

SRNT Subcommittee on Abstinence Measures (Hughes et al, In press)

Table 3. Recommended minimum reporting of abstinence measures in clinical trials

### For All Trials

Report PA<sup>a</sup> as the primary outcome measure where failure is defined as either seven consecutive days of smoking or smoking on at least one day on each of two consecutive weeks (B).<sup>b</sup>

Use the term CA<sup>a</sup> only to refer to PA that has no grace period (B).

Do not use the term SA<sup>a</sup> (B).

Include non-cigarette tobacco use in definitions of failure (B).

Do not include non-tobacco nicotine use (e.g., NRT) <sup>c</sup> in definitions of failure (B).

When feasible, report survival or event history analysis outcomes (B)

### Aid-to-Cessation and Proof of Concept Trials

Tie all f/u's<sup>c</sup> to the experimenter or subject-determined quit date (B).

Use a grace period for PA of 2 wks unless there is an a priori rationale for a different duration. If there is a priori rationale use no grace period (B).

Report 6 and/or 12 mo f/us (B).

Report PP as a secondary measure in which failure is defined as any smoking in the seven days prior to the f/u (B) If CO<sup>d</sup>, SCN<sup>d</sup> or some other non-cotinine measure is used to verify, also include a window that is biochemically verifiable (C).

Report PP which also uses a 30 day window (C).

### Cessation Induction Trials.

Tie all f/u's to the onset of treatment (B).

State the grace period for PA a priori based on the anticipated duration of treatment dissemination or other factors (B).

Report 6 and/or 12 mo f/us (B).

Report PP as a secondary measure in which failure is defined as any smoking in the seven days prior to the f/u (B). If CO, SCN or some other non-cotinine measure is used to verify, also include a window that is biochemically verifiable (C).

Report PP which also uses a 30 day window (C).

<sup>a</sup> PA = prolonged abstinence, CA = continuous abstinence, SA = sustained abstinence, PP = point prevalence

<sup>b</sup>A = multiple well-designed studies that showed a consistent pattern of findings, B = some evidence to support the recommendation but scientific support was not optimal and C = group achieved consensus but in the absence of scientific support.

<sup>c</sup> NRT = nicotine replacement therapy

<sup>d</sup> f/u = follow-up

<sup>e</sup> CO = carbon monoxide, SCN = thiocyanate

Table 4. Questions necessary to obtain abstinence measures<sup>a</sup>

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Since [end of grace period] have you ever smoked at least a part of a cigarette on each of 7 consecutive days? After [end of grace period] have you smoked any in each of 2 consecutive weeks? (PA) When was the first day of that 7 day or 2 week period you smoked? (Survival Analysis)

Since [quit date for aid-to-cessation trials or beginning of treatment/end of treatment for cessation induction trials] have you smoked at least a part of a cigarette on each of 7 consecutive days, or have you smoked any in each of 2 consecutive weeks? (CA) What was the first day of that 7 day or 2 week period you smoked? (Survival Analysis)

3. Have you smoked at least a part of a cigarette in the last 7 days? If no, in last 30 days? (PP & RPP)

<sup>a</sup> See Table 3 or text for definitions of CA, PA, PP, RPP