Clinical Reading Questions #10

HST 190: Introduction to Biostatistics

These discussion questions are based on Hernán et al. (2008).

1. Describe the discrepancy between the results of observational studies versus randomized trials regarding hormone therapy and coronary heart disease. Why did the authors' think this discrepancy existed?
2. Why do you think the authors wanted to compare "initiators" versus "non-initiators" of hormone therapy, rather than "users" versus "non-users"? How did the authors define "initiation"?
3. What was the purpose of modeling the observational data as a sequence of "trials"?
4. What was the purpose of accounting for "non-adherence" in the observational data? How did the authors account for "non-adherence"?
5. Discuss the findings in Table 6. Specifically, compare the estimated HR of $1.42(0.92, 2.20)$ when comparing "initiators" to "non-initiators" with the estimated HR of $0.98(0.60, 1.60)$ when comparing "selected initiators" to "non-initiators"? Discuss how "initiators" and "selected initiators" were defined, and how this might have changed the corresponding HR estimates.
6. Beyond confounding arising from a lack of randomization, what are the major challenges of using observational data to estimate causal effects? Are these challenges all specific to observational studies (and not RCTs)?

References

Hernán, Miguel A, Alvaro Alonso, Roger Logan, Francine Grodstein, Karin B Michels, Walter C Willett, JoAnn E Manson, and James M Robins. 2008. "Observational Studies Analyzed Like Randomized Experiments: An Application to Postmenopausal Hormone Therapy and Coronary Heart Disease." *Epidemiology* 19 (6): 766–79. https://doi.org/10.1097/EDE.0b013e3181875e61.