Overview and Objectives: Using Registries that include electronic health record data in comparative effectiveness research explores the role of research registries that include electronic health record data in comparative effectiveness research. Students will gain an understanding of different registry models, including establishing a registry, evaluating a registry, using registry data and the strengths and weaknesses of different registry models. We will discuss the use of registries with both identifiable and de-identified data. Ethical issues surrounding the use of these data sources for research will be discussed. We will use case studies to facilitate the learning of concepts discussed in class.

Responsibilities:

- Students are expected to attend class and participate in class discussions.
- Students are expected to have completed assigned reading prior to class.
- Students will complete a “stakeholder interview” with a patient, payer, provider, or other interested party regarding the comparative effectiveness question of interest. Write-up of interview will be turned in for evaluation.
- At the end of this course, students will design a study using a registry with electronic health record information to compare patient outcomes. The study may incorporate an existing registry or a registry that is created by the students (does not need to be implemented). This study will be presented to the group and incorporate elements that we have discussed in class. Students may work individually or in small groups to complete this assignment.
- Assignments are due by 5pm on the date specified. Assignments may be turned in either as hard copy or electronic copy. If you are submitting an assignment electronically, it is your responsibility to confirm that it has been received by 5pm. Failure to confirm receipt could result in the assignment being considered late. Late assignments will be accepted at the discretion of the course instructor. If you know that your assignment will be late, it is your responsibility to discuss that with the course instructor well in advance of the due date. Late assignments may receive a reduced grade.

Course Requirements:
This course consists of seven sessions that will include didactic lectures, class discussion, and presentation by guest faculty (14 contact hours). The final session (two contact hours) will include presentation of the final study design project.

- Class participation and attendance 20%
- Stakeholder interview discussion 10%
- Stakeholder interview write up 20%
- Preliminary written protocol 10%
- Final presentation 10%
- Final written protocol 30%

Attendance Policy:

- Course attendance is expected. The course instructor must be notified of all absences in at least 1 week in advance. It is your responsibility to notify the instructor in advance. Students are responsible for the content of material presented that day. Written assignments are to be turned in regardless of
class attendance. Please note that presentation and discussion grades are based on in-class activities. Circumstances of an unplanned and urgent nature will be considered on a case-by-case basis.

- Students are expected to sign-in to each class (computer provided in suite lobby). If a problem is encountered with the sign-in system, please contact the course instructor(s) as well as Lauren Talotta (talottals@upmc.edu) immediately.

**Course Grading Scale:**

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<thead>
<tr>
<th>Percentage</th>
<th>Grade</th>
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<tbody>
<tr>
<td>98-100%</td>
<td>A+</td>
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<tr>
<td>94-97%</td>
<td>A</td>
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<tr>
<td>90-93%</td>
<td>A-</td>
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<td>87-89%</td>
<td>B+</td>
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<td>83-86%</td>
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<td>80-82%</td>
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<td>77-79%</td>
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<td>73-76%</td>
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<td>70-72%</td>
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<td>67-69%</td>
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<td>63-66%</td>
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<td>&lt;60%</td>
<td>F</td>
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**Note:** All course information, including assignments and communication, will be available at [http://courseweb.pitt.edu](http://courseweb.pitt.edu). Any requests for clarification should be made in a timely manner to ensure that course deadlines are met. Queries will be answered within 48 hours, excluding weekends and holidays.

**Required Texts:**

Course readings will come from *Registries for Evaluating Patient Outcomes: A User's Guide Second Edition* produced by the Agency for Healthcare Research and Quality and relevant journal articles. Students are expected to complete readings prior to class.

**Academic Integrity:**

Students in this course will be expected to comply with the University of Pittsburgh's Policy on Academic Integrity ([http://www.provost.pitt.edu/info/ail.html](http://www.provost.pitt.edu/info/ail.html)). Any student suspected of violating this obligation for any reason during the semester will be required to participate in the procedural process, initiated at the instructor level, as outlined in the University Guidelines on Academic Integrity. This may include, but is not limited to, the confiscation of the examination of any individual suspected of violating University Policy. Furthermore, no student may bring any unauthorized materials to an exam, including dictionaries and programmable calculators.

**Course Schedule**

<table>
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<tr>
<th>Session #1: Introduction to Patient Registries focusing on those created from EHRs</th>
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**At the conclusion of this lecture, the student will be able to:**

1. Describe the current uses for patient registries
2. Assess the appropriateness of a registry to answer a particular research question

**Topics:**

1. Patient Registries
2. Planning a Registry

**Required Reading(s):**

**Homework assignment(s):**

1. Begin to identify research question for a registry. Discuss possible group work (this will be done in class).

2. Identify a stakeholder for your research question and conduct an interview with that stakeholder to understand why or why not that stakeholder views this as an important question. Oral presentation will occur during session 3, written presentation is due by 5pm of session 3.

