Biostatistical Consulting Project

For this project, I'd like you to put yourself in the shoes of a consultant working in the Biostatistics Center of a major medical research institution or a public health policy and advocacy organization. The Biostatistics Center provides a wide range of services to help clinical and academic investigators (or policy makers and finders) with the translating the statistical results of research into clinical and public health practice, and study design, statistical analysis, and implementation.

You're currently assigned to two different studies, one on asthma medication and another on self-administration of contraceptive injections. **After you've read the summaries and studied the figures below, please proceed to the Course Project Quiz to answer a series of questions about each.**

Please note that only one Course Project Quiz attempt is allowed per day because this is a culminating project.

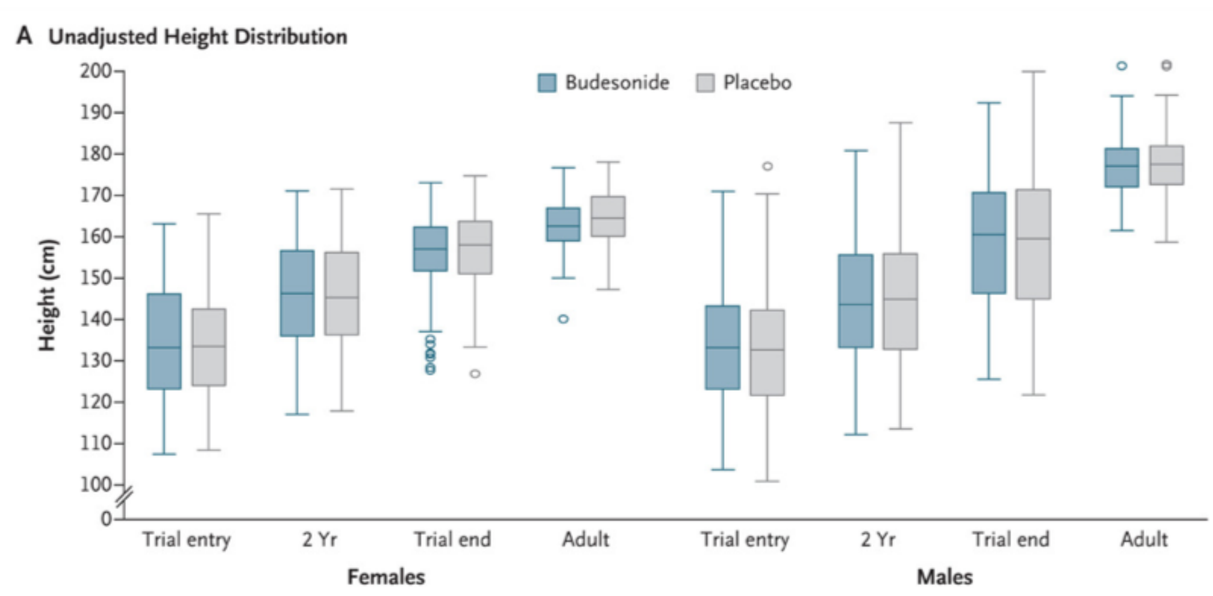
Asthma Medication Study

The first study is focused on the development of asthma medication. According to the Centers for Disease Control and Prevention, 6.1 million children in the United States have asthma, so this study has the potential to improve many lives. The research team needs to understand the previously published literature, including a study published in 2012 that reports on the effect on adult height of inhaled glucocorticoids during childhood. They've sent you the article and a list of questions about one plot in particular.

"From December 1993 through September 1995, we randomly assigned 1041 children between the ages of 5 and 13 years with mild-to-moderate asthma to one of three study groups in the double-blind, placebo-controlled CAMP trial."

Reference: Kelly H, et al. Effect of Inhaled Glucocorticoids in Childhood on Adult Height. New England of Medicine (2012), 367 (10)

The random assignment groups were Budesonide, Nedocromil, and placebo. The following graphic shows the distribution of female and male participant heights at different times in the study follow-up, presented for the Budesonide and placebo samples.



