

## Literature Review on OHIE Framingham Risk Score Expected Treatment Size

Jaskaran Bains

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- **BACKGROUND:** Framingham Risk Score (FRS)
  - OHIE: “The Framingham risk score was used to predict the 10-year cardiovascular risk. Risk scores were calculated separately for men and women on the basis of the following variables: age, total cholesterol and HDL cholesterol levels, measured blood pressure and use or nonuse of medication for high blood pressure, current smoking status, and status with respect to a glycated hemoglobin level  $\geq 6.5\%$ . Framingham risk scores, which are calculated for persons 30 years of age or older, range from 0.99 to 30%. Samples sizes for risk scores were 9525 participants overall, 3099 participants with high-risk diagnoses, and 3372 participants with an age of 50 to 64 years. A high-risk diagnosis was defined as a diagnosis of diabetes, hypertension, hypercholesterolemia, myocardial infarction, or congestive heart failure before the lottery (i.e., before March 2008).”
    - **Notes:** From this information, the expected treatment effect of the OHIE would be higher for subjects with more risk factors in the list above. As only a small portion of the OHIE subjects fall under these risk factors, this implies that the expected treatment effect will likely be much smaller than that found in literature studying a more at-risk population.
- **STUDY:** The Impact of Health Care Advice Given in Primary Care on Cardiovascular Risk (Lindholm et al)
  - <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2549500/pdf/bmj00590-0029.pdf>
  - **Summary:** A randomized controlled study to evaluate the benefits of intensive healthcare advice on 681 subjects (30-59 years old) with high lipid concentrations and at least two other cardiovascular risk factors.
  - **Relevant Data:** The mean treatment effect of the intensive care on the FRS was -0.068. The authors explain this result more plainly by saying that a 50 year old man with high cholesterol with an eight year risk of heart disease of 8.74% would normally see an increase to 9.51% in 18 months, but with the intensive care in this study it would only increase to 8.75%.
- **STUDY:** Physical Activity, Physical Fitness, and Framingham 10-Year Risk Score: The Cross-Cultural Activity Participation Study (LaMonte et al)
  - [http://journals.lww.com/jcrjournal/Abstract/2001/03000/Physical\\_Activity,\\_Physical\\_Fitness,\\_and.1.aspx](http://journals.lww.com/jcrjournal/Abstract/2001/03000/Physical_Activity,_Physical_Fitness,_and.1.aspx)
  - **Summary:** This study simply looked at the correlation (again, **not** an experimental study) of physical fitness and activity with the FRS.
  - **Relevant Data:** A graded reduction in the FRS was shown with increasing physical activity, from 5.8% (low activity) to 4.0% (moderate activity) and 3.6% (high activity).
    - **Note:** This is more for background information than use for an expected treatment effect, as the study was not an experiment.

- **STUDY:** Effects of Intensive Multiple Risk Factor Reduction on Coronary Atherosclerosis and Clinical Cardiac Event in Men and Women with Coronary Artery Disease (Haskell et al)
  - <http://circ.ahajournals.org/content/89/3/975.full.pdf>
  - **Summary:** Study tested whether intensive multiple risk factor reductions (both in lifestyle and medication) over the course of four years would have a significant reduction in atherosclerosis progression relative to simply remaining in regular physician care. Mean age of subjects was 56 years, and the mean baseline total cholesterol of subjects in both groups (227.2 mg/dL and 233.4 mg/dL) indicates that the subjects did not have high cholesterol as a collective group.
  - **Relevant Data:** In the usual care group, the change in the FRS over four years proved insignificant ( $-0.5 \pm 3$ ), while the change in the FRS in the intensive group was highly significant ( $-4.0 \pm 0.04$ ). These results are much larger than those found in the OHIE.