Course Outline and Syllabus for Students

Name: Micheline Piquette-Miller

Course Number: PHM 360

Course Title: Personalized Medicine.

Course Description:

This course will build upon the fundamental concepts in pharmacokinetics and pharmacogenomics taught in 1st and 2nd year in order to understand, describe and predict sources of inter-subject variability in drug response. The course is designed for students to understand basic principles used to individualize drug and dosage regimens for patients based on genetic, physiological and environmental factors as well as targeted drug therapy. It will also include critical evaluation of evidence and review of current guidelines or recommendations for dose or drug adjustments including the Clinical Pharmacogenetics Implementation Consortium (CPIC) guidelines. The format of the course will be a series of lectures, student presentations and in-class discussion of specific questions that are designed to illustrate these points.

Required: No

Elective: Yes

1. Course Learning Objectives:

Upon completion of this course, students will have achieved the following level of learning objectives:

Introductory / Intermediate/Advanced

Knowledge

Introductory Level:

Intermediate Level: To reinforce basic pharmacology, genetic and pharmacokinetic knowledge and give an overview of genetic, environmental and physiological factors which cause changes in drug absorption, disposition, metabolism and excretion which can lead to altered efficacy or toxicity.

Skills

Introductory Level: To be able to identify and predict potential sources of individual variability in drug disposition and response based on knowledge of drug properties and patient factors.

Intermediate Level: To be able to use basic principles of unique patient characteristics and determine how this information can be extrapolated to situations or problems seen in a clinical setting. To be able to critically evaluate the medical literature.
**Advanced Level:** The students will acquire the knowledge and skills to evaluate genomic and personalized medicine applications to clinical practice as well as examining the potential for drug-drug, drug-disease and drug-diet interactions. To develop strategies and competencies to incorporate “drug & dosage individualization” in a busy clinical setting.

**Attitudes/Values**

**Introductory Level:**

**Intermediate Level:** The field of personalized medicine is rapidly evolving. Vigorous research efforts and technological advances have inspired an unprecedented growth of information on the underlying genetic and physiological sources of variable drug disposition. And novel information is becoming available at a rapid pace. Therefore rather than simply presenting didactic lectures of information which may have already evolved once the students are in practice, it is important to instill the skills within the students to search the relevant information sources and be able to critically appraise drug or dose recommendations. They must also be able to present the rational and evidence to patients and physicians in order to implement these recommendations. Therefore developing the skills to critically evaluate the medical literature and confidence to present recommendations are important attitudes.

---

**2. Rationale for Inclusion in the Curriculum:**

Obtaining comprehensive knowledge on the sources of variability in drug response and developing skills to optimize drug and dosing decisions for individual patients based on this information is an important proficiency that all pharmacists should acquire. Pharmacists are the best positioned health care professionals to practice personalized medicine.

**3. Pre-requisites:**
Molecular Pharmacology PHM 140
Pharmacokinetics PHM 144
PHM 112 - Clinical Trials section

**4. Statement of agreement from course coordinators of courses for which this course is a pre-requisite:**
*Coordinator's Name and course name and/or number:*

Jim Wells PHM 140/ Carolyn Cummins PHM 144 / Anna Taddio PHM 112

**5. Co-requisites: (for the current and subsequent year):** None
7. Course Contact Hours and Teaching Methodologies:

<table>
<thead>
<tr>
<th>Didactic (lecture)</th>
<th>12-14 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large group problem-based or case-based learning</td>
<td>10-12 hours</td>
</tr>
<tr>
<td>Large Group Size (eg 30, 60, 120, 240)</td>
<td>~60 (selective) persons</td>
</tr>
<tr>
<td>Laboratory or Simulation</td>
<td>hours</td>
</tr>
<tr>
<td>Tutorial/Seminar/Workshop/Small Group</td>
<td>2 hours</td>
</tr>
<tr>
<td>Small Group Size (eg 5, 10, 15, 20, 25)</td>
<td>4 persons</td>
</tr>
<tr>
<td>Experiential</td>
<td>hours</td>
</tr>
<tr>
<td>On-line</td>
<td>hours</td>
</tr>
<tr>
<td>Other (please specify)*</td>
<td>hours</td>
</tr>
<tr>
<td>* Other specific information:</td>
<td></td>
</tr>
<tr>
<td>Total course contact hours</td>
<td>26 hours</td>
</tr>
</tbody>
</table>

8. Estimate and description of student's weekly out-of-class preparation time excluding exam preparation:

A group of 3-4 students will be assigned a topic. These topics will be broken down into 3-4 specific components which are dictated by the instructor. Each student within the group will be required to present and discuss one of the specific components of this topic in front of the rest of the class and answer questions once during the course; this will require out of class work in order to perform an in-depth review and evaluation of the medical literature relevant to the topic and questions that will be discussed. Members of a group may cooperate in this literature review and evaluation. Each group will have the opportunity to meet for 30-40 min with their assigned TA. The estimated time per student for this out of class work is 5 to 10 hours total.

