - A pregnant patient may wish to terminate pregnancy, if there is a substantial risk for producing a seriously malformed child, but could also wish to proceed with the pregnancy, if the risk is low.

(3) Formulation of public health policy decisions:
→ Pharmacoepidemiology studies also help the policy makers to assess whether a drug should be withdrawn from the market or allowed to remain.
→ Qualitative & quantitative information of PEY studies helps to address many issues.

→ Ex If an inappropriate prescribing is observed among prescribers, regulatory agencies may impose restrictions on specific drug or on practioners.

(4) Facilitation of pharmaco economic evaluations:
- Data from PEY studies can be used to measure the effects of drugs on overall health care costs & resource consumption.

PAGE :
DATE : / /

Ex Hospitalization due to serious adverse effects of a drug leads to more expenses as well as resource consumption, which could be avoidable.

Q. 1(B)

Q. 1(C) Define following term.

(1) Pharmacoeconomics

→ Pharmacoeconomic is the field of study that evalute the behaviour of individuals, firms & markets relevants to the use of pharmaceutical products services & programm & which frequently focues on the costs & consequences of that use.

→ PE has been defined as the description & analysis of the costs of drug therapy to health care system & society.

(2) cross - sectional studies

→ cross - sectional study examines the relationship between diseases & others variables of interest as they exist in a defined popn at a single point in time or over a short period of time.

PAGE :
DATE : / /

(3) odds ratio.

- It is measure of association b/w an exposure & an outcome like "relative-risk".

- Odd ratio in statistics & epidemiology is commonly abbreviated as "or".

$$OR = \frac{a/c}{b/c} = \frac{(a)(d)}{(b)(c)}$$

(4) Cohort study.

- A cohort is a nothing but a group
- A cohort study is a study of groups of patients having some common drug exposure of interest.

Q:-2(A) What is cost benefit analysis? discuss its merits & demerits.

→ cost benefit analysis is a method that allows for the identification, measurement & comparison of the benefits & costs of a program or treatment alternatives.

→ The benefits realized from a program or treatment alternatives are compared with the costs of providing it.

→ Both the costs & the benefits are measured & converted into equivalent dollars in the year in which they will occur.

PAGE :
DATE : / /

→ These costs & benefits are measured & converted into equivalent dollars in the year in which they will occur.

→ These costs & benefits are expressed as a ratio (a benefit-to-cost-ratio), a net benefit, or a net cost.

→ A clinician decision maker would choose the program or treatment alternative with the highest net benefit or the greatest benefit to cost (B:C) ratio.

→ If the B:C ratio is greater than 1, the program or treatment is of value.

→ If the B:C ratio equal 1, the benefit equal the cost.

→ If the B:C ratio is less than 1, the program or treatment is not economically beneficial.

→ CBA should be employed when comparing treatment alternatives in which the costs & benefits do not occur simultaneously.

→ CBA also can be used to evaluate a single program or compare multiple programs.

→ However, valuing health benefits in monetary terms can be difficult & controversial.

PAGE :
DATE : / /

→ The expression of some health benefits as monetary units is neither appropriate nor widely accepted.

→ Therefore, unless the benefits of a program or treatment alternatives are expressed appropriately in dollars, CBA should not be employed.

	cost of therapies	
	Drug A	Drug B
Costs		
Acquisition	300	400
Administration	50	0
monitoring	50	0
Adverse effects	100	0
subtotal	500	400
Benefits		
Days of work($)	1000	1000
Extra months of life($)	2000	3000
subtotal	3000	4000
cost - output ratio	3000 / 5000	4000 / 400.
	6 : 1	10 : 1.

Advantages

→ Decision making

disadvantages

- over-simplistic
- CBA is difficult to perform because it requires

PAGE :
DATE : / /

both cost & benefits to be measured in monetary terms.

→ productivity & quality of life is difficult to perform reliably & meaningfully.

Q:- 2(b) write about the various types of costs in Pharmacoeconomics.

Ans: (9 notes)

PAGE :
DATE : / /

Q:-9 What is the definition of cost? describe types of cost & examples.

- once a perspective is chosen, the costs & consequences associated w a given product or service can be identified & measured using Pharmacoeconomic methods.
- A comparison of two or more treatment alternatives should extend beyond a simple comparison of drug acquisition costs.

Types of costs:

(1) Direct medical
(2) Direct nonmedical
(3) Indirect nonmedical &
(4) Intangible costs.

(1) Direct medical costs:

- Direct medical costs are the costs incurred for medical products & services used to prevent, detect & treat diseases.

→ Direct medical costs are the fundamental transactions associated with medical care that contribute to the portion of gross national product spent on healthcare.

- Examples of these costs include drugs, medical supplies & equipment, laboratory &

diagnostic tests, hospitalizations & physician visits.

