**Literature Evaluation & Research Design Assignment (S23)**

**Name (Student ID Number) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Directions:**

* The following assignment has been designed as a comprehensive experience for you to apply the knowledge you have obtained in Unit 1: Biostatistics & Literature Evaluation of PHCY 432 (and in PHCY 442...).
* **Of note, some material assessed in the assignment will have been explicitly** **covered in the module, and other things may need to be researched on your own...In the REAL world you will find things you may need learn along the way!**
* **Show all work** on calculations and **be as specific as possible** when providing interpretations of statistical procedures and values
* Assume you are providing your responses to someone who has **NO KNOWLEDGE** of the studies you will be reviewing. In addition, this will **MAXIMIZE** your opportunities for partial credit when appropriate.
* This assignment is to be completed **on your own (using open resources)**, not discussed with classmates. All outside resources used in the completion of this project (other than the studies reviewed in the assignment) need credit for use by using **National Library of Medicine (NLM)** formatting.
* By submitting the assignment via Bb in SafeAssign you are attesting to following: *“The Literature Evaluation & Research Design (LERD) Assignment should be completed independently. Sharing or receiving any information related to the content or activities of the LERD Assignment is a violation of the Honor Code. All violations will be referred to the Honor Council. By submitting your assignment to Bb, I am verifying that I have read and understand the above statements, that I have not received any information about the content or activities of the LERD Assignment, and that I will not share any information about the content or activities of the LERD Assignment.”*

1. **Download and read the following articles:**
   1. Focht III, D. R., Spicer, C., & Fairchok, M. P. (2002). The Efficacy of Duct Tape vs Cryotherapy in the Treatment of Verruca Vulgaris (the Common Wart). Archives of Pediatrics & Adolescent Medicine, 156(10), 971.
   2. Spruance, S. L. (1997). Penciclovir Cream for the Treatment of Herpes Simplex Labialis: A Randomized, Multicenter, Double-blind, Placebo-Controlled Trial. JAMA, 277(17), 1374.
2. **In PPCP II we discussed several important preliminary questions to ask yourself to “get your bearings” on a particular article. What evidence can you provide that suggests why the Focht III. et al. study was needed?**

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1. **Briefly describe the study design of the Focht III. et al. article including type of study design, relevant variables (appropriately classified), null/alternative hypotheses, and the relevant outcomes of interest.**

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1. **How were subjects randomized in the Focht III. et al. study? Briefly outline the procedure? Was it truly random?**

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1. **On page 972, authors of the Focht III. et al. study state, *“We analyzed demographic variables, including age, sex, and location and baseline size of the warts using Chi Squared tests for categorical variables and the 2-tailed test for continuous variables to detect any differences between the 2 groups.”* Fill in the following table as appropriate.**

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| **Baseline**  **Characteristics** | **Categorical or continuous variable?** | **Statistical test used to assess?** |
| **Sex** |  |  |
| **Age** |  |  |
| **Location of Wart** |  |  |
| **Size of Wart** |  |  |

1. **Construct a 2 x 2 contingency table for the primary outcome of the Focht III. et al. study.**
2. **Interpret the p value for the primary outcome of the Focht III. et al. article.**

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1. **What is the rate of resolution when treated with duct tape? What is the rate of resolution when treated with cryotherapy?**

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1. **What is the risk reduction with duct tape? Interpret your calculated value.**

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1. **What is the number needed to treat for duct tape. Interpret your calculated value.**

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1. **Imagine you are a pediatric pharmacist. In a few sentences provide how your perspective on treatment options would change (or would not) from the Focht III. et al. article. Ensure to make patient-centric, economic, efficacy, safety, and statistical considerations in your argument.**

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1. **In PPCP II we discussed several preliminary statistical questions that should be answered before diving into the bulk of a primary research article? Assess those elements of the Spruance et al. article.**

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1. **On page 1376 of the Spruance et al. article, it is suggested that *“patients who applied penciclovir cream lost pain significantly faster (HR 1.22; 95% CI, 1.09-1.36; P <0.001) compared with patients who applied vehicle control cream.”* Interpret the 95% CI for the hazard ratio.**

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1. **Table 2. of the Spruance et al. article summarizes the impact of penciclovir treatment on the resolution of classical lesions. Interpret the odds ratios for proportion healed by day 6 in the investigator assessed data.**

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1. **Table 3. of the Spruance et al. article summarizes an analysis that was performed based on the lesion stage noted by the patient at the initiation of therapy. What statistical evidence do you have to suggest there is no difference cessation of viral shedding time? Interpret your evidence.**

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1. **The Spruance et al. article suggests in the abstract that the *“healing of classical lesions (vesicles, ulcers, and/or crusts was 0.7 day faster for penciclovir-treated patients compared with those who received vehicle control cream (median, 4.8 days v 5.5 days; hazard ratio [HR], 1.33; 95% confidence interval [CI], 1.18-1.49; P < 0.001).”***
   1. ***Interpret the statistical significance of the quotation above?***

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* 1. ***Interpret the clinical significance of the quotation above?***

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