Clinical Case & Evidence-Based Practice Annotations

Suggested completion date: By the end of week 6 in your clinical rotation.

Learning Objectives

After completing a literature review pertinent to the clinical case study selected the intern will be able to:

- Articulate the body of research related to medical nutrition therapy practices specific to the nutrition interventions they will suggest for the patient case study.
- Describe their understanding of medical nutrition therapy related to the patient's nutrition care and disease state.
- Establish a specific nutrition-related research question to focus a literature review and to make recommendations for evidence-based care.
- Connect current scientific discovery with nutrition interventions in clinical practice.

Tasks

1. **Ask a question about the chosen disease process with nutritional implications that you would like to answer.** Challenge yourself in this process and do not hesitate to ask a question that does not necessarily have enough evidence to support a consensus.
2. Based on the selected patient from Step 1 of your Clinical Literature Review & Case Study & Evidence-Based Practice Presentation, use the MSU Library Dietetic Research resource page, http://guides.lib.montana.edu/dieteticsLinks to an external site., to find a minimum of **4 articles** on the chosen topic.
3. **Write annotations of each article and submit the annotations as a Word file to Canvas for the director feedback before writing the literature review.**
    - Choose a minimum of 4 articles pertinent to your topic and case study; use at least 2 current research article published within the past 3 years. Please select from peer-reviewed and esteemed journals. Evaluate and summarize the article **with the PP-ICONS methodology**. Identify the Problem, Patient or population, Intervention, Comparison, Outcome, Number of subjects, Statistics.
    - Read – American Academy of Family Physicians. A simple method for evaluating clinical literature. "The 'PP-ICONS' approach will help you separate the clinical wheat from the chaff in mere minutes." https://www.aafp.org/fpm/2004/0500/p47.htmlLinks to an external site.

Each article annotation should:

- Begin with an AMA citation
- Clearly state the main points of the research and how they relate to your nutrition care question.
- Describe the type of study/study design (randomized clinical control trial, observational, cohort model, etc.).
- List the study size and participant criteria.
- Report results
    - For quantitative studies
        - Describe the intervention in detail (e.g., was the food provided by the study or patient, what was the dosage of the supplement, can the reader decide from your description how feasible the intervention would be for their patient population to implement?).
        - **Present results**
            - **Report the values <u>and</u> p-values to show the size *and* significance of the treatment effect compared to the control.**
            - **For example, by what percentage or score were HgbA1c values decreased in the control and interventional groups and report the p-value. That way the reader can understand the magnitude of the treatment effect and compare that treatment to other treatments. Beyond significance we need to understand was the diet intervention more or less effective than walking 15 minutes or doing 10 squats after a meal for decreasing HgbA1c, and was the decrease in HgbA1c worth the effort that a patient may but into the intervention.**
            - **Also report results that were not significant so the reader can understand which interventions were not effective**
    - For qualitative studies
        - Discuss how the data were generated and analyzed, relationship to the claim/research question, and conclusions. Discuss how these findings relate to the body of literature.
- Discuss limitations of the study with implications for future research
    - Identify any detected flaws in experimental design, inconsistencies in outcomes, or gaps in current research as related to your topic. What are the overall strengths? What are the overall weaknesses? What might be oversights?

All components of PP-ICONS may not be applicable to some studies, but it is still a good framework for reviewing journal articles.

Example annotation, for purposes of this example see the PP-ICONS labels in purple:

Geller SE, Shulman LP, Van Breemen RB, et al. Safety and efficacy of black cohosh and red clover for the management of vasomotor symptoms: a randomized controlled trial. *Menopause*. 2009;16(6):1156-66. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2783540/Links to an external site.

The study was a phase II randomized, double-blind placebo-controlled safety and efficacy trial investigation of (**P**roblem) vasomotor symptoms in per- or post-menopausal women (hot flashes) in response to conventional care or black cohost treatment conducted in Chicago, IL, USA. Black cohosh roots/rhizomes (Cimicifuga racemosa (L.) Nutt.) and red clover stems, leaves and flowers (Trifolium pratense L.) are common alternatives to hormone (estrogen) therapy. (**P**opulation) Participants were (**N**umber of subjects) 89 women (8 dropped out b and 1 woman lost to follow up) of 53 years average ago, 50% African-American, 44% white, 4/5 % Hispanic, and 1% Pacific Islander experiencing at least 35 vasomotor symptoms/week with BMI <38. See article for additional rule out medical history criteria. The investigators grew and harvested samples and completed purity and biological testing to ensure high quality herbal supplements. Participants were randomly assigned (**C**omparisons are placebo & conventional care) to placebo (n=22), conventional therapy (0.625 mg conjugate equine estrogen + 02.5 mg medroxy-progesterone acetate CEE/MPA, 2 capsules) (n=23), (**I**nterventions are black cohosh and red clover) 128 mg (2 capsules) black cohosh dry extract (n=21), 378 mg (2 capsules) red clover (n=22) for 12 months. (**O**utcomes tracked were primarily hot flash frequency and severity, here I listed secondary outcomes, as well) Women tracked and scored hot flash symptoms (1 mild, 2 moderate, 3 severe) and participated in screening visits to measure blood chemistry, lipids, and hormone levels at 6 mo and 1 year. Data were analyzed for participants who remained in the study at least 3 mo. (**S**tatistics – showing the treatment effect (%age change from placebo) and significance (demonstrated here by p-value) are absolutely essential. Do not report an “increase” or “decrease” without showing the amplitude of effect.) Eighty-nine percent of participants adhered (took ≥ 80% of study medications). All treatment groups had decreased vasomotor symptoms; black cohosh, 34% reduction; red clover, 57%; placebo, 63%; and, CEE/MPA, 94% with no statistically significant differences in the number of vasomotor symptoms, hot flashes alone, or intensity of hot flashes between botanical groups and placebo at 3, 6, 9, or 12 months, whereas the CEE/MPA group had 5 recorded symptoms per week at all timepoints,

compared to 71 occurrences at baseline ($p<0.0001$ at 3 and 6 mos, $p=0.0004$ at 9 and 12 mos), which was higher than expected. There were no significant differences between treatment groups in safety parameters. (Bonus: Comparison of findings/results/outcomes to the greater body of literature – might as well include in your annotation, because it will be required in literature review section of your introduction) One new finding is that red clover reduced anxiety per the Greene Anxiety score Scale vs placebo (1.64 pts vs. 0.08 pts mean reduction, $p= 0.04$). This study's findings align with previous studies that showed no efficacy or small beneficial effect of botanicals for hot flash relief compared to hormonal therapy. While previous studies showed reduction in symptoms with black cohosh, this study demonstrated no significant difference when compared with placebo, and a review of the literature suggests that a placebo effect may account for a 60% reduction in symptoms. (Conclusions – also essential, while not included in the PP-ICONS acronym) While many women continue to use black cohosh and red clover, this trial demonstrates that while it is not effective, it is safe.

Seek help if you need it:

Mary Anne Hansen, MSU EHHD Librarian: 406.994.3162 or mhansen@montana.edu

Regional Medical Library (a library resource person might be available at your facility): Click here to see the list of member facilities around the state

MSU Writing Center: http://www.montana.edu/writingcenter/