→ direct medical costs can be subdivided into fixed & variable costs.

(2) Indirect Nonmedical costs

- Indirect nonmedical costs are the costs of reduced productivity

Ex morbidity & mortality costs)

(3) - two techniques typically are used:
- human capital &
- willingness to pay (WTP) methods.

(3) Intangible costs

- Intangible costs are those of other nonfinancial outcomes of disease & medical care.

(4) Other costs

→ opportunity costs

→ opportunity costs represent the economic benefit foregone when using one therapy instead of the next best alternative therapy.

→ Incremental costs.

→ Incremental costs represent the

PAGE: 21
DATE: / /

additional cost that a service or treatment alternative imposes over another compared with the additional effect, benefit, or outcome it provides.

Q.2(c) Discuss the type of pharmacoeconomic evaluations.

Pg :- 15 (notes)

Add :- (2) Humanistic evaluation methods

→ methods for evaluating the impact of disease & treatment or disease on a patients HRQOL, Patient preferences, & Patient satisfaction are all growing in popularity & application to pharmacotherapy decision.

→ These effects often are displayed as physical, emotional & social effects on the patient.

→ ① ~~cost~~ pharmacoeconomics is the field of study that evaluates the behaviour of individuals, firms & markets relevant to the use of pharmaceutical products, services & programs & which frequently focuses on the costs & consequences of that use.

① cost minimization analysis → Q:-2
② cost effectiveness analysis
③ cost benefit analysis
④ cost utility analysis

② cost effectiveness analysis
- two drugs a & b of same cost but (a) is more effective then b then a is being selected.

$$CER = \frac{\text{cost of intervention}}{\text{effect of intervention}} = \frac{C}{E}$$

explanation :- Two drug's a & b of same cost but a is more effective then b then a is being selected.

benefits Advantages
③ decision making.

disadvantages

PAGE :
DATE : / /

- over simplistic
- productivity & quality of life is difficult to perform reliably & meaningfully.

CEA Advantages = CEA provides valuable data to support drug policy.

disadvantages = Time consuming.

③ cost benefit Analysis

- benefit is to be converted into monitoring units.
- Drug d is to be selected.

Advantages = the ability to identify the projects that maximize the welfare of the country.

disadvantages = complexity.

④ cost Utility Analysis

= the basic idea behind CUA is that one purpose of medical intervention is to improve the quality life.

→ with less quality of life in years.
→ more quality of life in years.

Advantages - can incorporate both morbidity & mortality.

PAGE:
DATE: / /

disadvantages :- No consensus on calculating utility weights.

PAGE :
DATE : / /

Q:-3(c) Discuss the role of pharmacoeconomics in formulary management decision.

→ Decisions on formulary listing require transparency & should be justifiable to all stakeholders.

→ they could have far-reaching consequences that may impact, a number of people such as patients, health care workers & employees of the manufactures.

→ Due to wide variety of drugs that are available on the market, their escalating costs & the continuous introduction of new ones.

→ This decision-making tasks is the responsibilities of pharmacy & Therapeutics committees whose members are appointed on the basis of their drug therapy expertise.

→ factors influencing the selection of drugs for formularies are the following:

(1) Emotional factors
- a member's dislike of a drug can be based on a case of bad side-effects that one of her/his patients.
→ such incidence was a rare occurance.

PAGE :
DATE : / /

② Hidden factors.
- positive & negative interaction that a member might have had with the pharmaceutical company.

③ Unconscious factors
- the mem. familiarity with the drug or class of drugs.
- Influence by the opinions of colleagues & well informed pts.
- It can also be simply out of a habit.

④

⑤ Hidden factor such as financial gain.
- IMP to exclude all the above mentioned factors as far as possible.
- That is by making use of an evidence based drug selection sys. for the formulary decision-making process.

* There are two models that have been applied successfully in the formulary process, namely.

(I) multi-Attribute utility Theory (MAUI)

- mAUI model is a structured methodology that developed to handled the tradeoffs among multiple alternatives by assessing the strengths & weakness of each alternatives.

- Numerous applications including the formulary process.

PAGE :
DATE : / /

→ Bettinger (2007) successfully applied mAUI in choosing the CE cost effective anti-psychotic agent from a choice of 5.

- Identified the following attribute - selection criteria, efficacy, adverse effects, cost.

② System of objectified judgement Analysis (SOJA)

- SOJA model is structured approach to the selection of drugs in the formulary process.

- selection criteria for a specific group of drugs is decided upon beforehand.

- Each individual criterion is allocated a relative weight, with efficacy, safety, & acquisition cost.

Q:-3(b) Discuss the significance & steps of drug utilization review.

Significance

① DUR programs play a key role in helping managed health care systems understand interpret & improve the prescribing, administration & use of medications.

