



Syllabus: pharmacoepidemiology (#131702584)
Second Semester 2021 /2022

COURSE INFORMATION	
Course Name: pharmacoepidemiology (face-to-face education) Semester: second Department: Clinical Pharmacy & Pharmacy Practice Faculty: Pharmaceutical Sciences	Course Code: 131702584 Section: per semester Core Curriculum: 2013 Study Plan
Day(s) and Time(s): :per semester Classroom: Pharmaceutical Sciences	Credit Hours: 3 Prerequisites:
COURSE DESCRIPTION	
<p>The course will be delivered by experienced trainers in the field who know the most critical aspects affecting Pharmacovigilance practitioners . Throughout the sessions, practical examples and frequently asked questions will be addressed through a rigorous and practical approach, our course will treat another different subject such as the international context of pharmacovigilance, and sources of information in pharmacovigilance, in order to document signal detection, ICSRs, PSURs, Referrals and more, presenting practical situations which may impact on daily activities. We will also be talking about the latest updates national and international guidance (FDA, EMA,...) for signal detection in pharmacovigilance, with practical examples of medical evaluation in signal management, focusing also on the issues most frequently encountered</p>	
DELIVERY METHODS	
<p>The course will be delivered through a combination of active learning strategies. These will include:</p> <ul style="list-style-type: none"> • PowerPoint lectures and active classroom-based discussion • Collaborative learning through small groups acting in an interdisciplinary context. • Relevant films and documentaries • Video lectures • E-learning resources: e-reading assignments and practice quizzes through Model and Microsoft Team • Workshops , and brain storming . 	

The course will be delivered through a combination of active learning strategies. These include:

- PowerPoint lectures and active classroom-based discussion

Students will be encouraged to participate and be actively involved in the learning process. Lectures will start with questions to inquire about the students' prior knowledge of the topic. These questions will also be repeated at the end of the lecture to gain insight into the students' competences (to verify whether students have understood the topic). During delivering the lecture presentation, time will be given to allow students to reflect about what they have learnt and think in and discuss some examples of short case studies.

- Relevant speakers
- Video lectures

FACULTY INFORMATION

Name	Dr Saba Madae'en
Academic Title:	Assistant Professor
Office Location:	Third Floor
Telephone Number:	Extension: 3416
Email Address:	saba@hu.edu.jo
Office Hours:	Per semester <i>Please send an e-mail (saba@hu.edu.jo) to meet at any other time.</i>

REFERENCES AND LEARNING RESOURCES

PHARMACOVIGILANCE Second Edition Editors RONALD D. MANN ELIZABETH B. ANDREWS

Pharmacoepidemiology EDITED BY Brian L. Strom MD, MPH fifth edition

STUDENT LEARNING OUTCOMES MATRIX

An alignment matrix of the **program** ILOs of the Bachelor of Pharmacy at The Hashemite University, the **course** ILOs and knowledge, skills and competencies as mentioned in the Jordan National Qualifications Framework (JNQF)

Field according to (JNQF)	Required to achieve (according to (JNQF))	Core curriculum learning outcomes	B.Sc. Pharmacy Program ILOs	Course Objectives	Course Student ILOs				Assessment Method
					A	B	C	D	
Knowledge	A systematic understanding of the theories, concepts, principles and circulations related to the field of learning, some of which are within the limits of the latest scientific findings	Foundational Knowledge	Learner	<ul style="list-style-type: none"> discuss the general concepts of pharmacovigilance define general concepts .of pharmacovigilance explain the scope of .pharmacovigilance tell the duties and responsibilities of pharmacovigilance .departments 					Exams , quizzes
Skills	Mastering the skills and tools required to solve complex problems in a specialized field of study	Essentials for Practice and Care	Caregiver	<ul style="list-style-type: none"> discuss the adverse drug .reaction reporting processes distinguish the adverse drug reaction declaration .forms describe the way to fill out the adverse drug reaction .declaration forms give samples to the adverse drug reaction .needing urgent declaration 					Exams , quizzes
	Demonstrate specialized and conceptual skills in the field of study	Approach to Practice and Care	Manager Promoter Provider Creative Thinker & Problem-Solver Educator Advocate Collaborator Includer Communicator						

