Overview and Objectives:

This special methods course will provide the critical bridge between the more general research skills, which are the focus of the Clinical Research Training Program, and the particular challenges of doing patient-oriented research in palliative care. This 1-credit course, along with “Principles and Practice of Palliative Care,” is the cornerstone of the CRTP Concentration in Palliative Care. It consists of the following components:

- Discussion of the use of specific research methods and their strengths and limitations in research on palliative care topics
- Review and critical appraisal of the methodologies used in both landmark and more recent research articles in palliative care

The course is taught in a graduate seminar fashion with an emphasis on discussion and critical analysis. Completing required reading prior to each session and preparing discussion points is mandatory.

Sessions will often be co-moderated by a palliative care physician and a researcher with the particular methodological expertise under discussion.

The learning objectives for the 16-hour, 8-session course include:

- Explore specific research methods commonly used in palliative care research
- Identify the strengths and limitations of these methods
- Develop familiarity with the work of faculty conducting research on palliative care topics
- Examine seminal research papers in palliative care.

Responsibilities and Course Requirements:

- Evaluation: Students will be evaluated on the basis of their active engagement with assigned readings, completion of discussion points prior to each session, and participation in class discussions.

- Requirements: Students will be required to attend and participate in all sessions. Absences must be requested and approved in advance. As written exercises, students will write a minimum of two discussion points (on at least two different reading assignments) for each session. These discussion points will be due by 11am on the day prior to each session and will be distributed to the leader for each session in advance. Discussion points may include questions raised by the readings and/or responses to the learning goals for each session. Discussion points should be ½-1 page in length.
Required Textbook(s):

- None

Supplemental Resources:


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/aii.html](http://www.provost.pitt.edu/info/aii.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.
Session 1: Studying Surrogate Decision Making in the ICU

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

1. Explain the ways that qualitative methods can be used for palliative care research
2. Discuss the methodological issues associated with qualitative research in palliative care
3. Describe the common method called ‘qualitative description’.

Topics:

1. Surrogate decision makers perspectives on discussing prognosis with physicians
2. Qualitative methods
3. Assessing rigor in qualitative research

Core Competency
Methodology: Compare strengths and weaknesses (feasibility, efficiency, generalizability, validity, and ability to derive unbiased inferences) of different research paradigms and methodologies.

Required Reading(s):

Session 2: Symptom Focused Research in Palliative Care

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

1. Provide two different validated instruments for assessing symptoms in palliative care symptoms
2. Explain the methodological issues associated with clinical trials designed to decrease symptoms in individual patients
3. Critically review studies of antidepressants for neuropathic pain
4. Design a new study of an antidepressant for metastatic cancer related neuropathic pain

Topics:

1. Epidemiological reviews of symptom focused research
2. Interventional studies of symptom focused research

Competencies

Problem Formulation: Critically review published studies that use various research methodologies and identify possible sources of bias and potential health disparities therein.

Methodology: Design basic features of research protocols based on specific research questions, appropriately addressing bias.

Methodology: Compare strengths and weaknesses (feasibility, efficiency, generalizability, validity, and ability to derive unbiased inferences) of different research paradigms and methodologies.

Measurement: Describe the characteristics underlying data quality and their ability to answer clinical or translational research problems.

Required Reading(s):

This reading is no longer available on line but Dr. Arnold asked that the notes be emailed for your review prior to class.

1. NIH Clinical Interactive Textbook on Clinical Interactive Symptom Research
   Chapter 1 – The Design of Clinical Trials for Treatment of Pain
   Chapter 2 – Development of a Clinical Trial
   Chapter 3 – Methods for Clinical Research in Constipation


Session 3: Education Research

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

1. Identify unique logistical, ethical, and funding issues in medical education research.
2. Describe the variables that one would want to measure when assessing palliative care education.
3. Provide the advantages and disadvantages of using survey, focus group and observational methodologies to assess students’ education in palliative care.

Topics:

1. Education Research

Competencies

Methodology: Design basic features of research protocols based on specific research questions, appropriately addressing bias.
Methodology: Compare strengths and weaknesses (feasibility, efficiency, generalizability, validity, and ability to derive unbiased inferences) of different research paradigms and methodologies.
Methodology: Identify potential funding sources for research projects.
Methodology: Understand and explain Federal regulations regarding human subject research, and prepare an IRB application.
Measurement: Describe the characteristics underlying data quality and their ability to answer clinical or translational research problems.
Ethics and Professional Norms: Provide examples of the norms of professional integrity with regard to designing and conducting research including: data collection, sharing, and protection; and reporting of findings.