PAGE :
DATE : / /

(2) Employers & heeuth planners find DUR programs valuable because the results are used to foster more efficient use of scare heeuth care resources.

(3) Pharmacists play a key role in this process because of their expertise in the area of pleeutical care.

(4) DURs afford the managed care pharmacist the opportunity to identify trends in prescribing within groups of pt's such as those c asthma, DM, BP.

(5) Pharmacists can then, in collaboration with other members of the heeuth care team, initiate action to improve drug therapy for both individual pt's & covered popn.

(6) DURs serve as a means of improving the quality of patient care, enhancing therapeutic outcomes, & reducing inappropriate pleeutical expenditures, thus reducing overall heeuth care costs.

<u>steps</u> Pg: 31 (notes).

Q:- What is DUR & classify DUR & write steps in drug use evaluation.

→ According to WHO, drug utilization evaluation is defined as the marketing distribution, prescription & use of drug in society, & special emphasis on resulting medical, social & economic consequences.

→ DUE is an ongoing authorized & systemic quality improvement process.

⇒ DUR are classified into three categories

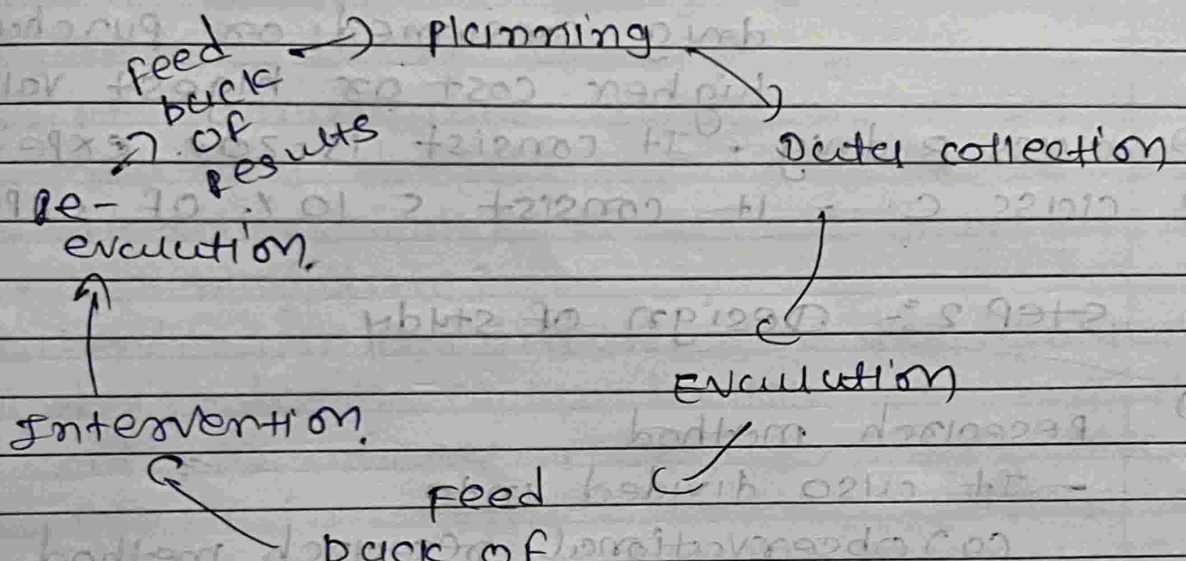
1) Prospective :-
- Evaluation of patient's therapy before medication is dispensed.

2) Concurrent
- ongoing monitoring of drug therapy during the course of treatment

3) Retrospective

- Reviews of therapy after the patient has received the medication.

DUR cycle



① Step :- 1 Identify drugs.

- Identify drug or therapeutic area of practise for possible inclusion in the programme.

- ABC or VEN analysis is another tool used to identify high priority or target drug.

- These areas can be identified through various sources of information.

such as : medication error reports,
ADR reports,
Feedback from prescribers or
clinical pharmacist

local microbiological data & medical & Pharmaceutical literatures.

It divide as

→ class A drug :- 75-80% of total value of drug consumed or purchased & higher cost or higest volume item
→ class B drug - It consist 15-20% expenditure.
→ class C = It consist 5-10% of expenditure.

Step 2:- Design of study

→ Research method
- It also divided into
(a) observational research method
(b) experimental method
(c) cross sectional studies.

→ other design methods are.
- prospective.
- concurrent
- restrospective etc.

Step-3 Define criteria & std

- After the DUE target has been selected. It is important to conduct a comprehensive literature review.

- It should be established using the hospital STG's (standard treatment guidelines)

Step 4:- Design the data collection form

- It is important to limit data collection to only the most Imp. & Relevent aspects of drug use.
- some aspects of drug use which are commonly surveyed during DUE are.

