HLSC 2003 Epidemiology
Active Engagement Assignment #4
Study Critique

Group Number: _____

Group Members Present:

1. _____ 2. _____ 3. _____ 4. _____

Study Background: A group of Portuguese researchers wanted to examine the association between veganism during pregnancy and Sudden Infant Death Syndrome (SIDS). The authors did not provide a biological rational for their hypothesis. This association has never been examined before in any country. The foods that make up a vegan diet are known to be the same in Portugal as other countries.

Methods: They randomly selected 1000 pregnant mothers in their first trimester from clinics across Portugal in 2009 and followed these women until their children were two years old. Hospital records were used to identify a woman's diet status (vegan or non-vegan) throughout the study. Clinicians followed a standard definition when classifying women as vegan/non-vegan. Coroners established cause of death by SIDS independently of this study. It is believed little error in the measurement of the exposure and outcome took place. Control for confounding was not built into the design.

Results: Infants of mothers who were vegan during pregnancy were 40% less likely to die of SIDS (95% CI = 0.58 to 0.62). A dose-response relationship could not be established as the study used dichotomous (yes/no) exposure and outcome measures. The researchers noted in the results that over the course of the study 600 women were lost to follow up. The researchers adjusted the analysis for age as a confounder. However, women who are vegan in Portugal are more highly educated, have a higher household income, are less likely to smoke, and exercise more frequently than non-vegans. These factors during pregnancy have been independently associated with reduced SIDS after birth in other studies. The researchers did not collect information on these factors and thus could not adjust the statistical findings for these variables.[1]

1. Study type: _____

2. What is the study exposure and outcome: _____ _____

3. Is the exposure a risk or protective factor? _____

[1] **Note**: This study example was created for the purposes of this exercise. It does not represent finding from an actual study.

4. What is the relative risk in this study? _____

Critique the Quality of this Study & Importance of the Findings

1. **Is association likely due to chance (i.e. is it statistically significant)?**_____

2. **Could association be due to systematic error?** List three possible types of error relevant to this study type, and indicate if each were a problem.

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3. **Could the association be due to confounding?** (Explain why or why not using the 3 steps to assess confounding)

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4. **Who does the association apply to?** (i.e., do the study findings apply to babies born only in Portugal or could the association also be generalized to babies born in other countries? Explain why or why not)

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5. **Is the association a cause-and-effect relationship?**

Hill's Postulate	**Criterion Met**	**Briefly State Why or Why Not**
1.		
2.		
3.		
4.		
5.		
6.		

Based on your critique of this study (via the 5 steps), how much confidence do you place in the findings (**1 =** no confidence should be placed in these findings; to **5 =** the Government of Canada should advise all pregnant women to follow a vegan diet immediately):

Group Assessment of Study (circle one): **1** **2** **3** **4** **5**

6. Name 2 factors that influenced your opinion on the quality of this study and its findings **the most**:

1._____

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2._____

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