				of adverse drug reaction declaration		
	Practice evaluation in planning, design, technical and/or supervisory functions related to products, services or processes			<ul style="list-style-type: none"> interpret the importance of adverse drug reaction reporting procedure in terms of general safety profile of the product distinguish the special situation in adverse drug reaction declaration processes, plan to minimize harm to patients.		Exams , quizzes
Competencies	Management of activities and projects	Personal & Professional Development Pharmaceutical Product Expert	Self-aware Leader Innovator Professional Manufacturer		1-Develop and apply communication skills in class room discussions regarding pharmacovigilance material or questions 2-Participate actively in classroom debate, assignments and speech deliveries on pharmacovigilance issues, on reporting adverse drug reactions, and actions that should be taken. 3-Conduct library research, personal interviews, and other information-gathering activities to inform speeches. On pharmacovigilance experiences. 4-Gain control and command over speech anxiety.	Exams , quizzes seminars
	Take responsibility for decision-making in work or study contexts				1-Collaborate with small group team members to assess and argue for or against certain pharmacovigilance issues using the appropriate scientific	Exams , quizzes seminars

					terminology. 2-Demonstrate leadership skills by mastering effective interpersonal and intercultural tolerance and inclusiveness in communication. 3-Establish the basic required knowledge in the field of pharmacoovigilance.	
	Take responsibility for group work and work effectively with peer guidance				1-Collaborate with small group team members to assess and argue for or against certain pharmacovigilance issues using the appropriate scientific terminology. 2-Demonstrate leadership skills by mastering effective interpersonal and intercultural tolerance and inclusiveness in communication. 3-Communication skills, covering both written and oral communications in adverse event reporting and formal pharmacovigilance communication.	Exams , quizzes seminars
	Transfer and apply diagnostic and creative skills in a range of contexts				1. Problem-solving skills, relating to qualitative and quantitative information, regarding minimization of harm to patients ,extending to situations where evaluations have to be made on the basis of limited information and	Exams , quizzes seminars

					<p>time.</p> <p>2-Study skills needed for continuing professional development.</p> <p>3-Apply creative and critical thinking skills in and outside class room related to patient safety .</p> <p>4-Interpersonal skills, relating to the ability to interact with other people and to engage in team-working.</p> <p>5-Time-management and organizational skills, as evidenced by the ability to plan and implement efficient and effective modes of working whether on exams or on homework.</p>	
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It is The Hashemite University policy to provide educational opportunities that ensure fair, appropriate and reasonable accommodation to students who have disabilities that may affect their ability to participate in course activities or meet course requirements. Students with disabilities are encouraged to contact their instructor to ensure that their individual needs are met. The University through its Special Need section will exert all efforts to accommodate for individual's needs.

Special Needs Section:

Tel: 00962-5-3903333 **Extension:** 4209

Location: Students Affairs Deanship/ Department of Student Welfare Services

Email: amalomoush@hu.edu.jo
amalomoush@staff.hu.edu.jo

COURSE REGULATIONS

Participation

Class participation and attendance are important elements of every student's learning experience at The Hashemite University, and the student is expected to attend all classes. A student should not miss more than 15% of the classes during a semester. *Those exceeding this limit of 15% will receive a failing grade regardless of their performance.* It is a student's responsibility to monitor the frequency of their own absences. **Attendance record begins on the first day of class irrespective of the period allotted to drop/add and late registration. It is a student's responsibility to sign-in; failure to do so will result in a non-attendance being recorded.**

In exceptional cases, the student, with the instructor's prior permission, could be exempted from attending a class provided that the number of such occasions does not exceed the limit allowed by the University. The instructor will determine the acceptability of an absence for being absent. A student who misses more than 25% of classes and has a valid excuse for being absent will be allowed to withdraw from the course.