1. Pt demographic
2. prescriber details
3. disease severity
4. co-morbidities
5. Indication for drug use.
6. drug-disease contraindications
7. side or adverse effects
8. Dosing Information
9. Duration of drug treatment
10. Drug or Drug class duplication.
11. Therapeutic duplication
12. Rx & adm
13. drug-drug & drug-food Interaction
14. monitoring & drug therapy
15. Pt education or instruction
16. cost of therapy
17. over or under utilization of drugs

Step 5 Data collection

- Data collection should be choosen carefully & should be familiar & how information is arranged in p'ceutical notes.

Step 6 Evaluation result

- Data evaluation is one of most critical step in DUE
- To summarize the main categories of result & to identify where exactly the data show

deviation are evaluated.

Step 7 Provide feedback of results.

- The success of any DUE strategy depends on feedback of the results to prescribers, other hospital staff involved in the study & to administrative heads.

Step 8 Develop & implement interventions.

- If a drug use problem was identified, the next step is to consider how the problem can be addressed.
- The choice & development of interventions requires careful planning.

Step 9. Re-evaluate to determine if drug use has improved.

→ Drug use & prescribing patterns need to be monitored to determine the success of interventions.

Step 10 Re-access & revise the DUE program

At the end of an evaluation cycle, the DUR committee should perform an evaluation of the DUR program, & if necessary, make policy & procedural changes to reflect actual practices, or to facilitate desired changes.

Step II :- Feedback of results.

1. It is important to circulate the results of the QUE to clinicians & other involved hospital staff.

PAGE :
DATE : / /

Q:-3(c) Write a note on outcome measures in P epidemiology.

Ans: Pg 12 (notes)

PAGE : 2
DATE : / /

Q.-6 Write about the drug use measures used in pharmacoepidemiological studies.

Drug use measures

1. monetary units
2. Number of prescriptions
3. Units of drugs dispensed
4. Defined daily doses
5. prescribe daily doses
6. medical adherence measurement.

(1) Monetary Units

- drug use has been measured in monetary units to quantify the amounts being consumed by popn.
- It can indicate the burden on society from drug use.
- disadvantage is quantities of drug actually consumed, are not known & prices may vary widely.

(2) Number of prescriptions

- It has been used in research, due to the availability & ease.
- Prescribition number analysis is used to get rough estimates like percentage of analgesics drugs, oral contraceptive or antibiotics used by the popn.

③ Units of drug dispensed

- Units of drugs represent measures like number of capsules or tablets or doses of vaccines.
- It is easy to obtain & can be used to compare usage trends within popn.
- Helps to analyze drug use trend in various countries, states or territories or country.
- Helps to compare the hypothesis generated related to drug use, like overuse or use under use.

④ defined daily doses (DDD)

- According to WHO, the DDD is the assumed average maintenance dose per day for a drug for its main indications in adults.

$$\text{Drug usage} = \frac{\text{Item used} \times \text{amount of drug per item}}{\text{DDD}}$$

⑤ prescribed daily doses

- It is the average daily dose of a drug that

has actually been prescribed?

→ It is calculated from representative sample of prescription.

→ disadvantage is that it doesn't indicate no. of popn exposed to drug.

(6) medical adherence measurements.

I. Biological assays
II. Pill counts
III. Weight of topical medications
IV. Electronic monitoring
V. patient interviews

Q:-4(A) Explain how softwares are useful in conducting Preconomic studies & list out the softwares that are available.

① CLEO

= CLEO is clinical & Economic outcomes. It evaluates health care, projects, interventions, by using formulas like-

- cost effectiveness analysis
- cost benefit analysis
- cost utility analysis
- cost of illness,

→ Results of above analysis displayed automatically & graphically.

② TREEAGE

- It is US-based software.
- mainly used for decision making analysis.

Application

- construction of complex markov models.
- study of simple & complex problems. to look best possible outcomes.

PAGE :
DATE : / /

③ MS - Excel

→ It is also us based software.
→ Microsoft Excel is a spreadsheet developed by Microsoft for windows, macOS (apple), Android and ios.
→ It features calculation, graphing tools, Pivot tables, & a macro programming language called visual Basic for application.

④ SPSS

→ Statistical package for the social sciences.
→ SPSS takes data from any type of file, then uses them to generate tabulated reports, charts.
→ SPSS can open all file formats that are commonly used for structured data such as:
- Spreadsheets from ms excel.
- Plain text files (.txt or .csv)
- Relational (SQL) databases.
- Stata (software) & SAS.

Advantages

- very robust statistical software.
- many complex statistical tests available.
- Easily & quickly displays data tables

limitations

- can be expensive
- Graphing features not as simple as excel.

PAGE :
DATE : / /

(5) SAS

- SAS: statistical Analysis system.
- SAS programs consist of data step - creates, manipulates & edits the data,
- proc step - analyzes the data.