Student presentations should include how the stakeholder was identified, that individual’s feedback regarding the topic, and how that input is incorporated into the question going forward. Written work should focus on the research question, stakeholder perspective, modifications based on stakeholder feedback, and plans for continued stakeholder involvement.

**Session #2: Designing a registry**

**At the conclusion of this lecture, the student will be able to:**

1. Identify the data elements that compose a registry
2. Discuss the benefits of different registry types (e.g. all secondary data vs. a mix of primary and secondary data
3. Identify key elements to allow the registry to be combined with future data (e.g., genomic information)
4. Identify stakeholders to involve in the design and implementation of a registry
5. Identify the pros and cons of registry models
6. Discuss the use of identifiable and de-identified data in registries

**Topics:**

1. Registry Design
2. Data Elements
3. Data Sources
4. Stakeholders perspectives (continued into next session with student presentation of stakeholder perspectives)
5. Exemplar registries

**Required Reading(s):**


**Due Today:**

1. Identification of final project groups and research question to be answered. This should be turned in through email by 5pm. Email should include 1) names of group members and 2) 1-2
sentences identifying preliminary research question. All group members should be copied on the email, only one email per group is required.

Session #3: Evaluating a Registry/ Student stakeholder presentations

At the conclusion of this lecture, the student will be able to:

1. Assess the quality of a registry

Topics:

1. Defining quality
2. Measuring quality
3. Quality domains
4. Stakeholders pannel

Required Reading(s):


Due Today:

Stakeholder presentations and write-ups. Student presentations should include how the stakeholder was identified, that individual’s feedback regarding the topic, and how that input is incorporated into the question going forward. Presentations should be approximately 5 minutes in length.

Written work should be 1-2 pages in length and focus on the research question, stakeholder perspective, modifications based on stakeholder feedback, and plans for continued stakeholder involvement.

Session #4: Interfacing with Electronic Health Records

At the conclusion of this lecture, the student will be able to:

1. Understand the use of incorporating data collected for clinical care into a registry
2. Understand the benefits and limitations of data collected for clinical care compared to data collected for research purposes
3. Identify issues of privacy associated with the use of electronic health records

Topics:

1. Data appropriate for abstraction from an EHR
2. Interoperability of EHR and registries
3. Patient privacy related to registries
4. Exemplar UPMC EHR resources

Required Reading(s):

Homework assignment(s):

1. Preliminary written proposals due next session. These proposals should be approximately 2 pages in length and include a brief background as to why the proposed question is important, the project aim(s), the registry source, and the methods that will be used.

Session #5: Registry Ethics

At the conclusion of this lecture, the student will be able to:

1. Describe the privacy considerations inherent to a registry
2. Discuss the ethical consideration of using de-identified clinical data for research purposes
3. Understand data ownership in registries containing clinical data

Topics:

1. What do privacy, disclosure, and confidentiality mean
2. Ethical concerns related to health information registries
3. Applicable regulations to registries
4. Registry oversight and data ownership
5. Regulatory panel

Required Reading(s):


Due Today:

1. Preliminary written proposals. Comments will be returned to students during session 6. If you will not be at session 6, please make sure you discuss comments with other group members or make arrangements to get comments from the instructor.

Session #6: Study Design and Analysis for Registries

At the conclusion of this lecture, the student will be able to:

1. Describe the design and analytic challenges posed using registries
2. Discuss analytic techniques for registries with identifiable vs. de-identified data

Topics:

1. Data analytic techniques for research registries

Required Reading(s):

Session #7: Operating a Registry

At the conclusion of this lecture, the student will be able to:

1. Identify the resources needed to operate a registry
2. Understand policies and procedures necessary to ensure that the registry runs effectively
3. Discuss possible pitfalls in creating and operating a registry

Topics:

1. Developing oversight for a registry
2. Recruiting participants for a registry
3. Data collection—primary and through linking
4. Making a registry available for other research
5. Case Study in registry operations

Required Reading(s):


Homework assignment(s):

1. Final student presentations and written proposals due next session (8)

Session #8: Student presentations

Due Today:

1. Student presentations. Presentations should be approximately 10 minutes in length and focus on the research question, modifications from stakeholder discussions, the registry that will be used (including the design elements of that registry), and the approach to answer the research question.
2. Written proposals should be 4-6 pages in length and include the aims of the proposal, the significance of the question answered, the registry used, including details regarding the design of that registry, and the approach to answer the research question.