New Course Outline

Course Number:       PHM360H1
Course Title:        Personalized Medicine

Outline Version Code:

Course Description:
This course builds upon fundamental pharmacokinetic concepts taught in the first and second years in order to understand, describe and predict the sources of intra- and inter-individual variability in drug disposition and response in different patient population groups. The course is designed for students to understand the underlying basic principles used to individualize drug and dosage regimens for patients based on genetic, physiological and environmental factors. Critical evaluation of evidence and review of current guidelines for dose or drug adjustments based on genetic factors and the potential for drug-diet, drug-drug or drug-disease interactions will be covered. Recent advances in pharmacogenomics and targeted drug therapy will also be covered. The format of the course to address these issues will be a series of didactic lectures followed by student presentations, debates and in-class discussion of specific questions that are designed to illustrate these points.

Semester:           ☒ Winter
Course Type:        ☒ Selective

1. Course Learning Objectives:
Upon completion of this course, students will have achieved the following level of learning objectives:
Introductory = knowledge and comprehension of concepts, definitions
Intermediate = application of concepts to simple situations
Advanced = application of concepts to more complex situations with ability to synthesize and evaluate

Knowledge
Introductory Level:
Intermediate Level:
- To reinforce and build upon basic pharmacology, genetic and pharmacokinetic knowledge and provide expanded information on the genetic, environmental and physiological factors which cause changes in patient drug response such as altered efficacy or increased toxicity.

Advanced Level:

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.
- 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 present only 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 critical evaluate the medical literature and confidence to present recommendations are important attitudes.

Advanced Level:

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 promote and practice personalized medicine.

3. Pre-requisites:
PHM140H1
PHM144H1

4. Co-requisites:

5. Course Contact Hours and Teaching Methodologies:

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Hours</th>
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</thead>
<tbody>
<tr>
<td>Didactic (lecture)</td>
<td>12</td>
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<tr>
<td>Large group problem-based/ case-based learning</td>
<td>14</td>
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<tr>
<td>Laboratory or Simulation</td>
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<tr>
<td>Tutorial/Seminar/Workshop/Small Group</td>
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<tr>
<td>Experiential</td>
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<tr>
<td>On-line</td>
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<tr>
<td>Other (please specify)</td>
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<tr>
<td><strong>Total Course Contact Hours</strong></td>
<td><strong>28</strong></td>
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6. Estimate and description of student's weekly out-of-class preparation time excluding exam preparation: Groups of 6-10 students will be assigned a topic or debate. The debates will be assigned by the instructor and the debate groups divided into affirmative or negative and presentations will follow standard debate format. For the topic presentations - the 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.

7. Topics Covered and Lecture Specific Learning Objectives

Week 1
Lecture Topic: An overview on sources of variability in drug response

Lecture Learning Objectives:
- Identify potential sources of variation in drug concentration and response
- Understand underlying genetic, environmental and pathophysiological factors responsible for patient differences in drug response.
- Evaluate clinical significance.

Week 2
Lecture Topic: An overview on sources of variability in drug response

Lecture Learning Objectives:
- Identify potential sources of variation in drug concentration and response
- Understand underlying genetic, environmental and pathophysiological factors responsible for patient differences in drug response.
- Evaluate clinical significance.

Week 3

Lecture Learning Objectives:
- Describe barriers to clinical implementation of pharmacogenetics.
- Describe CPIC, the underlying assumptions of the CPIC guidelines and how they can be used to make specific prescribing decisions when genetic information is available.
- Identify information sources for interpreting pharmacogenetics information.
**Week 4**

**Lecture Topic:** Pharmacist-driven implementation of PGx in Community Practice Sites. PGx Case studies and pharmacist-patient interactions.

**Lecture Learning Objectives:**
- Describe the role of pharmacists in the implementation of pharmacogenetics.
- Understand common barriers and difficulties in implementing PGx testing services in a busy community setting.
- Review case studies and pharmacist recommendations based on PGx test results.

