Compliance with Ecological Momentary Assessment (EMA) protocols and its effects on study data

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Background

- It is commonly noted that non-compliance with ecological momentary assessment (EMA) protocols has the potential to systematically bias study data. The underlying assumption is that participant non-compliance is non-random.
- The degree to which participants comply with study monitoring procedures is almost universally expressed in terms of their completion of time-based assessments (e.g., random prompt compliance). Such compliance is easy to measure, as both the numerator and the denominator for the calculation are knowable.
- Failing to answer time-based assessments is not the only way that participants can deviate from study procedures. Also possible to calculate time and event-contingent compliance. Unclear how (or if) these measures are related.
- The purpose of this study was to document the relationship between three measures of protocol compliance – namely, responding to random prompts, logging events CPD, and daily monitoring duration –, and to explore their impact on self-reported affect, arousal and craving.

Table: Number (and proportion) of assessments completed during periods of the day, and the number (and proportion) of participants contributing any assessments to those time period.

Time period	Number (%) of assessments prompts (n = 8,621)	Number (%) of participants contributing any observations (n=73)
12:01am – 4:00am	374 (4.34%)	47 (64.38%)
4:01am – 8:00am	258 (2.99%)	44 (60.27%)
8:01am – noon	1448 (16.80%)	68 (93.15%)
12:01pm – 4:00pm	2269 (26.32%)	72 (98.63%)
4:01pm – 8:00pm	2459 (28.52%)	72 (98.63%)
8:01pm - midnight	1813 (21.03%)	70 (95.89%)

Note: Assessments includes completed (but not missed or skipped) random prompt assessments and full cigarette assessments.

Method

- Data were taken from a multi-site study interested in the social determinants of smoking.
- Participants (n=73) used study-issued smartphones to monitor their smoking and activities in real time for up to four weeks (M=27.2 days per participant).
- Monitoring was done with a smartphone running study-specific EMA software (HBART: www.utas.edu.au/pharmacy/research/bsrg/hbart).

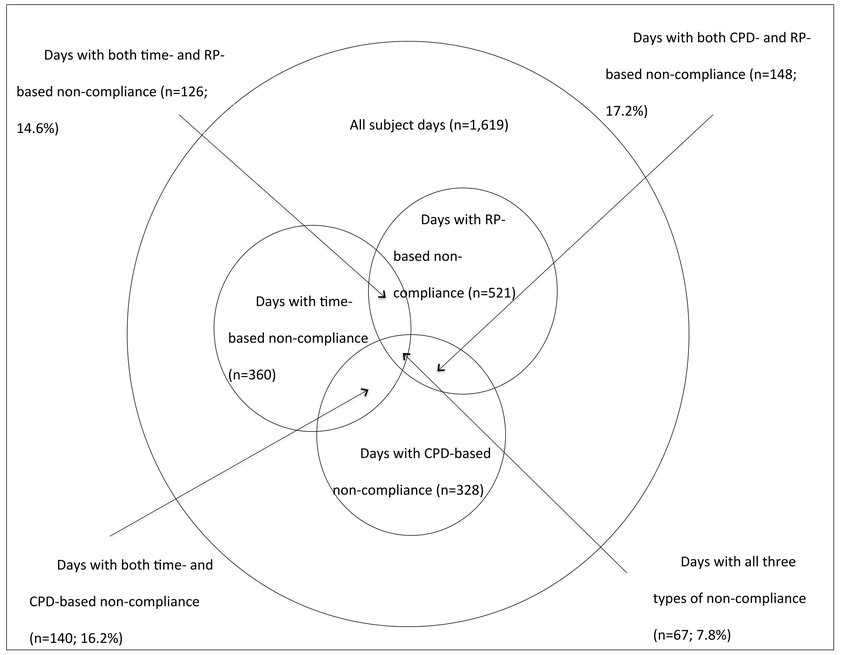

Figure. Number of non-compliant days as proportion of total days of monitoring by type of non-compliant behaviour.
Notes: RP-based = days (N=521) of monitoring during which subjects completed <75% of RP (includes days were no RP were issued). CPD-based = days of monitoring (N=328) during which participants logged <50% of average CPD (as reported in baseline survey). Time-based = days (N=360) of monitoring in which participants actively participated for <12 hours. Percentages shown are proportions of days with any form of non-compliance behaviour (n=862).

Analyses & Results

- Given the focus on compliance, we did not trim participants based on their daily random-prompt compliance. However, each participant's first and last day of observation were excluded from our analyses as only partial monitoring was conducted on those days.
- On average participants responded to 77% of random prompts per day, however on a third of all monitoring days fewer than 75% of random prompts were completed; this accounted for less than two thirds of days during which any non-compliant behaviour was observed (Figure & Table).
- Within subject daily mean levels of affect were not related to daily random prompt compliance, and nor were mean levels of arousal or craving (all p-values > .097). However, when we examined the daily range of these variables we found a significant effect of compliance: as compliance improved, the daily range of affect, arousal and craving increased (all p-values < .001). These effects of compliance, however, became non-significant (all p-values > 301) when the number of observations obtained on a given day was included in the models (all p-values < .001). The same pattern was seen with maximum values.

Conclusions

- Compliance with study protocols did not predict mean daily levels of affect, arousal or craving, but did predict both range and maximum values of these variables.
- The assessment of random prompt compliance may not be an adequate proxy measure of other forms of non-compliant behaviour.
- Researchers should take care to monitor participant compliance with study protocols as poor compliance may impact on data quality.

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