

Critical Appraisal of Pharmacotherapy Literature 2 PHMD 3004 Fall 2024

Credit hours: 2 credit hours

Class contact hours: 26 contact hours (September 3 – December 9, 2024)

Course Schedule:

Tuesdays 9:00 am – 10:00 am [1st Floor LT]

Tuesdays 10:15 am – 11:15 am [1st Floor LT]

Any unavoidable schedule changes will be announced in class, posted on UM Learn, or communicated by email.

Staff:

Course Coordinator: Dr. Shweta Mital

Email: Shweta.Mital@umanitoba.ca

Co-Instructor: Dr. Robert Renaud (Robert.Renaud@umanitoba.ca)

Office hours:

Contact the course coordinator if you have any course-related or academic questions or concerns. Your e-mail will be promptly responded to. If your question cannot be addressed via e-mail, then an appointment will be made for discussion.

Traditional Territory or Land Acknowledgment

The University of Manitoba campuses are located on original lands of Anishinaabeg, Ininiwak, Anisininewuk, Dakota Oyate and Dene, and on the National Homeland of the Red River Métis. We respect the Treaties that were made on these territories, we acknowledge the harms and mistakes of the past, and we dedicate ourselves to move forward in partnership with Indigenous communities in a spirit of Reconciliation and collaboration.

Course Description

This course develops skills in the critical appraisal of research in the fields of pharmacoepidemiology and pharmacoconomics with emphasis on how this research may inform decisions regarding medication safety, drug approval, and drug evaluation. May not be held with PHRM 3520 or the former PHRM 3510. Registration is normally restricted to students in Year 3 of the program.

Purpose of the Course:

The purpose of the course is to build on learning from PHMD 1004 and 2004, with a focus on developing and enhancing skills relating to medical statistics, literature evaluation, and basic pharmacoeconomic principles.

Course Objectives:

Upon completion of this course, students will:

1. Develop conversational ability to describe and evaluate medical statistics.
2. Develop competence to do literature evaluation at a professional level.
3. Explain the purpose and application of health technology assessments in drug pricing and drug coverage in Canada.
4. Describe the concepts of cost-effectiveness and budget impact analyses and explain how these analyses (and literature evaluation more broadly) are used to make healthcare funding decisions.
5. Describe basic pharmacoeconomic principles to patients and other members of the healthcare team, to assist in the understanding of drug funding decisions.

Assumed background:

Successful completion of PHMD 1004 – Introduction to Pharmacotherapy Literature and PHMD 2004 - Critical Appraisal of Pharmacotherapy Literature.

Teaching and learning methods:

PHMD 3004 comprises of didactic lectures, class discussions and interactive group activities. Students are expected to complete any pre-readings prior to class, are encouraged to ask questions and participate in class discussions and activities.

Attendance

This course will be offered in-person. Students are expected to attend all classes unless there is a medical or other valid reason. Please email the course coordinator in advance if you are unable to attend a class.

Recommended texts and course materials:

All course materials and links to web resources will be posted on UM Learn.

Class schedule (*assessments in bold text)

| Date | Description | Instructor |
|--|---|---|
| September 3, 2024 | Introduction to Pharmacoeconomics and the Canadian Health Care System | Dr. Shweta Mital |
| September 10, 2024 | Drug pricing and drug coverage | Dr. Shweta Mital |
| September 17, 2024 | Economic evaluation of drugs | Dr. Shweta Mital |
| September 24, 2024 | Budget Impact analyses Other considerations in Health Technology Assessment | Dr. Shweta Mital |
| October 1, 2024 | Critically appraising pharmacoeconomics evidence | Dr. Shweta Mital |
| October 8, 2024 | Putting things in context: In-class group activity Brief reflection to be submitted at end of class | Dr. Shweta Mital |
| October 15, 2024 | Economics in pharmacy practice | Dr. Shweta Mital |
| October 22, 2024 | Mid-term exam (Pharmacoeconomics) | In person exam on Examssoft – 1st Floor Lecture theater |
| October 29, 2024 | Refresher: Describing data & Hypothesis tests Difference of means | Dr. Robert Renaud |
| Pharmacoeconomics Assignment Due November 5, 2024 | | |
| November 5, 2024 | Tests of Association / Correlation Linear regressions Medical Statistics and Outcome Measures Number needed to treat and relative risk | Dr. Robert Renaud |
| November 12, 2024 | Fall Break – no class | |
| November 19, 2024 | Competing Risks Advanced Confounding Control Propensity score example | Dr. Robert Renaud |

| Date | Description | Instructor |
|--|---|---|
| Pharmacoepidemiology Assignment Due November 26, 2024 | | |
| November 26, 2024 | Statistical Inference - Analysis of Variance (Comparing multiple Groups) | Dr. Robert Renaud |
| December 3, 2024 | Comparing clinical trial evidence with real world evidence Advanced bias detection: immortal time and lead time bias | Dr. Robert Renaud |
| December 20, 2024 | Final Exam (Pharmacoepidemiology) | In person exam on Examsoft – Room 071 Apotex |