Advantages

- SAS business intelligence tool presents a report on past businesses.
- makes analysis easy & effective
- causes time waste reduction.

disadvantages

- Relatively high cost
- slow adapting to new techniques

(6) EPI INFO

- A free public domain software package developed by the centers for disease control & prevention for the global community of medical & public health professionals.
- It can be used to rapidly
- Develop an electronic data entry form
- Enter data into this form.

PAGE:
DATE: / /

Application

- ANOVA analysis
- T-test
- Non-parametric statistics.
- Estimation of risk ratios.
- Analysis of complex survey data.

Q:-4(B) Explain prevalence & incidence with suitable examples.

(1) prevalence:

- It is the proportion of people affected with a disease or exposure to a particular drug in a population at a "specific point or period of time".
- It is usually determind by surveying the population of interest.
- prevalence varies between 0-1, it can be expressed as percentages.
- It is a census type of measure, indicating how frequently a disease is at a period of time.

PAGE :
DATE : / /

Uses

- Estimates the magnitude of health or disease problem in the community.
- To identify the potential high risk population community.
- It is especially useful for administrative and planning purpose.
- Mathematically, prevalence = A/B
  A = no. of popⁿ ☐ disease at a given time.
  B = Total no. of popⁿ at a given time.

⇒ Ex If there are 1000 patients with epilepsy in a district of 10,00,000 population.

Then prevalence of epilepsy = $\frac{1000}{10,00,000}$

$= 0.001\%$.

(2) Incidence

- It is a measure of the risk of developing some "new condition" within a specific period of time.
- In the case of descriptive studies two measurements of 'incidents'.

(1) Cumulative incidence
(2) Incidence density or Incidence rate.

PAGE :
DATE : / /

(1) cumulative incidence.

→ It is a number of new cases within a specific period of time, divided by the size of popn initially at risk.

→ It is used for the measure of the risk of disease or probably probability of developing the disease during specified period

CI = No. of new cases of disease (or) injury during specified period
Size of popn at start of period.

Ex: If Popn initially contain 1000 non disease persons & 28 develop a condition over two years of observation, the incidence proportion is 28 cases per 1000 persons.

(2) Incidence rate

- It is the number of new cases per popn at risk in a given period of time.

IR = number of new cases of disease (or) injury during specified period
Total time each person was observed

* Relationship b/w prevalence & incidence

P = I × D.

D = Duration. (longer duration of disease greater the prevalance)

PAGE :
DATE : / /

Q:-4(c) write a note on drug induced birth defects.

Ans :- Pg : 46 (notes)

oversimplifies complex health outcome.

Q: (7) Role of pharmacist in drug induced birth defects.

→ The role of pharmacist in addresing drug induced birth defect is multifaceted & crucial for ensuring the safety of both the pregent patient & developing fetus.

* Role of pharmacist.

(1) medication counseling & Education:- Role is to educate patient about the potential risks & benefits of medication.

(2) medication Review & risk Assessment :- They can actively review patient's medication profiles, identify drug & potential teratogenic effects & ~~dress~~ assess the risk of birth defect associated c specific medication.

(3) Teratogenicity information resource :- pharmacist should maintain up to date knowledge on teratogenicity & access reliable information resource to guide evidence-based decision-making.

(4) Interprofessional collaboration:- collabration c other healthcare professional, including physician, & genetic counselor is essential

(5) Patient monitoring & follow up :- Pharmacist should monitor pregnant patient regulatory, especially those on medication & potential teratogenic effect. timely identification of any adverse effect allow for prompt intervention or modification of treatment plan.

(6) Patient Advocacy :- Pharmacist serve as advocate for pregnant individual ensuring that their concerns are heard & addressed by the healthcare team.

(7) promotion of preconception care :- pharmacies can actively contribute to ~~pre~~ conception care by providing information on family planning, optimizing medication regimens when planning consist so many drugs.

(8) Continuing education & professional development
- Pharmacist should engage in ongoing education to stay current & the latest research & guideline related to medication safety in pregnancy.

Q1-5(A) Explain the merits & demerits of cohort & case control studies.

Cohort studies

Advantages

- Subjects in cohorts can be matched, which limits the influence of confounding variables.
- Standardization of criteria/outcome is possible.
- Easier & cheaper than a randomized controlled trial (RCT)

Disadvantages

- Cohorts can be difficult to identify due to confounding variables.
- No randomization, which means that imbalances in patient characteristics could exist.
- Blinding/masking is difficult.
- Outcome of interest could take time to occur

PAGE :
DATE : / /

Case control studies

Advantages

- can obtain findings quickly
- can often be undertaken c minimal funding
- Efficient for rare diseases.
- can study multiple exposures.
- Generally requires few study subjects.

Disadvantages

- can not generate incidence data
- subject to bias
- Difficult if Records keeping are either inadequate or unreliable
- selection of controls can be difficult.