Required Reading(s):

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

1. Define complicated grief (persistent complex bereavement disorder) and describe related symptoms and risk factors.
2. Describe various tools for measuring complicated grief and associated measurement challenges.
3. Discuss research on strategies for prevention and treatment of psychiatric disorders in older adults.
4. Explore future research priorities and unanswered questions in bereavement research.

Topics:

1. Grief and related psychiatric disorders in older adults
2. Prevention and treatment of complicated grief
3. Tools used to measure complicated grief
4. Psychiatric intervention studies with older adults.

Competencies

Methodology: Design basic features of research protocols based on specific research questions, appropriately addressing bias.

Methodology: Compare strengths and weaknesses (feasibility, efficiency, generalizability, validity, and ability to derive unbiased inferences) of different research paradigms and methodologies.

Measurement: Describe the characteristics underlying data quality and their ability to answer clinical or translational research problems.

Required Reading(s):

Session 5: Evidence Synthesis in Palliative Care

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

1. Describe basic concepts in systematic review and meta-analysis
2. Explain methodological issues associated with systematic review and meta-analysis, particularly as they relate to palliative care interventions
3. Discuss common methodological limitations in the palliative care evidence base

Topics

1. Tradeoffs between sensitivity and specificity when defining a review/meta-analysis
2. Measuring and addressing heterogeneity
3. Risk of bias and methodological quality
4. Outcomes measurement and pooling

Competencies

Methodology: Compare strengths and weaknesses (feasibility, efficiency, generalizability, validity, and ability to derive unbiased inferences) of different research paradigms and methodologies.

Applied Analytic Techniques: Describe appropriate data analysis plans for addressing specific research questions.

Required readings


**Session 6: Quality Improvement/System Change Research in Palliative Care**

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

1. Summarize the process of rapid sequence quality improvement
2. Describe the methodological issues associated with quality improvement research
3. Design a study to determine if the quality of dying has been improved by a palliative care service OR to determine if the quality improvement process in a nursing home has improved pain management in nursing home patients

**Topics:**

1. Measuring the impact of palliative care services

**Competencies**

*Methodology:* Design basic features of research protocols based on specific research questions, appropriately addressing bias.

*Methodology:* Compare strengths and weaknesses (feasibility, efficiency, generalizability, validity, and ability to derive unbiased inferences) of different research paradigms and methodologies.

**Required Reading(s):**


Session 7: Informed Consent in Palliative Care

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

1. Describe the components of informed consent.
2. Discuss research on the quality of informed consent for clinical procedures and participation in research trials.
3. Explain ethical and logistical issues associated with informed consent in palliative care research.

Topics:

1. The meaning and quality of informed consent
2. Ethical and logistical issues raised by research in palliative care

Competencies

Methodology: Understand and explain Federal regulations regarding human subject research, and prepare an IRB application.

Sampling: Determine appropriate and ethical methods to assemble and retain informed study participants.

Ethics and Professional Norms: Provide examples of the norms of professional integrity with regard to designing and conducting research including: data collection, sharing, and protection; and reporting of findings.

Required Reading(s):


Session 8: Quality of Life/Dying/Patient Preferences in Palliative Care Research

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

1. Provide the advantages and disadvantages of the various instruments used to measure quality of life in end-of-life care
2. Articulate the analytical issues which complicate measuring patient assessed quality of life in palliative care
3. Describe the methodological issues involved in using surrogate's assessment in palliative care research
4. Design a study examining the effect of discussions of advance care planning on the quality of life of patients with metastatic cancer and their families.

Topics:

1. Quality of life/dying/patient preferences in palliative care research

Competencies

Methodology: Design basic features of research protocols based on specific research questions, appropriately addressing bias.

Methodology: Recognize the impact of diverse populations and local demography on research designs, and modify research design accordingly.

Measurement: Describe the characteristics underlying data quality and their ability to answer clinical or translational research problems.

Applied Analytic Techniques: Describe appropriate data analysis plans for addressing specific research questions.

Required Reading(s):

5. Review different instruments used to measure quality of life (available at): http://www.echer.brown.edu/poc/BIBLIOGRAPHIES.HTM
   http://www.nperc.org/resources/resources_list.htm?cat_id=1246