Self-Administration of Injectable Contraceptive Study

According to the World Health Organization, "Promotion of family planning – and ensuring access to preferred contraceptive methods for women and couples – is essential to securing the well-being and autonomy of women, while supporting the health and development of communities." As a result, it's important to find ways to eliminate the barriers that prevent families from using modern contraceptive methods.

Like last time (in the Summarization and Measurement Course), the principal investigator of a research team is still grappling with the results of a brand new study recently conducted in Uganda. She is particularly interested in your interpretation of the null and alternate hypotheses, the p-values, and the results of a log-rank test performed by the study authors.

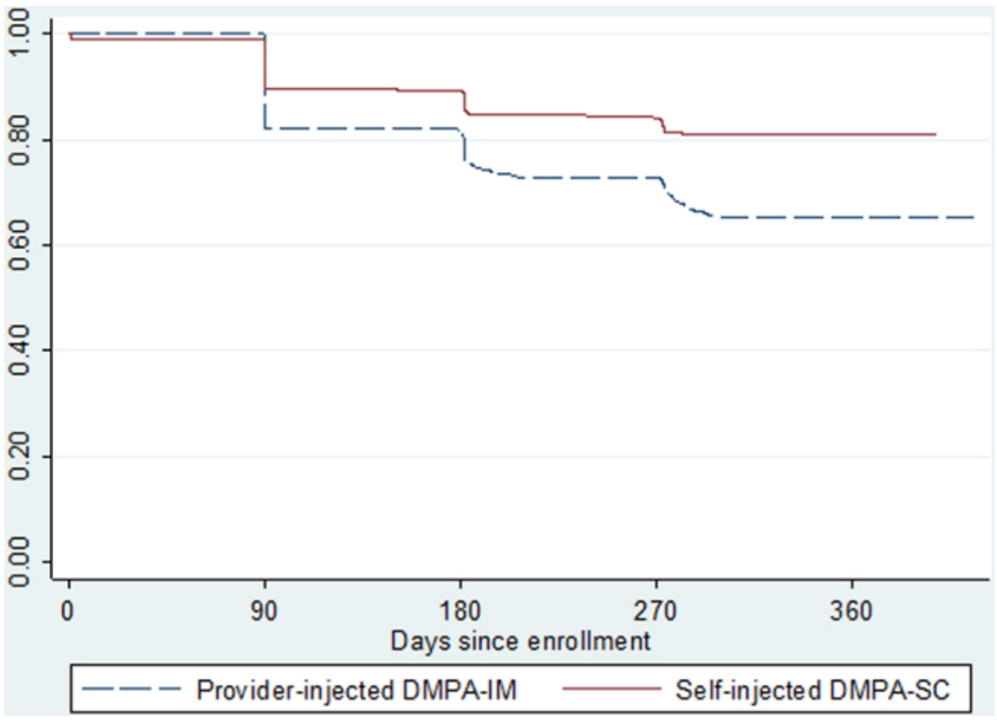
The following abstract portion is taken from a 2018 article published in *Contraception*.

Reference: Cover J et al.: Continuation of injectable contraception when self-injected vs. administered by a facility-based health worker: a nonrandomized, prospective cohort study in Uganda. Contraception 98 (2018) 383–388)

Objective: The purpose of this study was to compare 12-month continuation rates for subcutaneous depot medroxyprogesterone acetate (DMPA-SC) administered via self-injection and DMPA-IM administered by a health worker in Uganda.

Study design: Women seeking injectable contraception at participating health facilities were offered the choice of self-injecting DMPA-SC or receiving an injection of DMPA-IM from a health worker. Those opting for self-injection were trained one-on-one. They self-injected under supervision and took home three units, a client instruction guide and a re-injection calendar. Those opting for DMPA-IM received an injection and an appointment card for the next facility visit in 3 months. We interviewed participants at baseline (first injection) and after 3 (second injection), 6 (third injection) and 9 (fourth injection) months, or upon discontinuation. We used Kaplan–Meier methods to estimate continuation probabilities.

The following graphic shows the estimated Kaplan-Meier curves tracking contraception discontinuation for both groups (these curves track the proportion of subjects who have not discontinued contraception usage over the follow-up period).



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Please proceed to the Course Project Quiz to answer a series of questions about these two studies.