**Week 5**

**Lecture Topic:** Mid-term

**Lecture Learning Objectives:**

**Week 6**

**Lecture Topic:** Pharmacogenetic and pharmacogenomic testing technologies and advances.

**Lecture Learning Objectives:**
- Students will understand the technologies available for genotyping.
- Students will be able to identify the strengths and weaknesses of each technology.
- Students will be able to evaluate PGx tests on their coverage of gene polymorphisms and allele variants.

**Week 7**

**Lecture Topic:** PGx & antidepressants. PGx & analgesics. Warfarin PGx debate.

**Lecture Learning Objectives:**
- Students will be able to employ their knowledge of pharmacological principles to understand how pharmacogenetic information may be used to guide dosing of analgesics and antidepressants using clinical implementation guidelines.
- Students will be able to debate on the topic of whether pharmacogenetic-guided dosing of warfarin should be employed.
**Week 8**

**Lecture Topic:** HLA-B variants & ADRs. PGx & calcineurin inhibitors. Clopidogrel PGx debate

**Lecture Learning Objectives:**
- Students will be able to employ their knowledge of pharmacological principles to understand how an individual's HLA-B genotype may predict the risk of adverse drug reactions with antiretroviral and anticonvulsant medications.
- Students will be able to debate on the topic of whether pharmacogenetic-guided dosing of clopidogrel should be employed.

**Week 9**

**Lecture Topic:** Novel PGx studies. TMPT PGx debate. Targeted Drug Therapy A.

**Lecture Learning Objectives:**
- Students will be able to apply pharmacological principles to understand how personalized therapy of certain malignancies may be achieved by using pharmacogenetic information and targeted drugs.
- Students will be able to debate on the topic of whether there should be standard TPMT genotype testing prior to initiating mercaptopurine therapy.

**Week 10**

**Lecture Topic:** Targeted Drug Therapy B. Preemptive PGx testing debate. Metabolomics.

**Lecture Learning Objectives:**
- Students will be able to apply immunological and pharmacological principles to understand how personalized therapy of certain malignancies may be achieved by using CART-immunotherapy.
- Students will be able to debate on the topic of whether clinical trials support the implementation of preemptive genetic testing.

**Week 11**

**Lecture Topic:** Pharmacoepigenetics. Microbiota. PGx- simvastatin debate.

**Lecture Learning Objectives:**
Students will be able to:
- Explain how epigenetic modifications may alter the activity of drug metabolizing enzymes and drug targets;
- Demonstrate an understanding of the physiological processes that are influenced by the microbiome and how manipulating the microbiome may be used therapeutically;
- Debate on the topic of whether pharmacogenetic testing should be used to guide statin therapy.
**Week 12**

**Lecture Topic:** Environmental & Physiological Factors. Drug-disease interaction; DDI – transporters; DDI-metabolism

**Lecture Learning Objectives:**
- Students will be able to integrate their knowledge of pharmacological principles to the application of predicting drug-disease, drug-metabolizing and drug-transporter interactions.

**Week 13**

**Lecture Topic:** DDI- drug targets. Obesity/ NASH considerations. Targeted Therapy C.

**Lecture Learning Objectives:**
Students will be able to:
- Explain how new gene-editing technologies are being used to develop personalized drug therapies;
- Explain how genome-wide association studies are being used to identify novel drug targets.