On average, students need to spend 15 hrs of study and preparation weekly. At the beginning of the lectures, be on time and don't leave before the end of the lecture without an accepted excuse. **If you missed a class, it is your responsibility to find out about any announcements or assignments you have missed.** For any clarification, please communicate your instructor at her posted office hours or by appointment. Listen well to the lecture, if you have a question, ask your instructor. You will find the course material at the course team after the lecture.

Sharing of course materials is forbidden. No course material including, but not limited to, course outline, lecture hand-outs, videos, exams, and assignments may be shared online or with anyone outside the class. Any suspected unauthorized sharing of materials, will be reported to the university's Legal Affairs Office. If a student violates this restriction, it could lead to student misconduct procedures.

Plagiarism

Plagiarism is considered a serious academic offence and can result in your work losing marks or

being failed. HU expects its students to adopt and abide by the highest standards of conduct in their interaction with their professors, peers, and the wider University community. As such, a student is expected not to engage in behaviours that compromise his/her own integrity as well as that of The Hashemite University.

Plagiarism includes the following examples, and it applies to all student assignments or submitted work:

- **Use of the work, ideas, images or words of someone else without his/her permission or reference to them.**
- **Use of someone else's wording, name, phrase, sentence, paragraph or essay without using quotation marks.**
- **Misrepresentation of the sources that were used.**

The instructor has the right to fail the coursework or deduct marks where plagiarism is detected

Late or Missed Assignments

In all cases of assessment, students who fails to attend an exam, class project or deliver a presentation on the scheduled date without prior permission, and/or are unable to provide a medical note, will automatically receive a fail grade for this part of the assessment.

- Submitting a term paper on time is a key part of the assessment process. Students who fail to submit their work by the deadline specified will automatically receive a 10% penalty. Assignments handed in more than 24 hours late will receive a further 10% penalty. Each subsequent 24 hours will result in a further 10% penalty.
- In cases where a student misses an assessment on account of a medical reason or with prior permission; in line with University regulations an incomplete grade for the specific assessment will be awarded and an alternative assessment or extension can be arranged.

Missed Assessments

In all cases of assessment, students who fails to attend an exam on the scheduled date without prior permission, and/or are unable to provide a medical note, will automatically receive a failure .grade for this part of the assessment

- In cases where a student misses an assessment on account of a medical reason or with prior permission; in line with university regulations an incomplete grade for the specific assessment will be awarded and an alternative assessment or extension can be arranged.

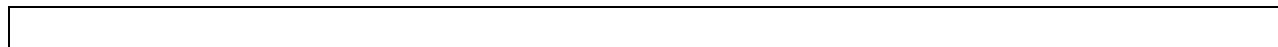
Cheating

Cheating, academic misconduct, fabrication and plagiarism will not be tolerated, and the university policy will be applied. Cheating policy: The participation, the commitment of cheating will lead to applying all following penalties together:

- Failing the subject, he/she cheated at
- Failing the other subjects taken in the same course
- Not allowed to register for the next semester
- The summer semester is not considered as a semester

Student Complaints Policy

Students at The Hashemite University have the right to pursue complaints related to faculty, staff, and other students. The nature of the complaints may be either academic or non-academic. For more information about the policy and processes related to this policy, you may refer to the students' handbook.



Course Calendar and Assessment

Students will be graded through the following means of assessment and their final grade will be calculated from the forms of assessment as listed below with their grade weighting taken into account. The criteria for grading are listed at the end of the syllabus

Students will be graded through the following means of assessment:

Assessment	Grade Weighting	Deadline Assessment
Mid Exam	35%	~ 6 th week
Workshops	15%	12 th week
Final Exam	50%	~ 15 th /16 th week

Description of Exams

Test questions will predominately come from material presented in the lectures. Semester exams will be conducted during the regularly scheduled lecture period. Exam will consist of a combination of multiple choice, short answer, match, true and false and/or descriptive questions.