Assessment program:

Students will be required to complete an in-class group activity, two take-home assignments, and two in-class exams (mid-term and final exams).

| Evaluation | Task |
|---------------------------------|---|
| In class group activity | The class will be divided into groups. Each group will be assigned a drug (students will be notified of their assignment 2 weeks before the activity, i.e., by September 24). On the day of the activity, students will discuss and debate within their group arguments in favor of and against a higher/lower price of the assigned drug. At the end of the class, each group will submit a brief reflection of the arguments that they discussed/debated, the position taken by each group member and the consensus price that the group agreed upon. |
| Mid-term exam | Multiple choice and short-answer questions based on pharmacoeconomics lectures and class discussions. |
| Pharmacoeconomics assignment | Questions involving critical evaluation of a cost-effectiveness article. |
| Pharmacoepidemiology assignment | Statistical questions and literature evaluation based on pharmacoepidemiology lectures and class discussions. |
| Final exam | Statistical questions and literature evaluation based on pharmacoepidemiology lectures and class discussions. |

The assessments will test student's understanding of material covered in lectures and class discussions as well as their ability to assimilate and apply this knowledge to real-world studies

and decision contexts. Feedback in the form of written comments and/or grades will be provided. Students will have access to exams for review. Marks achieved during the course will be posted on UM Learn. Final letter grades at the end of the course will be posted on Aurora.

Assessment criteria and grading:

| Evaluation | Proportion of Final Grade | Due Date |
|---------------------------------|---------------------------|-------------------|
| In-class group activity | 5% of final grade | October 8, 2024 |
| Mid-term Exam | 30% of final grade | October 22, 2024 |
| Pharmacoeconomics Assignment | 15% of final grade | November 5, 2024 |
| Pharmacoepidemiology Assignment | 20% of final grade | November 26, 2024 |
| Final Exam | 30% of final grade | December 20, 2024 |

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|---------------------------|----|--------|----|
| Final Grades: $\geq 90\%$ | A+ | 65-69% | C+ |
| 80-89% | A | 60-64% | C |
| 75-79% | B+ | 50-59% | D |
| 70-74% | B | <50% | F |

Assessment policies:

- Assignment submissions are expected on the due date, as outlined. If extensions for written reports are necessary, they may be requested up to 48 hours prior to the assignment due date and should be submitted in writing to the Course Coordinator.
- Late assignments will have 5% of total marks for the assignment deducted for each day/partial day. (including weekend days) beyond the due time. This continues until the assignment is submitted, however after 5 days the maximum mark that may be awarded for a late submission is capped at 60%.
- Assignments may NOT be rewritten for a higher grade.
- Concerns regarding grading are to be discussed with the Course Coordinator.

Note: All students MUST MAKE THEMSELVES AVAILABLE FOR LECTURES, GRADED IN-CLASS ASSESSMENTS AND EXAM PERIODS AS INDICATED IN THE UNIVERSITY GENERAL CALENDAR, THE COLLEGE OF PHARMACY EXAM TIMETABLE, STUDENT HANDBOOK, AND COURSE OUTLINE. **Deferred exams will not be granted to accommodate vacations. Only illness, bereavement, or exceptional compassionate circumstances will be considered for deferred exams or assignments. Students participating**

on University of Manitoba sanctioned sports teams (Bison Sports) should discuss arrangements (if necessary) with the course coordinator.

Course Technology:

It is the general University of Manitoba policy that all technology resources are to be used in a responsible, efficient, ethical and legal manner. Students can use technology in classroom settings only for educational purposes approved by the instructor and/or the University of Manitoba Student Accessibility Services. Students should not participate in personal direct electronic messaging / posting activities (e-mail, texting, video or voice chat, wikis, blogs, social networking (e.g. Facebook) online and offline “gaming” during scheduled class time. ·

The use of generative artificial intelligence tools (genAI) or apps for assignments in this course, including tools like ChatGPT and other AI writing or coding assistants, is prohibited.