Q:-5(b) write a note on cost minimization analysis with examples.

Ans :- Pg : 5 (notes).

Q:-2. Discuss about the cost minimization metho

→ cost minimization analysis is the most basic technique.

→ CMA is a economic evaluation method to identify, measure, value & compare the costs & consequences.

→ CMA involves the determination of the least costly alternative when comparing two or more treatment alternatives.

→ The two alternatives must be equivalent therapeutically.

→ once this equivalency in outcome is confirmed the costs can be identified, measured, & compared in monetary units.

→ cost should extend beyond the comparison of drug acquisition cost & include the cost of drug prepⁿ, administration & storage when needed.

→ least expensive agent should be preffered.

Process

→ Obtain acquisition price for each medicine & calculate price for course of that to be compared dose per day, no of days.

- calculate Pharmacy, nursing & physician cost associated
- calculate equipment cost associated
- calculate laboratory cost
- calculate any other significant factor
- calculate & compare total medicine cost for each medicine.

Benefits

- simple method

limitation

- outcomes must be equivalent for analysis.

Example: two drug can be used to lower the level of blood cholesterol. No other side effects or any other costs associated with the drugs.

- Drug A costs 2000/month Drug B cost 1500/month both reduce cholesterol level by same drug

So drug B is preferred.

PAGE :
DATE : / /

Q:- 5(c) Write a note on attributable risk & relative risk with suitable examples.

Pg :- 1 (notes).

PAGE: 1
DATE: / /

① What is risk, discuss about the different concept of risk in pharmacoepidemiology?

→ Risk is the likelihood the probability of experiencing some type of harm or losing something that one values.

Flow of Risk in epidemiology.

True risk

Pharmacoepidemiological considerations (Bias, confounding etc).

Statistical considerations (sampling, model)

measured

eliminated risk

Measurement of Risk

① Attributable risk
② Relative risk
③ Time - risk relationship
④ Odd ratio.

(1) Attributable risk.

It is also called - Rate difference or risk difference.

Attributable risk is the "difference in rate of a condition" b/w an exposed popⁿ & an

unexposed population

→ mostly calculated in cohort studies, where individuals are assembled on exposure status & followed over a period of time.

→ Then, the investigators count the occurrence of the disease.

→ cohort is then subdivided by the level of exposure & the frequency of disease is compared b/w subgroups.

→ one is considered exposed & another unexposed.

$$AR = R_{exposed} - R_{non\text{-}exposed}$$

	cases	controls	total
exposed	A	B	A+B
unexposed	C	D	C+D
total	A+C	B+D	A+B+C+D

$$\%\ AR = \frac{R_{exposed} - R_{non\text{-}exposed}}{R_{exposed}} \times 100$$

(8) Relative Risk

→ Relative Risk is called as risk ratio

→ It is the ratio of the probability of an event occurring in an exposed group to the probability of the event occurring in non-exposed group.

→ Relative Risk = proportion of events in experimental group / proportion of events in control group.

→ RR above 1 indicates treatment or exposure is associated to the outcome & below 1, means that the treatment is negatively associated to the outcome.

→ When the rate in the exposed group is equal to the rate in the comparison group RR will be equal to 1.

→ An RR of 2 means, the rate in the exposed group is twice that of non-exposed group

Interpreting RR of disease

RR = 1 — No association

RR > 1 — Positive association (possibly causal)

RR < 1 — Negative " (possibly protective)

Ex Probability of developing allergy among users of perfume was 20% & among those not using perfume 1%.

Risk	Allergy's rules	a = 20	c = 7
Perfume user	a	b = 80	PAGE: 99 4
Perfume non-user	c	d	DATE: / /

RR = a/(a+b)

= 20/100

= 0.20

③ odd ratio

- It is measure of association b/w an exposure & an outcome like "relative risk".

→ odd ratio in statistics & epidemiology is commonly abbreviated as "OR".

→ like "Relative Risk" determines probabilities is OR odds are used.

→ odd Ratio can be calculated by,

$$OR = \frac{a/c}{b/c} = \frac{(a)(d)}{(b)(c)}$$

④ Time risk Relationship

→ The outcome of an exposure to a drug is related to the time.

→ It is also true, the risks associated to medicines

→ certain events like anaphylactic reactions happen immediately after taking an injection, while certain other risk events occur after days or months or even years.

→ Ex Prazosin.

Q:- 6(A) write a short note on meta-Analysis.

Ans: pg (47) (notes)

Q:-12 Write Importent of meta-analysis.

→ Definition of meta-analysis: The statistical analysis of a large collection of analysis result for the purpose of integrating the findings.

→ The basic purpose of meta-analysis is to provide the same methodological rigor to a literature review that we require from experimental research.