Homework: Will be given for each chapter, while the chapter in progress you are supposed to work on them continuously and submit in next lecture when I finish the chapter.

You are also expected to work on in-chapter examples, self-tests and representative number of end of chapter problems. The answers of self-tests and end of chapter exercises are given at the end of the book.

Quizzes: Unannounced quizzes will be given during or/and at the end of each chapter based upon the previous lectures. It will enforce that you come prepared to the class.

No make-up exams, homework or quizzes will be given. Only documented absences will be considered as per HU guidelines.

Description of Exams

Test questions will predominately come from material presented in the lectures and the lectures themselves. Semester exams may be conducted during the regularly scheduled lecture period. Exam may consist of a combination of multiple choice, short answer, match, true and false, and/or descriptive questions.

No make-up exams will be given. Only documented absences will be considered as per HU guidelines. Make-up exams may be different from regular exams in content and format.

Grades are not negotiable and are awarded according to the following criteria:

Letter Grade	Description	Grade Points
A+	Excellent	4.00
A		3.75
A-		3.50
B+	Very Good	3.25
B		3.00
B-		2.75
C+	Good	2.50
C		2.25
C-		2.00
D+	Pass	1.75
D	Pass	1.50
F	Fail	0.00
I	Incomplete	-

WEEKLY LECTURE SCHEDULE AND CONTENT DISTRIBUTION

“Lecture hours and weeks are approximate and may change as needed”

Note: For Chem 101 sections with 2 lecture periods per week (S/T, M/W or T/R), one lecture period covers 1.5 lecture hours (80 minutes). The course content specifies the sections in chapters 1-10 of the textbook that will be included in quizzes, homework and exams.

“Lecture hours and weeks are approximate and may change as needed”

Note: For the 2 lecture periods per week (S/T, M/W), one lecture period covers 1.5 lecture hours (75 minutes). The course content specifies chapters of the textbook that will be included in exams.

Introduction	What is pharmacovigilance and how has it developed?,	Week 1	1 lecture
Topic 1	Basic concepts,	Week 2	2 lectures
Topic 2	Adverse drug reactions,	Week3	2 lectures
Topic 3	Drug interactions	Week 4	2 lectures
Topic 4n	Types and sources of data,	Week 5	2 lectures
Topic 5	The process of pharmacovigilance	Week 6	2 lectures
Topic 6	Causation – was the drug responsible?	Week 7	2 lectures
Topic 7	Overview – a risk management process,	Week 8	2 lectures

<i>Topic 8</i>	Signal detection,	Week 9	2 lectures
<i>Topic 9</i>	Evaluation and investigation,	Week 10	2 lectures
<i>Topic 10</i>	Taking action,	Week 11	2 lectures
<i>Topic 11</i>	Communication,	Week 12	2 lectures
<i>Topic 12</i>	Regulatory aspects of pharmacovigilance,	Week 13	2 lectures
<i>Topic 13</i>	Overview – a risk management process,	Week 14	2 lectures
University Exams Week 15			

ASSESSMENT RUBRICS

Assessment Rubrics to be determined by the department. Add samples below.

