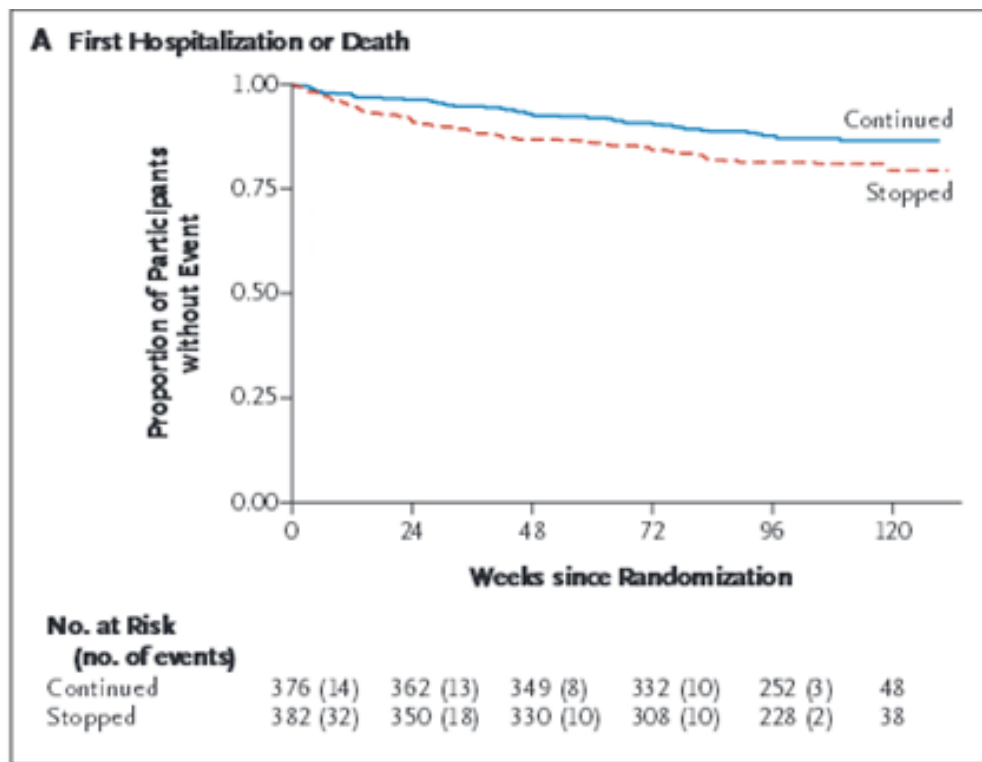


Self-Evaluation Problems Class 7

A study¹ compared outcomes between HIV-infected children *randomly assigned* to either **continue** or **stop** prophylaxis therapy after receiving at least 96 weeks of anti-retroviral therapy. Below are the **Kaplan-Meier survival curve estimates** ($\hat{S}(t)$) of time after randomization to *either* first hospitalization or death for the two groups.



- Approximately what is the estimated proportion of children in the “**Stopped**” group who had been either hospitalized or had died *within* 24 weeks after randomization into the study? (Circle only one response).
 - 10%
 - 90%
 - 2%
 - 98%
 - 25%

¹ Bwakura-Dangarembiz M, et al. A Randomized Trial of Prolonged Co-trimoxazole in HIV-Infected Children in Africa (2014). *New England Journal of Medicine* 370 (1):41-53.

2. The p-value given by the **log rank test** comparing the two survival curves is 0.007. Assuming a significance level (α) of 0.05, one can conclude that the observed differences in the Kaplan-Meier curves between the two groups are:
- Relatively likely* if there is **no difference** in survival over the study follow-up period (at the population level) for the two randomization groups.
 - Relatively likely* if there is a scientifically important difference in survival over the study follow-up period (at the population level) for the two randomization groups.
 - Relatively unlikely* if there is **no difference** in survival over the study follow-up period (at the population level) for the two randomization groups.
 - Relatively unlikely* if there is a scientifically important difference in survival over the study follow-up period (at the population level) for the two randomization groups.
 - Reflecting a 0.7% chance that the null hypothesis of no survival difference is true.
3. What can be inferred about the **estimated hazard ratio (HR)** of first hospitalization or death for the children randomized to the “**Continued**” group compared to children randomized to the “**Stopped**” group?
- HR = 0
 - HR = 1
 - HR > 1
 - HR < 1
 - It is not possible to estimate this from the information given.
4. Three-hundred seventy-six (376) children were randomized to the “**Continued**” group, and 48 (13%) children were still at risk of hospitalization or death at 120 weeks. However, the corresponding Kaplan-Meier curve estimate at 120 weeks for this group is approximately 90%. How can this have happened?
- Some of the observations in the “Continued” group were censored prior to 120 weeks.
 - The researchers estimated the Kaplan-Meier curve using only the data on patients who were hospitalized or died during the 120 weeks after randomization.
 - The researchers estimated the Kaplan-Meier curve using only the data on patients who were not censored during the 120 weeks after randomization.
 - The Kaplan-Meier estimate at 120 weeks is the risk of surviving beyond 120 weeks among only those who were at risk of having the event at 120 weeks.
 - The hazard of hospitalization or death for the children in the “Continued” group was assumed to be constant over time.
5. How does the Kaplan-Meier approach to estimating the survival function utilize information from censored observations?
- It drops all censored observations from the sample before the curve is estimated.
 - It uses the censored observations when considering who is “at risk” of an event at each given time in the follow-up period.
 - It treats the censoring times as event times.
 - It treats the event times as censoring times.
 - It assumes that all censored observations have the event by the end of follow-up.