Reporting of Follow-up Time

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Outline

- Why report follow-up time in cohort studies in oncology?
- How is follow-up time currently reported?
- What is reverse Kaplan-Meier?
- Is reverse KM necessary?
- What should be reported?
Why Report Follow-up Time?

The interpretation of the results of a survival analysis depends in great measure upon the time frame in which the study was carried out and the completeness of follow-up of the subjects being investigated.  
(Doug Altman, BrJCancer 1995)
Why Report Follow-up Time?

Time to event studies must have sufficient follow-up to capture enough events and thereby ensure there is sufficient power to perform appropriate statistical tests. (Clark and Altman, BrJCancer 2003)
How is Follow-up Currently Reported?

- Reporting of follow-up is generally poor (Altman 1995; Schemper 1996)
- About 50% papers did not include any summary follow-up time
- 30% of the papers did not report method of median follow-up estimation
- Two of the more popular methods for estimating median follow-up are: median follow-up time among *survivors*, and the “reverse Kaplan-Meier”
What Is Wrong With Observed Median?

▷ “The median follow-up time of all patients is of questionable value because it is directly affected by the times of the observed events”

▷ “The median follow-up time of survivors only can be quite unstable if the number of survivors is small” (Altman 1995)
Reverse Kaplan-Meier

- Recent popularity
- Calculated in the same manner as KM for survival function, but with the meaning of event status indicator reversed, i.e. death censors the true, but, unknown, observation time of an individual, and censoring is the endpoint of interest.

  “the unobservable follow-up time of a deceased patient is interpreted as the follow-up time that potentially would have been observed had that patient not died.” (Schemper 1996)

- \( mT_{\text{observed}} \leq mT_{\text{survivors}} \leq mT_{\text{reverseKM}} \)
What is Wrong With Reverse KM?

- Conceptually problematic - potential follow-up in the absence of death
- “the unobservable follow-up time of a deceased patient is interpreted as the follow-up time that potentially would have been observed had that patient not died.” (Schemper 1996)
- Why invoke such a non-sensical counterfactual?
- Why not simply report start and end dates of accrual and the date of analysis? (Shuster, JCO 1991)
- If a summary is needed, also report the observed median
What is Value of Median Follow-up?

Shuster (1991)

- Describes maturity of data
- Describes stability of KM survival curve
- Describes the time-interval of validity of KM curve
- Describes quality of follow-up

“Unfortunately, median follow-up (whichever definition) cannot fulfill any of these roles. There are many factors that influence the survival curve that no single measure of follow-up is appropriate.”
It is believed by this writer that many clinical investigators are unaware of the fact that the KM curve adjusts for variable lengths of follow-up and provides an unbiased estimate of the true population survival curve, provided that competing losses are uninformative. Hence, they invented a term to a perceived need that, in fact, does not exist.

Shuster (1991)