Classroom Participation: Oral Presentation

Element	Excellent			Satisfactory			Needs Improvement			Points	
	8	7	6	5	4	3	2	1	0		
Organization	<ul style="list-style-type: none"> readings; logical sequence of readings to support points; and closing slide are included appropriately articulates 	<ul style="list-style-type: none"> readings; logical sequence of readings to support points; and closing slide are included appropriately articulates 	<ul style="list-style-type: none"> occasionally articulates "fit" of readings with topic at hand. 	<ul style="list-style-type: none"> sometimes uses readings to support sequence of information. There is some logical sequence of information. Title slide and closing slides are included. 	<ul style="list-style-type: none"> 4 	<ul style="list-style-type: none"> 3 	<ul style="list-style-type: none"> - rarely uses readings to support points; - rarely articulates "fit" of readings with topic at hand 	<ul style="list-style-type: none"> 2 	<ul style="list-style-type: none"> 1 	<ul style="list-style-type: none"> 0 	<ul style="list-style-type: none"> There is little or no logical support points; information articulates "fit" of readings with topic at hand or closing slides are not included.
Slide Design (text, colors, background, illustrations, size, titles, subtitles)	<ul style="list-style-type: none"> "fit" of readings with topic at hand. 	<ul style="list-style-type: none"> "fit" of readings with topic at hand. 	<ul style="list-style-type: none"> hand. 	<ul style="list-style-type: none"> hand. 	<ul style="list-style-type: none"> 4 	<ul style="list-style-type: none"> 3 	<ul style="list-style-type: none"> Little to no attempt has 	<ul style="list-style-type: none"> 2 	<ul style="list-style-type: none"> 1 	<ul style="list-style-type: none"> 0 	<ul style="list-style-type: none"> Little to no attempt has
	<ul style="list-style-type: none"> Presentations are attractive and appealing to viewers. responds frequently to questions; - routinely 	<ul style="list-style-type: none"> Presentations are attractive and appealing to viewers. responds frequently to questions; - routinely 	<ul style="list-style-type: none"> often a willing participant - responds occasionally to questions; 	<ul style="list-style-type: none"> often a willing participant - responds occasionally to questions; 	<ul style="list-style-type: none"> 4 	<ul style="list-style-type: none"> 3 	<ul style="list-style-type: none"> become a willing participant - rarely able to respond to questions; 	<ul style="list-style-type: none"> 2 	<ul style="list-style-type: none"> 1 	<ul style="list-style-type: none"> 0 	<ul style="list-style-type: none"> become a willing participant - rarely able to respond to questions;
Content	<ul style="list-style-type: none"> volunteers point of view Presentation covers topic completely and in depth. 	<ul style="list-style-type: none"> volunteers point of view Presentation covers topic completely and in depth. 	<ul style="list-style-type: none"> occasionally volunteers point of view. 	<ul style="list-style-type: none"> Presentation includes point of view. 	<ul style="list-style-type: none"> 4 	<ul style="list-style-type: none"> 3 	<ul style="list-style-type: none"> Presentation includes little or no information. 	<ul style="list-style-type: none"> 2 	<ul style="list-style-type: none"> 1 	<ul style="list-style-type: none"> 0 	<ul style="list-style-type: none"> Presentation includes little or no information.
	<ul style="list-style-type: none"> Information is clear, appropriate, and accurate. - acts appropriately 	<ul style="list-style-type: none"> Information is clear, appropriate, and accurate. - acts appropriately 	<ul style="list-style-type: none"> often a willing participant - acts appropriately, or flawed 	<ul style="list-style-type: none"> often a willing participant - acts appropriately, or flawed 	<ul style="list-style-type: none"> 4 	<ul style="list-style-type: none"> 3 	<ul style="list-style-type: none"> never a willing participant - Information is confusing, inaccurate, or flawed. 	<ul style="list-style-type: none"> 2 	<ul style="list-style-type: none"> 1 	<ul style="list-style-type: none"> 0 	<ul style="list-style-type: none"> never a willing participant - Information is confusing, inaccurate, or flawed.