- providing a report of primary research using statistical methodology & analysis is called "quantitative synthesis" or "meta-analysis"

- meta analyses are generally centered on the relationship between one explanatory & one response variable. The This relationship, "the effect of x on y defines the analysis.

- some people consider meta-analysis as "conducting research about previous research.

Uses

- To establish statistical significance of studies that has conflicting results.
- To develop a more correct estimate of effect magnitude.
- To provide a more complex analysis of harms, safety data, & benefits.
- To examine subgroups with individual numbers those are not statistically significant.

- If the individual studies utilized randomized controlled trials (RCT), combining several selected RCT results would be the highest-level of evidence on the evidence hierarchy, followed by systemic reviews, which analyze all available studies on a topic.

Advantages

- Greater statistical power
- Confirmatory data analysis
- Greater ability to extrapolate to general population affected.
- Considered an evidence-based resource.

Disadvantages

- Difficult & time consuming to identify appropriate studies.
- Not all studies provide adequate data for inclusion & analysis.
- Require advanced statistical techniques.
- Heterogeneity of study populations.

Q.6(B) Write applications of hospital pharmaco epidemiology.

→ Hospital pharmacoepidemiology involves the study of medication use & its effects within hospital setting. some key appⁿ include:

(1) Drug utilization studies
→ Analyzing patterns of medication use within hospitals to optimize prescribing practices, reduce medication errors, & improve patient outcomes.

(2) medication safety
→ Investigating adverse drug events (ADEs) medication errors, & their causes to enhance patient safety protocols & minimize risks associated with medication use.

(3) Pharmacovigilance
→ monitoring & reporting of ADRs within hospital populations to identify potential safety concerns associated with specific

PAGE :
DATE : / /

medication or drug classes.

(4) Antibiotic stewardship
- Implementing strategies to promote appropriate antibiotic use, reduce antimicrobial resistance, & prevent health care-associated infections.

(5) clinical decision support.
- Developing & implementing clinical decision support systems to provide evidence-based recommendations for medication management, dosing & monitoring.

(6) Formulary management.
- Assessing the effectiveness & safety of medications included in hospital formularies & making evidence-based decisions regarding formulary additions, deletions or restrictions.

(7) Health outcomes Research.
→ Investigating the impact of medications on patient outcomes, such as length of hospital stay, readmission rates, mortality & quality of life.

(8) Economic Evaluation.
- medication interventions, including drug therapies, medication management programs, & pharmacy services in hospital setting.

PAGE :
DATE : / /

(9) Quality Improvement initiatives.
- using pl epidemiological data to identify areas for improvement in medication related processes.

(10) Education & training.
- providing education & training to health care professionals on medication safety, rational prescribing practises, & the use of pl epidemiological data to optimize patient care.

Q:- 6CC) write a note on case reports.

- case report is an example of observational descriptive study in pl epidemiology
- It is a non-experimental method, & is one of the simplest methos in pharmaco-epidemiology.
- Quite often, experts consider it as one of weakest form of evidence for causation.
- case reports are simply reports of events observed in single patients.
- case reports are useful for raising hypothesis about drug effects, which ~~would~~ should be tested ~ more rigorous study design.

PAGE :
DATE : / /

- In case report, one cannot know, if the patient reported is either "typically of those with the exposure". or "typicaly of those with the disease".
- case reports are hypothesis generating report
- A case report is not ordinarily used to make a report.
- The strength of a case report rests on its cability to produce signals.

Example

- Dr. Wiliam McBride of sydney, Aus, who published the first report indicating that thalidomide, might be a human teratogen, as a letter in the lancet on 16th december 1961.
- The signal generated letter helped to confirm that thalidomide could produce fetal abnormalities.
- The case report of 'Hyper-trichosis" with the use of "minoxidil" for hypertension.

PAGE :
DATE : / /

Advantages

- They serve as an altering mechanism for clinician's, investigators & others that a drug or group of drugs could produce a given effect.

- prompts clinicians to be aware of the potential problems & to report other such occurrences.

- They may directly lead to hypothesis generation that can guide research.

Disadvantages

- case reports are the weakest form of evidence for causation. It is very rare that a case report can be used to make a statement about causation.

Q:-7(a) What is prescription event monitoring? Write its advantages, disadvantages & applications.

→ PEM is a non-interventional, observational cohort form of pharmacovigilance.

→ It is the method of studying the safety of new medication used by the general practitioner

PAGE :
DATE : / /

Advantages

→ calculation of incidence density
→ carried out on a national scale
→ comparison of 'reasons for withdrawal' & incidence density.
→ outcome of exposed pregnancies
→ signal generation & exploration
→ Delayed reactions can be detected.
→ Disease investigation.

disadvantages

- No method of measuring compliance
- No method to determine the non-prescription medication.
- Non-return of green forms
- Does not extend to hospital monitoring
- Data collection is an operational difficulty.