### 8. Assessment Methodologies Used:

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Course Learning Objectives Addressed</th>
<th>Assessment Method Used</th>
<th>Percent of Course Grade</th>
<th>For Group Work: Individualized or same mark for all group members</th>
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<tbody>
<tr>
<td>☐ Assignment</td>
<td>Group Presentation Topics/ Debates will be assigned to groups.</td>
<td>Group presentation (10%)</td>
<td>20% total</td>
<td>Same mark for all group (worth 10%)</td>
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<tr>
<td>✖️ Presentation</td>
<td>Individual Essay - short summary of a specific research publication / comparison of two research studies / discussion on specific issue relevant to presentation or debate topic.</td>
<td>Individual Essay (10%)</td>
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<tr>
<td>☐ Participation</td>
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<tr>
<td>☐ Mid-term</td>
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<tr>
<td>☐ Final Exam</td>
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<tr>
<td>☐ Assignment</td>
<td>A very short survey containing 1 or 2 brief questions or vote on debate will be given to class during each of the presentation days (March 5 – April 10) to be handed in at end of class.</td>
<td>Provide brief comments on presentation days</td>
<td>10%</td>
<td>n/a</td>
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<tr>
<td>☒️ Participation</td>
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### Mid-term
- Midterm will cover material presented by instructors (didactic lectures). Jan-reading week.
- Short and long answer questions (ie: point form or paragraph descriptions).
- 30%

### Final Exam
- Final exam will be on material covered in presentations/debates. (Reading week-final class). Non-cumulative
- Primarily short and long answer format but will also include some MCQ and True/False.
- 40%

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

9. **Policy and procedure regarding late assignments/examinations/laboratories:**
   
   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.

10. **Policy and procedure regarding missed 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 (written or oral) 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.

    Supplemental examinations will be offered as per Faculty policy.

11. **AFPC Education Outcomes addressed (check all those that apply):**
    
    - Refer to [AFPC Educational Outcomes for Professional Programs](#) for further information about the role and key competencies.

    As **Care Providers**, pharmacy graduates:

    **CP1 – Practice within the pharmacist scope of practice and expertise**

    - CP1.1 Apply knowledge from the foundational sciences to make decisions relevant to the contemporary and evolving scope of pharmacist practice;
☐ CP1.2 Integrate AFPC Communicator, Collaborator, Leader-Manager, Health Advocate, Scholar, and Professional roles in their practice of pharmacy;

☐ CP1.3 Recognize and respond to the complexity, uncertainty and ambiguity inherent in pharmacy practice;

☒ CP1.4 Explain the benefits, risks and rationale associated with pharmacist-provided care as an important step in obtaining and documenting consent to pharmacist care;

☐ CP1.5 Recognize and take appropriate action when signs, symptoms and risk factors that relate to medical or health problems that fall into the scope of practice of other health professionals are encountered.

CP2 – Provide patient-centred care

☒ CP2.1 Collect, interpret, and assess relevant, necessary information about a patient’s health-related care needs;

☒ CP2.2 Formulate assessments of actual and potential issues and in collaboration with the patient and other health team members as appropriate, prioritize issues to be addressed in a given patient encounter;

☒ CP2.3 Create and document plans in collaboration with the patient and other health team members as appropriate, and make recommendations to prevent, improve or resolve issues;

☒ CP2.4 Implement plans in collaboration with the patient and other health team members as appropriate, including:

- CP2.4.1 obtaining consent
- CP2.4.2 making a referral or consulting others
- CP2.4.3 adapting, initiating, renewing/continuing, discontinuing or administering medication as authorized
- CP2.4.4a dispensing and/or
- CP2.4.4b compounding and/or
- CP2.4.4c delegating/authorizing such tasks to others appropriately
- CP2.4.5 engaging the patient or care-giver through education, empowerment and self-management, and
- CP2.4.6 negotiating the role of pharmacy and non-pharmacy team members in continuity and transitions of care.

☐ CP2.5 Follow-up by monitoring, evaluating progress toward achievement of the patient’s goals of therapy, adjusting plans in collaboration with the patient and health team members across the care continuum.