Language	<ul style="list-style-type: none"> during all role plays; - spelling, grammar, usage, and punctuation are accurate; - routinely volunteers point of view. 	<ul style="list-style-type: none"> during all role plays; - spelling, grammar, usage, and punctuation are accurate; - routinely volunteers point of view. 	<ul style="list-style-type: none"> during role plays; there are minor errors in spelling, grammar and/or punctuation - responds to questions; - occasionally volunteers point of view. 	<ul style="list-style-type: none"> during role plays; there are minor errors in spelling, grammar and/or punctuation - responds to questions; - occasionally volunteers point of view. 	<ul style="list-style-type: none"> 4 	<ul style="list-style-type: none"> 3 	<ul style="list-style-type: none"> There are significant errors in spelling, grammar and/or punctuation - rarely able to respond to direct questions; - rarely volunteers point of view. 	<ul style="list-style-type: none"> 2 	<ul style="list-style-type: none"> 1 	<ul style="list-style-type: none"> 0 	<ul style="list-style-type: none"> There are significant errors in spelling, grammar and/or punctuation - rarely able to respond to direct questions; - rarely volunteers point of view.
Delivery	<ul style="list-style-type: none"> - always communicated with enthusiasm, proper voice projection and clear preparation; - always arrived there sufficient eye contact with audience solicits instructors' perspective - sufficient use of other non-verbal communication skills. Appropriate delivery pace was used. 	<ul style="list-style-type: none"> - always communicated with enthusiasm, proper voice projection and clear preparation; - always arrived there sufficient eye contact with audience solicits instructors' perspective - sufficient use of other non-verbal communication skills. Appropriate delivery pace was used. 	<ul style="list-style-type: none"> rarely unprepared; rarely arrives late; occasionally to voice projection and/or insufficient preparation, incomplete work, and/or insufficient contact. of non-verbal communication skills. 	<ul style="list-style-type: none"> There was some preparation; communication is generally clear, but lacks complete work, and/or insufficient perspective outside class. Insufficient use of non-verbal communication skills. 	<ul style="list-style-type: none"> 4 	<ul style="list-style-type: none"> 3 	<ul style="list-style-type: none"> There was some preparation; communication is generally clear, but lacks complete work, and/or insufficient perspective outside class. Insufficient use of non-verbal communication skills. 	<ul style="list-style-type: none"> 2 	<ul style="list-style-type: none"> 1 	<ul style="list-style-type: none"> 0 	<ul style="list-style-type: none"> There was some preparation; communication is generally clear, but lacks complete work, and/or insufficient perspective outside class. Insufficient use of non-verbal communication skills.
	<ul style="list-style-type: none"> Answers to questions are 	<ul style="list-style-type: none"> Answers to questions are 	<ul style="list-style-type: none"> 12 	<ul style="list-style-type: none"> Most answers 	<ul style="list-style-type: none"> 4 	<ul style="list-style-type: none"> 3 	<ul style="list-style-type: none"> Answers 	<ul style="list-style-type: none"> 2 	<ul style="list-style-type: none"> 1 	<ul style="list-style-type: none"> 0 	<ul style="list-style-type: none"> Answers
Interaction	<ul style="list-style-type: none"> Answers to questions are 	<ul style="list-style-type: none"> Answers to questions are 	<ul style="list-style-type: none"> 12 	<ul style="list-style-type: none"> Most answers 	<ul style="list-style-type: none"> 4 	<ul style="list-style-type: none"> 3 	<ul style="list-style-type: none"> Answers 	<ul style="list-style-type: none"> 2 	<ul style="list-style-type: none"> 1 	<ul style="list-style-type: none"> 0 	<ul style="list-style-type: none"> Answers

with Audience	coherent and complete. <ul style="list-style-type: none"> Answers demonstrate confidence and extensive knowledge. 	to questions are coherent and complete. <ul style="list-style-type: none"> Answers somehow demonstrate confidence and extensive knowledge. 	to questions are neither coherent nor complete. <ul style="list-style-type: none"> Is tentative or unclear in responses. 	
	Total Score (Y x 5/16) =			

- يمكن اجراء التعديلات المناسبة حسب طبيعة المقرر وبالتنسيق مع الكلية المعنية وتحديد أنواع التعلم بوضوح (الالكتروني، مدمج، وجاهي) ونماذج التعلم (نسبة التعلم الوجيه الالى الالىكتروني ونسبة التعلم المتزامن الالى غير المتزامن) التي سوف يتم اتباعها أثناء تدريس المساقات وبما يتواءم مع نسب الادمج المشار اليها في كتاب مجلس التعليم العالي رقم مع/1427 .