



T-104  
2022

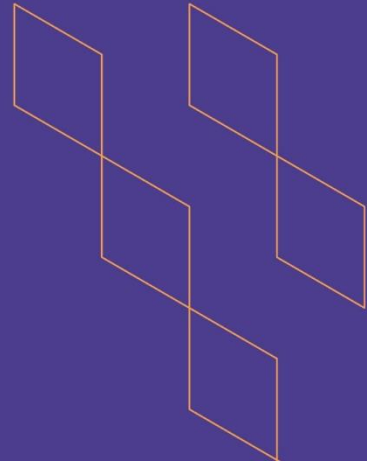
# Course Specification





T-104  
2022

## Course Specification



Course Title:	<b>Pharmacoepidemiology</b>
Course Code:	<b>555-PHP-2</b>
Program:	<b>Pharmaceutical Sciences</b>
Department:	<b>Clinical Pharmacy</b>
College:	<b>College of Pharmacy</b>
Institution:	<b>Najran University</b>
Version:	
Last Revision Date:	14-12-2023



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## A. General information about the course:

Course Identification	
1. Credit hours:	2+0
2. Course type	
a.	University <input type="checkbox"/> College <input type="checkbox"/> Department <input type="checkbox"/> Track <input type="checkbox"/> Others <input checked="" type="checkbox"/>
b.	Required <input checked="" type="checkbox"/> Elective <input type="checkbox"/>
3. Level/year at which this course is offered: 10 <sup>th</sup> Level/ 5 <sup>th</sup> Year	
4. Course general Description	
<p>This course is intended to provide an overview of pharmacoepidemiology and discuss key concepts and principles in the study of the utilization, safety, and effectiveness of medications in large populations. Pharmacoepidemiology applies the methods of epidemiology to the content area of clinical pharmacy.</p> <p>This course introduces students to pharmacoepidemiologic methods, including study designs, data sources, measurement of medication use and outcomes, sources of, and techniques to reduce, bias and confounding. This course will integrate priority areas in the field and review examples of current research and evaluate their public health and policy implications.</p>	
5. Pre-requirements for this course (if any):	
None	
6. Co- requirements for this course (if any):	
None	
7. Course Main Objective(s)	
<ul style="list-style-type: none"> <li>To provide students with an introduction to basic principles of pharmacoepidemiology necessary for conducting and interpreting pharmacoepidemiologic research.</li> <li>To evaluate various studies investigating the safety and effectiveness of medications and explain their strengths and weaknesses.</li> <li>To understand research methods, data sources and study designs, and analytic techniques to address confounding and bias, often employed in pharmacoepidemiologic research.</li> <li>To increase awareness and understanding of novel applications of pharmacoepidemiology in health disparities research, including equitable access and safe use of essential medicines locally and globally.</li> </ul>	

### 1. Teaching mode (mark all that apply)

No	Mode of Instruction	Contact Hours	Percentage
1.	Traditional classroom	30	100
2.	E-learning		
3.	Hybrid <ul style="list-style-type: none"> <li>Traditional classroom</li> <li>E-learning</li> </ul>		
4.	Distance learning		



## 2. Contact Hours (based on the academic semester)

No	Activity	Contact Hours
1.	Lectures	30
2.	Laboratory/Studio	0
3.	Field	0
4.	Tutorial	0
5.	Others	0
	Total	30

## B. Course Learning Outcomes (CLOs), Teaching Strategies and Assessment Methods

Code	Course Learning Outcomes	Code of CLOs aligned with program	Teaching Strategies	Assessment Methods
1.0	Knowledge and understanding			
1.2	Demonstrate the basic knowledge of pharmacoepidemiology and the principles of regulatory framework for clinical drug safety	K2	Lectures	Written exam
2.0	Skills			
2.2	Evaluate the pharmacoepidemiologic reports and utilize the results in different pharmaceutical fields.	S2	Lectures	1. Written exam 2. Assignments
2.4	Utilize measures of disease occurrence and association to optimize safe medication use in relevant practice and patient care.	S4	Lectures	1. Written exam 2. Assignments
3.0	Values, autonomy, and responsibility			
3.2	Advocate patient rights to safe and effective medication use in relevant practice setting.	V2	Lectures	1. Written exam 2. Assignments
3.4	Review skills to work in pharmaceutical companies and pharmacy benefits management, and government public health, medicine, and other related sectors.	V4	Lectures	1. Written exam 2. Assignments

