

7-DAY PAR DATA HANDLING RULES

The Stanford 7-day Physical Activity Recall (7-day PAR) is used to assess longitudinal changes in spontaneous physical activity induced by the intervention. It is assessed at six month time points throughout the two-year intervention period (two during each DLW period: four assessments at baseline and two each at 6M, 12M, 18M and 24M). During Phase I CALERIE, we observed that the 7-day PAR well reflected the activity energy expenditure (AEE) as assessed by the DLW across a broad range of values with a consistent offset of approximately 200 kcal per day. The information is taken as an interview survey and therefore there is a good deal of data interpretation and assessment of appropriate values that is performed during the collection of the data by study personnel that have been trained in conducting the survey. The Committee has reviewed the preliminary data report provided by the statistical team regarding this measure and assessed the current data problems. The members therefore believe that only the following further handling rules are required.

In general collection of these data were excellent. There were 26 subject / visits that did not have protocol specified PARs reported. 17 of these were baseline visits among subjects who were not randomized, and 9 were follow-up visits among randomized subjects. All randomized subjects had all four PARs at baseline. Two subjects were missing both Month 12 PARs. Three subjects were missing a single Month 24 PAR, and one subject was missing both Month 24 PARs.

1) Sleep minutes not recorded.

There were PAR data reported for a total of 2,090 subject / weeks, or 14,630 days. Fifty of these days do not have total sleep time for the day. We have been querying these. Eleven of these look like they were missing a date component and might be reparable. If the remaining, 39 cannot be resolved by querying.

Sleep minutes not recorded should be considered the difference between recorded minutes and the 24 hours during the day of record. Energy expenditure therefore should be set to resting and no activity energy expenditure should have been considered to have been recorded during these periods.

2) Collection days fall outside DLW period

Out of the 14,630 PAR days, 106 days fell outside the DLW period. Among the 106 that fell outside the DLW period:

64 were 1 day outside the DLW period (i.e., 1 day before DLW started, or 1 day after DLW ended)

9: 2 days outside

4: 3 days outside

3: 4 days outside

2: 5 days outside

1: 6 days outside

1: 7 days outside

22: greater than 7 days outside the DLW window (the more egregious dates are being queried).

We suggest that any record that has any days within 7-days of the corresponding DLW period can be used. That is, even if a 7-day record only has one day within the specified DLW period then the entire record is valid. Any records that do not have any days within the corresponding DLW period should be excluded.

3. Rounding Activity Minutes.

According to the PAR MOP, '...a participant must do at least 10 min of an activity in 1 activity category during one period of the day for it to be counted; this amount is recorded and rounded to 15 min.'

There a small number of activity categories with less than 10 minutes during one period of the day (n=13).

These should we hardcoded to 0.

There are over 50,000 values for activity minutes in the 9 separate period of day x intensity categories. Over 94% of these values are already rounded to the closest 15 minutes. However, that leaves about 2,700 values that are not rounded. Should the statistical programmer round these values to the closest 15 minutes

All activity minute period values should be rounded to the closest 15 minutes.