9. Course Coordinator and contact information:

Micheline Piquette-Miller
Office: 1003 Leslie Dan Pharmacy Building, E-mail: m.piquette.miller@utoronto.ca
Mary Erick
Office: 618 Leslie Dan Pharmacy Building, Email: mary.erclik@utoronto.ca

10. Course Instructors and contact information:

Micheline Piquette-Miller
Office: 1003 Leslie Dan Pharmacy Building, E-mail: m.piquette.miller@utoronto.ca
Mary Erick
Office: 618 Leslie Dan Pharmacy Building, Email: mary.erclik@utoronto.ca
11. Required Resources/Textbooks/Readings:

Lectures, presentation abstracts and specific components to be discussed will be posted on Blackboard.

12. Recommended Resources/Textbooks/Readings:


- Lectures, student abstracts and additional material will be posted on blackboard.

- PubMed (PubMed includes Medline, life science journals and online books) will be used to search the medical literature.
13. Topic Outline/Schedule:

**Week 1-3 (6 hrs)**
Overview on sources of variability in drug disposition and response.

**Week 4**
Clinical Implementation of Pharmacogenetics (PGx) and Dosing Guidelines.

**Week 5**
Technological Advances in Genomics and Molecular Biology

**Week 6**
Pharmacogenetic Testing in Community Pharmacies.

**Week 7**
Future Directions in Personalized Medicine.

**Week 8**

**Week 9**
*Group Presentations.* **Topics:** CYP2D6 & CYP2C19 polymorphisms - race and genetic variants. *PGx guided dosing of antidepressant and antipsychotic therapy. *PGx guided dosing in pain management.

**Week 10**
*Group Presentations.* **Topics:** *PGx guided dosing of clopidogrel. *PGx guided dosing of Thiopurines. *PGx guided dosing of statins.

**Week 11**

**Week 12**

**Week 13**
Review by instructors.

*CPIC* - Clinical Pharmacogenetics Implementation Consortium Guidelines available.
14. Assessment Methodologies Used:

The two assessment methodologies that will be utilized are oral examination and short written answer exams.

### Learning Objectives Addressed

**Assessment 1:** The ability of a student to put together relevant information and deliver a presentation as well as discuss specific issues in front of the class will be evaluated by the instructors. This will test their ability to logically address a problem and critically evaluate what they have read. Both material presented and presentation skills will be evaluated. Each student will provide a copy and abstract (summary up to 250 words) of their individual presentation for evaluation. Each group will have 30 minutes for their presentation. This assessment tests factual knowledge as well as reinforcing a critical and analytical attitude.

**Assessment 2:** The ability to answer factual questions or critically evaluate a point from the literature that has been discussed will make up a major part of the exam but there are always questions that require the use of principles to discuss problems that have not been discussed. This assessment tests both factual knowledge and the ability to use this knowledge to solve clinical problems.

**Assessment 4:** The ability to answer factual questions or critically evaluate a point from the literature that has been discussed will make up a major part of the exam but there are always questions that require the use of principles to solve problems that have not been discussed. This assessment tests both factual knowledge and the ability to use this knowledge to solve clinical problems.

### Assessment Method Used

**Assessment 1:** Presentation and abstract– the ability of a student to present specific concepts and recommendations in front of the class will be evaluated by the instructor. The written abstract will be evaluated based on completeness of information. **Assessment 2:** Short answer exams

**Assessment 3:** Survey (1-2 questions). Participation. Full credit received for handing in survey during class.

**Assessment 4:** Short answer exams

### When Administered

**Assessment 1:** One assessment of the preparation of information and presentation skills by the instructors once during the course

**Assessment 2:** Term test in 2nd month of the course

**Assessment 3:** A total of 6 short questionnaires given throughout term.

**Assessment 4:** Final exam at the end of the course.

### Percentage of Course Grade
**Assessment 1:** 20%  [10% based on group presentation; 10% based on individual written abstract of their section. The written abstract (assignment) must be submitted to the course instructors within 24 hours of their presentation dates].

**Assessment 2:** Term test. Short answer exams, 30%

**Assessment 4:** A total of 6 short questionnaires. 10%

**Assessment 3:** Final exam, 40% (the final exam is non-cumulative)

### Remediation Opportunities?

- **Assessment 1:**
- **Assessment 2:**
- **Assessment 3:**
- **Assessment 4:**

---

*Expectation for pass grades for all Pharmacy courses is 60%.*

---

15. **Policy and procedure regarding make-up assignments/examinations/laboratories:**

Missed Exam/Test Policy
Students who miss an examination or a test and who have a valid petition filed with the Registrar’s office will be eligible to complete a make-up examination or test. The format of this examination or test will be at the discretion of the course coordinator, and may include, for example, an oral examination.

Missed Assignment Policy:
Students who fail to submit an assignment by the specified due date, and who have a valid petition filed with the Registrar’s office will be eligible to submit the completed assignment, or an alternative assignment based on course requirements, with no academic penalty. For each day’s delay in submitting the assignment, 5% of the assignment mark will be deducted to a maximum of 35%. The assignment will not be accepted 7 days past the due date.

Missed Presentation Policy:
If a student is unable to be present for their assigned presentation date, they must reschedule to present with a different group. A student who misses a presentation and has a valid petition filed with the Registrar’s office will be eligible for remediation. The format of this remediation will be at the discretion of the course coordinator, and may involve presentation to the course coordinators.

16. **Policy and procedure regarding supplemental assignments/examinations/laboratories:**

Supplemental examinations will be offered as per Faculty policy.