CP3 – Actively contribute, as an individual and as a member of a team providing care, to the continuous improvement of health care quality and patient safety

☒ CP3.1 Recognize and respond to harm and potential harm from health care delivery, including patient safety incidents;
As Communicators, pharmacy graduates:

**CM1 – Communicate in a responsible and responsive manner that encourages trust and confidence**

☐ CM1.1 Select and use oral, non-verbal and written communication strategies (tools, techniques, technologies, etc.) effectively so that the patient’s best interests are foremost;

☐ CM1.2 Provide timely, clear responses that are tailored to the context and audience;

☒ CM1.3 Express facts, evidence, opinions and positions accurately and effectively, with clarity and confidence;

☐ CM1.4 Listen, actively solicit and respond appropriately to ideas, opinions and feedback from others;

☐ CM1.5 Use language, pace, tone, and non-verbal communication that is suitable for:

   a) the intended outcomes of the communication, and

   b) the complexity, ambiguity, urgency and/or difficulty of a situation, conversation or conflict

☐ CM1.6 Seek and synthesize relevant information from others in a manner that ensures common understanding and where applicable, clarifies and secures agreement and/or consent;

☐ CM1.7 Compose and share oral, written, and electronic information in a manner that optimizes patient safety, dignity, confidentiality, and privacy.

**CM2 – Communicate in a manner that supports a team approach to health promotion and health care**

☐ CM2.1 Engage in respectful, empathetic, compassionate, non-judgmental, culturally safe, tactful conversations with patients, communities, populations, and health team members;

☐ CM2.2 Demonstrate awareness of the impact of one’s own experience level, professional culture, biases and power and hierarchy within the health team on effective working relationships, communication and conflict resolution with health team members and adapt the approach to the situation appropriately;

☐ CM2.3 Demonstrate accuracy and appropriateness of communication as well as respect for the role of other health team members when disclosing information about harmful or potentially harmful situations;

☐ CM2.4 In word and in action, convey the importance of teamwork in patient-centred care, patient safety, health care quality improvement and health program delivery.

As Collaborators, pharmacy graduates:
CL1 – Work effectively with members of the health team including patients, pharmacy colleagues and individuals from other professions

☐ CL1.1 Establish and maintain positive relationships;
☐ CL1.2 Recognize, respect and negotiate the roles and shared/overlapping responsibilities of team members;
☐ CL1.3 Join with others in respectful, effective shared decision-making.

CL2 – Hand over the care of the patient to other pharmacy team members and non-pharmacy team members to facilitate continuity of safe patient care

☐ CL2.1 Determine when and how care should be handed over to another team member;
☐ CL2.2 Recognize, respect and honour the negotiate shared and overlapping responsibilities of patients, pharmacy team members and other health members when handovers occur;
☐ CL2.3 Demonstrate safe handover of care, using oral, written, and electronic communication, during a patient transition to a different care provider or setting.

As Leader-Managers, pharmacy graduates:

LM1 – Contribute to optimizing health care delivery and pharmacy services

☐ LM1.1 Work with others to apply quality improvement strategies and techniques to optimize pharmacy care;
☐ LM1.2 Contribute to a culture of patient safety;
☐ LM1.3 Confirm the quality, safety, and integrity of products;
☐ LM1.4 Use health informatics to improve the quality of care, manage resources and optimize patient safety.

LM2 – Contribute to the stewardship of resources in health care systems

☐ LM2.1 Apply evidence and management processes to achieve cost appropriate care;
☐ LM2.2 Allocate health care resources for optimal patient care;
☐ LM2.3 Contribute to the management of finances and health human resources in pharmacy practice settings;

LM3 – Demonstrate leadership skills

☒ LM3.1 Demonstrate leadership skills to enhance pharmacy practice and health care.

LM4 – Demonstrate management skills
☐LM4.1 Work with others to apply the principles of effective management and supervision of health human resources and medication use systems;

☐LM4.2 Use effective strategies to manage and improve their own practice of pharmacy.

As Health Advocates, pharmacy graduates:

HA1 – Respond to an individual patient’s health needs by advocating with the patient within and beyond the patient care environment

☒HA1.1 Work with patients to address determinants of health that affect them and their access to needed health services or resources;

☐HA1.2 Work with patients to increase opportunities to adopt healthy behaviours;

☐HA1.3 Incorporate disease prevention, health promotion and health surveillance into interactions with individual patients.

