Eidgenössische Technische Hochschule Zürich
Swiss Federal Institute of Technology Zurich

Departement Chemie und Angewandte Biowissenschaften
Institut für Pharmazeutische Wissenschaften

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FIDELIO Course Planning

Course Title: "How to critically appraise real-world evidence in medicine"

Date: December 2-4, 2020
Location: Online via zoom
Meeting ID: 952 2762 1481
Password: 458804
Instruction: Prof. Dr. Andrea Burden

Course overview: This 3-day course will provide students with a basic understanding of the methods of clinical epidemiology, as applied to clinical research. The topics to be addressed will include an introduction to epidemiology, common study designs, bias, measurement issues, confounding, and causal inference in observational research. Clinically we will focus on issues relating to the study of diabetes and bone health.

Course objectives: By the end of this course, students should be able to:

- Conceptualize key concepts in epidemiology and pharmacoepidemiology.
- Distinguish between common study designs and databases in observational research.
- Identify different sources of bias in research and hypothesize how each bias may impact research results.
- Critically appraise current medical research in the field of diabetes and bone using their content knowledge of the medical area and their newly gained knowledge of study design, data selection, and bias.

Course format: The course format will include a combination of lectures and application. In particular the students will encourage to apply the concepts to their own area of interest during the in class exercises. Each day will consist of "in class" teaching on zoom and "out of class" time to work on homework and assignments. The first day (December 2nd) will consist of 5 hours in class teaching, providing students with 2 – 3 hours out of class time to work offline in their groups. On day three, the students will have 4 hours of online teaching, followed by 4 hours of out of class time to work in their groups.

Group work will be enabled through the use of break-out rooms in zoom, which will be activated at the end of each day. Students will also be given the opportunity to log-off and set up a zoom session among themselves. During the break-out sessions, the instructor (Andrea Burden) will remain on zoom so that students can request that she join their breakout room to answer questions. To facilitate the group work, google docs will also be set-up for each group.

A detailed overview of the three day format can be found on page 2.

Assignment (ungraded): On Friday December 4th, the students will put the knowledge and skills g into practice. They will be put into small groups of 3 to 5 students and each group will be assigned a publication to critically appraise. On day 2 they will see an example presentation of a critical appraisal they can model theirs after. Each group will be provided with a one-hour time slot for their presentations – 20 minute presentation and 40 minutes for discussion with the group on the key methodological aspects. While each group will be assigned one article that they focus on, they are expected to read and appraise the other articles. *Note: Currently 3 articles are identified for the group presentations. If more guest students join the course, I will add one additional article.

Student feedback: After course we will provide students with a link to a survey monkey where they can provide their assessment of the course anonymously.

Eligibility: The course is open to all ESRs in the Fidelio program. Additionally, we will consider opening 6 additional spots to motivated members (students or staff) at the Fidelio partner institutions. To enrol, email Andrea Burden directly with information on your current place of study or employment and a short description of why you wish to join the course.

DAY 1: December 2nd 2020

Session 1: 9:30 – 12:30

Topics covered

- Introduction to epidemiology and real world observational research
- How and where does (pharmaco)epidemiology fit in clinical research
- Overview of study design hierarchy (RCTs, Cohort, Case Control, Cross-Sectional)

In class exercise

- Identifying the study designs from published abstracts (use sli.do for online polling)
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Lunch (12:30 – 13:30)

Session 2: 13:30 – 15:30

Topics Covered

- Defining a research question
- Introduction to critical appraisal (bias and confounding)
- Group formation for final assignment – group presentation of critical appraisal of article

In class exercise

- Work in small groups (break-out rooms on zoom) to think of the appropriate study design and database to answer three different research questions – 1 hour

Break (15:30 – 16:30) Dedicated time to read the assigned articles and begin methodological discussions

Session 3: 16:30 – 17:45

- Break-out room discussions (45 min) to discuss assigned critical appraisal.
- Q & A and consolidation of day one (30 min)

Homework

- Read articles :
  - Leutner et al. (2019) "Diagnosis of osteoporosis in statin-treated patients is dose dependent" ARD, 78: 1706-1711
  - Boniol et al. (2018) "Incretin-based therapies and the short-term risk of pancreatic cancer: results from two retrospective cohort studies
  - Cheung et al. (2019) Metformin and gastric cancer Risk in diabetic patients after Helicobacter pylori eradication. *J Natl Cancer Inst,* 111: djy144
  - Lin et al. (2018) Tamoxifen usage correlates with increased risk of Parkinson's disease in older women with breast cancer: a case-control study in Taiwan. *Eur J Clin Pharmacol*, 74: 99-107

DAY 2: December 3rd 2020

Session 4: 9:30 – 12:30

Topics Covered

- Specific biases common to cohort and case-control designs (immortal time bias, protopathic bias, time-window bias, attrition bias, time-lag bias)

In class exercise

- In class journal club with group discussions to appraise the paper by Leutner

Lunch (12:30 – 13:30)

Session 5: 13:30 – 15:00

Topics Covered

- Understanding common measures of risk (incidence, prevalence, relative risk, hazard ratio, odds ratio, case fatality rates)

In class exercise

- Calculate and interpret measures of risk
- Discuss implication of perception bias and misclassification

Break (15:00 – 15:15)

Session 6: 15:15 – 17:00

- Dedicated time for break-out room discussions among groups to prepare their individual group presentations

Session 6: 17:00 – 18:00

- Q & A and consolidation of day two

Homework

- Work in groups to finalize the presentations
- Read assigned articles to prepare for group presentations

DAY 3: December 4rd 2020

Session 7: 9:30 – 11:30

Topics covered

- Essentials in systematic reviews and meta-analyses
- How do regulators use and appraise clinical data to make decisions on medications?

Lunch (11:30 – 13:30) Extended lunch break to allow final preparations for presentations

Session 8: 13:30 – 17:00

- Gone hour group presentations (x3), with 15 minute breaks between groups

Break (17:00 – 17:15)

Session 9: 17:15 – 18:00

- Course summary
- Q&A and student feedback