Applications

→ Duplication in data in minimized
→ powerful tool for generating more value out of existing databases
→ large Projects ~~regarg~~ in regarding the census of an entire country can be plann.
→ more detailed information can be obtained
→ Becomes easier to follow cohorts.

PAGE :
DATE : / /

→ Searching for signal
→ Assessment of important AE
→ medically important events
→ Reason for stopping the drug
→ Ranking of ID & reason for withdrawal
→ Automated signal generation.
→ long latency adverse reactions
→ Comparison with external data.
→ outcomes of pregnancy.

Q:7(b) Differentiate cost effective & cost utility analysis.

PAGE :
DATE : / /

Q.7(c) describe Ad Hoc data sources & automated data systems.

Ad Hoc data sources

- The data sources available as Ad hoc sources are those that are collected during post-marketing surveillance studies.

★ different Ad Hoc Data sources.

(1) spontaneous reporting
→ spontaneous reporting systems are the most common method used in pharmacovigilance to generate signals on new or rare adverse events, which is not discovered during clinical trials.
→ very useful in generating hypothesis & to find out possible explanations for the adverse event in question.

Ex - signal identified via spontaneous reporting confirmed by a formal pharmacoepidemiology study.

(2) Global drug surveillance:

→ Global reporting of concerns about suspected adverse drug reactions is a vital alerting tool.

→ National centers should report monthly frequency.

PAGE :
DATE : / /

→ the medical dictionary for regulatory Activities is being used worldwide.

③ case - control surveillance (CCS)

→ like prescription drugs, non-prescription drugs can also have serious adverse effects & unintended benefit.

→ CCS relies on self-reports of medication & dietary supplement use.

EX - Inverse association between aspirin & risk of colorectal cancer was documented in CCS.

↓

Publication provoked many subsequent studies which confirmed the association.

limitations
- potential for selection bias &
- potential for recall bias.

④ Prescription event monitoring

→ PEM is a pi epidemiological study in which a cohort of users of a medicine is defined from prescriptions & followed-up for a defined period (often - 6-12 months) so as to identify all adverse events occuring in the early post-treatment period.

PAGE :
DATE : / /

- It is one form of pl covigilance. It is complementary to spontaneous reporting of suspected ADRs.

(2) automated data systems

→ Automated data is a creation & implemention of technology that automatically process data.

→ the technology include computers & other electronic communications that gather, store, process, prepare & distribution data.

→ The main purpose is, to quickly & effectently process large amount of information & minimum human interaction.

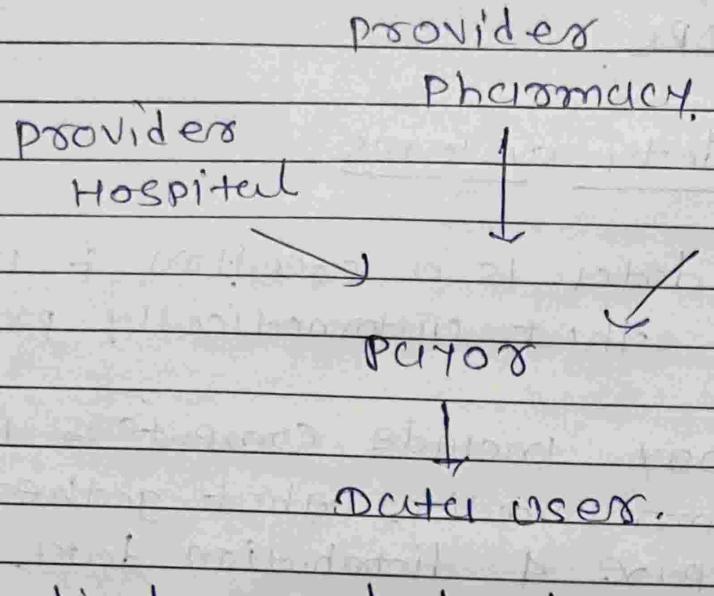
(1) IDEAL DATABASE

- Ideal database include records from:
  (1) Inpatient & outpatient
  (2) Emergency care
  (3) mental heath care
  (4) All prescribed & OTC medications.
  (5) All laboratory & radiological tests
  (6) Alternative therapies.

- other requirements.
  (1) All parts are easily linked by means of a patient's unique identifier.
  (2) Records are updated on a regular basis.
  (3) Records are updated on a regular basis.

PAGE :
DATE : / /

② claims databases.



③ medical record databases.

→ MRD are more recent development arising out of the increasing use of computerization in medical care.

→ The validity of the diagnosis's data in these databases is better than that is claims

④ Group health cooperative

→ Data from health maintance organization has been used extensively to evalute drug usage.

⑤ HMO Research network

⑥ United health group.
- these databases have been used extensively to study drug safety & adverse drug reactions