Course materials are provided on UM Learn and can be accessed electronically at <https://universityofmanitoba.desire2learn.com/d2l/login>

Voluntary Withdrawal (VW):

Course feedback and assessment will be provided before the voluntary withdrawal (VW) date. For the 2024-25 academic year, the VW date for this course is November 19, 2024. PLEASE NOTE HOWEVER, STUDENTS CONTEMPLATING VOLUNTARILY WITHDRAWING FROM A COURSE SHOULD SPEAK TO THE DEAN’S OFFICE BEFORE DOING SO. THERE ARE SIGNIFICANT CONSEQUENCES OF WITHDRAWING FROM A COURSE DURING THE PROFESSIONAL PROGRAM.

Academic Integrity (Plagiarism, Cheating and Personation):

Please review the official College of Pharmacy Policies on Plagiarism and Cheating, clearly outlined in your Pharmacy Student Handbook for 2024-2025 and the University of Manitoba Academic Calendar at: <https://catalog.umanitoba.ca/undergraduate-studies/general-academic-regulations/>

These policies directly apply to this course.

The coordinator and instructors of this course and the University of Manitoba hold copyright over the course materials, presentations and lectures which form part of this course. **No audio or video recording of lectures or presentations is allowed in any format, openly or surreptitiously, in whole or in part without permission of the course coordinator.** Course materials (both paper and digital) are for the participant’s private study and research.

Student Accessibility Services (SAS):

If you are a student with a disability, please contact SAS for academic accommodation supports and services. Students who have, or think they may have, a disability (e.g. mental illness, learning, medical, hearing, injury-related, visual) are invited to contact SAS to arrange a confidential consultation.

Student Accessibility Services <http://umanitoba.ca/student/saa/accessibility/>
520 University Centre
204-474-7423
Student_accessibility@umanitoba.ca

Student Support:

Please refer to the attached **Schedule "A"** for a list of student supports provided by the University of Manitoba.

Meeting AFPC Educational Outcomes and NAPRA Competencies:

| Course Objectives At the completion of this course, the student should be able to: | AFPC Educational Outcome (2017) Achieved | NAPRA Competency Achieved | Learning Level (ICE – Ideas, Connections, Extensions) | Performance Level (Novice, Functional, Competent) | CPSI Competency Domain |
|---|---|---|---|---|---|
| Develop conversational ability to describe and evaluate medical statistics. | CP2: Provide patient-centred care CM2: Communicate in a manner that supports a team approach to health promotion and health care. PR1: Committed to apply best practices and adhere to high ethical standards in the delivery of pharmacy care. | Patient Care (2.2), Knowledge and Research Application (6.1), Communication and Education (7.2) | Connections | Competent | Domain 3: Communication |
| Develop competence to do literature evaluation at a professional level. | HA2 Respond to the needs of communities or populations they serve by advocating with them for system-level change. CM1: Communicate in a responsible and responsive manner that encourages trust and confidence. SC3: Contribute to the creation of knowledge or practices in the field of pharmacy. SC4: Teach other pharmacy team members, the public and other health care professionals including students | Health Promotion (5.1, 5.2), Knowledge and Research Application (6.2), Quality and Safety (9.2) | Extensions | Competent | Domain 4: Safety, Risk, and Quality Improvement |
| Explain the purpose and application of health technology assessments in drug pricing and drug coverage in Canada. | LM2 Contribute to the stewardship of resources in health care systems. (LM 2.1, 2.2, 2.3) | 5. Health Promotion (5.1.1) | Ideas | Functional | Domain 5: Optimize Human and System Factors |

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| Explain the purpose and application of health technology assessments in drug pricing and drug coverage in Canada. | LM2 Contribute to the stewardship of resources in health care systems. (LM 2.1, 2.2, 2.3) | 6. Knowledge and Research Application (6.2, 6.3) | Ideas | Functional | Domain 5: Optimize Human and System Factors |
| Describe the concepts of cost-effectiveness and budget impact analyses and explain how these analyses (and literature evaluation more broadly) are used to make healthcare funding decisions. | LM2 Contribute to the stewardship of resources in health care systems. (LM 2.1, 2.2, 2.3) LM3 Demonstrate leadership skills LM4 Demonstrate management skills HA2 Respond to the needs of communities or populations they serve by advocating with them for system-level change. | 6. Knowledge and Research Application (6.1) | Connections | Competent | Domain 5: Optimize Human and System Factors |
| Describe basic pharmacoeconomic and health technology assessment principles to patients and other members of the healthcare team, to assist in the understanding of drug funding decisions. | CM1 Communication (CM1.1, 1.5, 1.7) SC1 Scholar (SC1.1, SC2.3, SC3.1, SC3.2) | 6. Knowledge and Research Application (6.2, 6.3) 7. Education (7.1) | Connections, Extensions | Competent | Domain 3: Communication |