DUKE UNIVERSITY SCHOOL OF NURSING

N562 Applied Genomics and Personalized Medicine in Clinical Care

Course Number: N562

Course Title: Applied Genomics and Personalized Medicine in Clinical Care

Course Description: The focus of the course is on the clinical application of genomics for the prevention, prognosis, and treatment of complex disease states. Health professionals will acquire knowledge and skills to evaluate genomic and personalized medicine applications to clinical practice. Learning approaches will include didactic lectures, case studies, and exploration of actual genomic test results.

Enrollment Eligibility: None

Credit: 2
Semester: Spring 2014
Location: Pearson Building Room 1009

Faculty: Allison Vorderstrasse, DNSc, APRN, CNE
Assistant Professor, Duke University School of Nursing
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Office hours: TBD and by appointment

Any of the faculty may be contacted with questions about the course logistics and content. Students are encouraged to contact faculty for guidance and clarification of content.

Teaching Assistant: Adrienne Niederriter
Email: adrienne.niederriter@gmail.com
Office hours: TBD and by appointment
Accommodations
Students who believe they may need accommodations in this class based on mental or physical impairments must contact the Student Disability Access Office, as soon as possible at 919-668-1267 or http://www.access.duke.edu/.

Computing & Sakai Online Learning System
This course is supplemented with materials online using the Sakai learning system (https://sakai.duke.edu/). Once you register, you will be enrolled in Sakai. When you log in with your Duke (DUHS) username and password, you will have full access to the course materials. All students and audits have access to computing/technical support available via the DUSON Center for Information Technology and Distance Learning.

Review the following document for location, hours, and contact information: (http://www.nursing.duke.edu/sites/default/files/current_students/itduson.pdf). The help desk phone number is: 919-684-9200.

Course and Teacher Evaluations
During the last few weeks of this course, you will be sent information about completing an evaluation of the course itself and the faculty who taught it. It is the student’s professional responsibility to complete those evaluations and give thoughtful, constructive feedback about what worked well and what could be changed to strengthen this course. Please discuss any questions about these evaluations with the course faculty or your advisor. Your evaluations are confidential, anonymous to faculty, and will in no way affect your grade in the course.

Honor Code
The Duke School of Nursing Honor Code is always in effect. It can be found at: http://students.nursing.duke.edu/PersonalIntegrityPolicy.pdf. Students are asked to read this carefully prior to submission of assignments. For each assignment submission, please copy/paste the following statement on the cover page prior to submission:

"I attest that I have read the Duke University Honor Code and have completed this assignment in full compliance with the honor code." —(Your Name)

COURSE OBJECTIVES

1. Analyze the purpose, strengths and limitations of current and emerging genome technologies for clinical and personal applications.  
   Outcome criteria: Compare and contrast genomic technologies for diagnosis, risk assessment, treatment, and prevention. Discuss strengths/weaknesses of genome-based applications and direct-to-consumer testing. Differentiate analytic validity, clinical validity, and clinical utility. Discuss barriers to application of genomic testing in clinical contexts.  
   Evaluation: Participation in discussions and completion of pharmacogenomics case study, quizzes, clinical utility assignment, and personalized medicine paper.

2. Evaluate genomic approaches for risk assessment, and prevention, prognosis and treatment of complex multifactorial disease states.
Outcome: Evaluate real and case-study based genomic test results for various clinical scenarios. Analyze and interpret genomic test results with traditional risk factor information. Evaluation: Participate in discussions. Complete clinical utility assignment, and personalized medicine paper.

3. Identify strategies for communicating genetic/genomic risk to patients and families.
   Outcomes: Compare and contrast role of clinicians and genetic counselors in genomic medicine. Identify approaches for communicating testing information and results for individuals and families. Discuss psychosocial impact of genomic testing on individuals and families. Evaluation: Actively engage in class discussions. Completion of clinical utility assignment and personalized medicine paper.

4. Discuss characteristics of personalized medicine and its impact on health care.
   Outcomes: Define two philosophical paradigms of personalized medicine. Identify major characteristics of genomic and non-genomic approaches to personalized medicine. Discuss factors related to clinical implementation of personalized medicine. Discuss the potential impact of personalized medicine approaches on the health care system, individuals, and families. Evaluation: Actively engage in class discussions. Completion of pharmacogenetic case study, quizzes, clinical utility assignment, and personalized medicine paper.

ASSIGNMENTS AND GRADING

Submission: Unless otherwise indicated by instructors, assignments are to be submitted at the beginning of class on the due date listed.

*Audit requirements: Attendance and active participation are expected of auditors. Auditors are not required to participate in homework, quizzes, or assignments, but may do so and will receive feedback.

Participation (10%). Please inform instructors prior to absences. Active participation is expected in each class session and students are expected to demonstrate increased evidence of critical thinking and synthesis of information as the semester progresses.