## C. Course Content

No	List of Topics	Contact Hours
1	Introduction to pharmacoepidemiology and its principles	2
2	Data source and collection	2
3	Risk estimates and Descriptive Studies	2
4	Observational studies (cohort studies)	4
5	Observational studies (case-control studies)	4
6	Interventional study design	2
7	Data source and collection	2
8	Principles of sampling	2
9	Potential errors in studies (Bias, confounding)	6
10	Types of variables. Validity and issues of interpretations	2
11	Statistical concepts: confidence interval, hypothesis test, p value, statistical power	2

12	Examination and assessments	2
Total		30

## D. Students Assessment Activities

No	Assessment Activities *	Assessment timing (in week no)	Percentage of Total Assessment Score
1.	Quiz	Regular class test	10%
2.	Midterm exam	6-7	25%
3.	Presentation	9	10%
4.	Assignments/ Clinical visit	9	10%
5.	Observation card	10	5%
6.	Final exam	12-13	40%
<b>7</b>	<b>Total</b>		<b>100%</b>

\*Assessment Activities (i.e., Written test, oral test, oral presentation, group project, essay, etc.)

## E. Learning Resources and Facilities

### 1. References and Learning Resources

Essential References	<ul style="list-style-type: none"> <li>Hartzema AG, Tilson HH and Chen A. Pharmacoepidemiology and Therapeutic Risk Management. Harvey Whitney Press, Inc. Cincinnati 2008.</li> <li>Hartzema AG, Porta M, Tilson HH. Pharmacoepidemiology: An Introduction. Harvey Whitney Press, Inc. Cincinnati, 1998. Rothman, KJ. Epidemiology – An Introduction, 2nd Edition, Oxford University Press. ISBN: 978-0-19-975455-7</li> <li>Raymond S. Greenberg, Stephen R. Medical Epidemiology,</li> <li>Yi Yang, Donna West-Strum. Understanding Pharmacoepidemiology. 2011</li> <li>Brenda Waning, Michael Montagne. Pharmacoepidemiology: Principles and Practice. 2001</li> </ul>
Supportive References	<ul style="list-style-type: none"> <li>Micromedex (data based software), British national formulary (current edition)</li> </ul>
Electronic Materials	<a href="http://lib.nu.edu.sa/DigitalLibrary.aspx">http://lib.nu.edu.sa/DigitalLibrary.aspx</a> <a href="http://www.rxlist.com">www.rxlist.com</a>
Other Learning Materials	Other references or handouts can be provided during the course

### 2. Required Facilities and equipment

Items	Resources
facilities (Classrooms, laboratories, exhibition rooms, simulation rooms, etc.)	<b>A Lecture containing at least 25 seats</b>
Technology equipment (projector, smart board, software)	<ul style="list-style-type: none"> <li><b>Computer lab</b></li> <li><b>Internet access</b></li> </ul>
Other equipment (depending on the nature of the specialty)	

## F. Assessment of Course Quality

Assessment Areas/Issues	Assessor	Assessment Methods
Effectiveness of teaching	Head of departments and students	Indirect Questionnaires (indirect)
Effectiveness of students' assessment	Faculty members and students	Indirect Questionnaires (indirect)



Assessment Areas/Issues	Assessor	Assessment Methods
Quality of learning resources	Student peer reviewer	Direct Indirect
The extent to which CLOs have been achieved	Students	Questionnaires (Indirect)
Other		

**Assessor** (Students, Faculty, Program Leaders, Peer Reviewer, Others (specify))

**Assessment Methods** (Direct, Indirect)

## G. Specification Approval Data

COUNCIL /COMMITTEE	CLINICAL PHARMACY DEPARTMENT COUNCIL
REFERENCE NO.	
DATE	