HA2 – Respond to needs of communities or populations they serve by advocating with them for system-level change in a socially accountable manner

☐HA2.1 Work with community or population to identify the determinants of health that affect them;

☐HA2.2 Participate in health promotion and disease prevention programs.

As Scholars, pharmacy graduates:

SC1 – Apply medication therapy expertise to optimize pharmacy care, pharmacy services and health care delivery

☒SC1.1 Use knowledge and problem-solving to arrive at recommendations and decisions that are appropriate, accurate, and practical;

☐SC1.2 Use professional experience to solve routine, previously encountered problems;

☒SC1.3 Use established decision-making frameworks and apply learning required to manage new situations and problems.

SC2 – Integrate best available evidence into pharmacy practice

☒SC2.1 Generate focused questions related to needs for information, recommendations and decisions in practice;

☒SC2.2 Use systematic approaches in the search for best available evidence;

☒SC2.3 Critically appraise health-related research and literature;
SC2.4 Incorporate best available evidence in the decision-making process.

SC3 – Contribute to the creation of knowledge or practices in the field of pharmacy

☐ SC3.1 Apply scientific principles of research and scholarly inquiry;

☐ SC3.2 Apply ethical principles that underlie research and scholarly inquiry.

SC4 – Teach other pharmacy team members, the public and other health care professionals including students

☐ SC4.1 Provide effective education to others;

☐ SC4.2 Employ appropriate teaching roles when teaching others;

☐ SC4.3 Deliver effective feedback in teaching and learning situations;

☐ SC4.4 Use appropriate learning assessment and evaluation strategies when working with patients, team members, students and teachers.

As Professionals, pharmacy graduates:

PR1 – Committed to apply best practices and adhere to high ethical standards in the delivery of pharmacy care

☐ PR1.1 Exhibit professional behaviour whether face-to-face, in writing, or via technology-enabled communication. Professional behaviour includes, but is not limited to:

  a) demonstrating honesty, integrity, humility, commitment, altruism, compassion, respect for diversity and patient autonomy;
  b) being accessible, diligent, timely and reliable in service to others;
  c) abiding by the principle of non-abandonment;
  d) maintaining appropriate interpersonal boundaries;
  e) maintaining professional composure, demeanor, and language even in difficult situations, and;
  f) maintaining privacy and confidentiality;

☐ PR1.2 Use ethical frameworks as one component of professional judgment;

☐ PR1.3 Recognize and respond to situations presenting ethical dilemmas, including conflicts of interest;

☐ PR1.4 Engage in activities that:

  a) protect the public, and;
  b) advance the practice of pharmacy.

PR2 – Able to recognize and respond to societal expectations of regulated health care professionals
☐ PR2.1 Take responsibility and accountability for actions and inactions;
☐ PR2.2 Demonstrate a commitment to patient safety and quality improvement;
☐ PR2.3 Honour the laws, ethical codes, and regulatory requirements (by-laws, standards, policies) that govern the self-regulated profession of pharmacy;
☐ PR2.4 Demonstrate an understanding of federal, provincial/territorial, and municipal laws, policies and standards that apply to pharmacy workplaces;
☐ PR2.5 Demonstrate an ability to maintain competence to practice through evaluating areas for improvement and planning, undertaking learning activities to address limitations in competence and/or performance and incorporating learning into practice;
☐ PR2.6 Identify and respond to unprofessional, unethical, and illegal behaviours in pharmacists, other pharmacy team members, and other health professionals.

PR3 – Committed to self-awareness in the management of personal and professional well being

☐ PR3.1 Set professional and personal goals, priorities, and manage their time to balance patient care, workflow, and practice requirements;
☐ PR3.2 Examine, reflect upon, and manage personal attributes (knowledge, skills, beliefs, biases, motivations, emotions, etc.) that could influence self-development and professional performance;
☐ PR3.3 Adapt their practice of pharmacy to fulfill evolving professional roles;
☐ PR3.4 Recognize and respond to self and colleagues in need.