Quizzes (10% each for total of 20%). Quiz 1-complete between January 30th 5 pm - February 3, 2014 at 8 pm. Students will complete online quizzes in Sakai, each comprised of 20 multiple choice questions (5 pt each). Quiz 1 will cover content from weeks 1 through 3 of the course. Quiz 2 – complete between March 26th 5 pm-March 30th 8pm. Quiz 2 will cover content from weeks 5, 7, 10 and 11.

GROUP Pharmacogenetics Case Exercise (20%). Due in class February 18, 2014. Student partners (2 students) will evaluate assigned mock pharmacogenetics cases. Partner groups will be assigned in class on February 11, with time during class to start preparing their case reports. Groups will submit a 1 page provider information summary as outlined below. The groups will record a mock provider/patient video session covering the patient interaction below. Summary and video are due at the beginning of class on February 18th. We will view the videos in class and discuss them.

Case reports should include:
• Provider information (1 page written summary):
  o Accurate & complete validity and results information regarding the PGX test(s)
  o Impact of test results on prescription of medications/dosages
  o Background research or information relevant to the case/test(s)
• **Patient interaction (video):**
  o Background information relevant to the diagnosis/medication
  o Impact or explanation of test results for medication management
  o Social, personal or demographic challenges or considerations related to the testing and/or results.

**Personalized Medicine Topics. Select by March 4, 2014.**
Students should choose from one of the potential topics listed in the online link that will be provided in Sakai and sign up for their chosen topic. Only one student can choose each topic.

**GROUP Clinical utility exercise (20%). Due in class April 1, 2014.** Students in groups of 3 will each select a testing platform or panel (available genetic/genomic or personalized medicine panel from binder of available platforms) and develop a clinical utility presentation. Students will develop a 3-slide presentation: 1) what the panel is/includes and is marketed for; 2) evidence and background of personalized medicine; 3) applications for the platform/panel – when would you use it in clinical practice? Each student will present their platform as a PowerPoint to the class and invited faculty.

Clinical utility presentations should be sure to include:
• Apply knowledge of genetic/genomic concepts to clinical care.
• Evaluate research in the literature to support application of clinical genomic test/platform – i.e., analytic, clinical validity and utility.

**Personalized medicine integration report (30%). Due at the start of class, April 15, 2014.**
Students will develop a 7-8 page (4 pages for each of the provider/patient reports) report that synthesizes knowledge acquired through the course and discusses how a specific genomic/personalized medicine application may be valuable in determining risk, diagnosis, or treatment for a common, complex disorder, in a personal context.

Students will review the application of personalized medicine for a chosen disease or clinical indication. The review will evaluate how personalized medicine is currently applied in different clinical settings (e.g., urban/rural, general/specialty medicine, investigational/routine) and reflect on how future advances may alter management of care for that disease/indication. Students may use 23andMe data sets as example case studies to inform the review. The report should be written for two target audiences: providers and patients. Be sure to use lay language in the patient focused report. The final product should be able to be used as a ‘web resource’ for providers or patients, and therefore may be submitted as a web page format OR as a traditional paper format that could later be posted to the web.

Specifically, the report should include:
• Abstract that synthesizes each report in 350 words or less (5% of grade for report).
• Reflection on possible clinical recommendations that could be considered and justify them for a clinical context or 23andMe case example.
• Presentation of major factors considered in the estimation of risk, determination of diagnosis, or recommendation for treatment for this disease (i.e., How much weight does each contribute to your determination of personal risk/diagnosis/treatment?).
• Discussion of why personalized evaluation may or may not be appropriate for evaluating disease risk/diagnosis/treatment and how it may differ in a public health context.
• Evaluation of the non-genetic factors essential to clinical management and decision-making.
• Evaluation of potential non-genetic personalized medicine strategies that providers and patients may want to consider in the clinical context.
• Brief review of the epidemiology of the disease and known risk factors
• Brief review of the genomics of the disease
• Presentation of existing genetic test options and reliability/validity and clinical utility/validity
• Relevant citations

**DUSON uses the following standardized grading scale:**

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<th>Grade</th>
<th>Range</th>
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<tr>
<td>A</td>
<td>93 - 100</td>
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<tr>
<td>A−</td>
<td>90 - 92</td>
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<tr>
<td>B+</td>
<td>87 - 89</td>
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<tr>
<td>B</td>
<td>83 - 86</td>
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<tr>
<td>B−</td>
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<td>C−</td>
<td>70 - 72</td>
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<td>F</td>
<td>69 and below</td>
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**Textbook:** No textbook will be used in this course; however, readings and web resources (such as tutorials/videos/etc.) will be posted each week for review. It is expected that students review these readings prior to the start of each class in order to be adequately prepared for in-class discussions and applied activities.

**Major Topics:** Through didactic lessons and evaluation of actual genomic test results (and/or personal genome option) the learner will address the following:

- Foundational concepts in genomics
- Principles of genomic technologies and testing
- Non-genomic approaches for personalized medicine
- Direct-to-Consumer (DTC) applications of genomics
- Pharmacogenetics & Clinical applications of genomics
- Genomic risk assessment and communication
- Translational genomics